Message

From: EPA Press Office [press=epa.gov@cmail19.com]
on behalf of EPA Press Office [press@epa.gov]
Sent: 3/26/2018 2:50:18 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Ban On "Secret Science" In EPA Regulation Makes Sense

U.S. ENVIRONMENTAL PROTECTION AGENCY
NEWS RELEASE
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THE OKLAHOMAN

Ban On "Secret Science" In EPA Regulation Makes Sense

Editorial
March 26, 2018
http://newsok.com/article/5588210/ban-on-secret-science-in-epa-regulation-makes-sense

The Environmental Protection Agency has announced it will now base new regulations only on the findings of scientific studies whose data and methodology are made public so they can be subjected to independent review. That's a sound move in line with basic scientific transparency and professionalism.

Yet it's being treated as a sign of impending apocalypse by some on the left, which says much about the questionable validity of that group's policy prescriptions.

In an interview with The Daily Caller News Foundation, Administrator Scott Pruitt said the EPA will end its use of studies that do not publish underlying data, only conclusions. "Otherwise, it's not transparent. It's not objectively measured, and that's important," Pruitt said.

In the past, the EPA has advanced air-quality regulations that imposed massive costs based primarily on the findings of two studies done in the 1990s that linked fine particulate pollution to premature death. Neither study made associated data public.

U.S. Rep. Lamar Smith, R-Texas and chairman of the House Committee on Science,

Space and Technology, has long criticized the use of “secret science” and authored legislation to curtail its use by regulators. Last year, Smith said the EPA had “routinely relied on questionable science based on nonpublic information that could not be reproduced, a basic requirement of the scientific method.”

“Americans deserve to see the science for themselves,” Smith said. “If the EPA has nothing to hide, why not make the scientific data it uses for its regulations publicly available? What was the EPA hiding?”

That will strike most people as a fair question. But to some activists, the idea that science should involve review and scrutiny is apparently anathema. In response to a prior effort to ban “secret science” at the EPA, Andrew Rosenberg, director of the Union of Concerned Scientists' Center for Science and Democracy, said transparency would “gut the EPA at the expense of public health and safety.”

That same group has claimed release of data would require publicizing the confidential patient data of individuals. But Steve Milloy, publisher of JunkScience.com and a senior fellow at the Energy and Environmental Legal Institute, notes that California already makes similar data available in its “Public Use Death Files,” and that has been accomplished without violating patient privacy.

Other critics object that there are costs involved in scrubbing data sets so patient privacy is protected. Perhaps, but that doesn't mean the public should be kept in the dark about the data and methods used to justify literally billions in new regulatory burden.

Scientific studies are as susceptible to human error and even outright fraud as any other endeavor — particularly when such studies are used in the political realm. Facilitating transparency and independent review will reduce the chances of bad science harming Americans with half-baked regulations, and should enhance the case for regulations when the underlying science has withstood independent scrutiny.

Given the stakes for public health and the national economy, Americans must be assured government regulations are based on sound science, not someone's “trust me” assurances.

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Message

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Sent: 3/26/2018 2:15:03 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Pruitt Leads the Way on Regulatory Rollback

U.S. ENVIRONMENTAL PROTECTION AGENCY
NEWS RELEASE
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REAL CLEAR POLICY

Ken Cuccinelli: Scott Pruitt Leads the Way on Regulatory Rollback

Real Clear Policy
Ken Cuccinelli
March 26, 2018
https://www.realclearpolicy.com/articles/2018/03/26/pruitt_leads_the_way_on_regulatory_rollback_110563.html

This month, the Environmental Protection Agency released its EPA Year in Review for 2017-2018. To call it impressive would be a gross understatement. With Administrator Scott Pruitt leading the charge, the agency has shown unrivaled commitment to carrying out the president's agenda of deregulation.

Before taking over at the EPA, Pruitt was as a leading opponent of regulatory overreach by the agency. As general of Oklahoma, for instance, he dissolved the Environmental Protection Unit and instead created a Federalism Unit to fight President Obama's aggressive regulatory agenda. He brought more than a dozen lawsuits against the EPA, fighting such rules as the Cross State Air Pollution Rule and the Clean Water Rule, and successfully challenging the Clean Power Plan.

Now, as EPA administrator, Pruitt is taking even more direct action and doing so in a cooperative and transparent manner. When Office of Management and Budget Director Mick Mulvaney discussed the deregulation effort at the Conservative Political Action Conference last month, he highlighted the rules that were top priority for the administration's regulatory roll back: the Waters of the United States rule and the Clean Power Plan. Both fall within Pruitt's jurisdiction at the EPA. No surprise that action on EPA regulations has moved to the forefront of the administration's agenda.

From his first days at the agency, Pruitt took steps to facilitate cooperation with the states on environmental

policy. Federalism is an essential principle of American governance, and Pruitt has put this principle into practice. During his first year, Pruitt travelled to 30 states to discuss the EPA's work, personally meeting with 34 governors — Democrats and Republicans — as well as over 350 stakeholder groups. This level of personal involvement is nearly unparalleled, even inside an administration with such a clear focus on deregulation. And it is paying dividends.

The EPA Year in Review booklet is nearly 40 pages long, outlining the regulatory rollback, increased transparency, and government reform measures accomplished in the last year alone. This includes finalizing 22 deregulatory actions and savings of more than $1 billion in regulatory costs, which previously fell on Americans' shoulders. By comparison, a similar document out of the Department of Labor, headed by Secretary of Labor Alexander Acosta, is only four pages long.

As he says in a letter at the front of the EPA Year in Review, Administrator Pruitt "look[s] forward to working together to accomplish even more progress in 2018." We applaud Mr. Pruitt's accomplishments in his first year as head of EPA, and hope that his success provides an example to other agencies. Executive agencies can take the lead on growing the economy by freeing Americans from excessive regulatory burdens. This, the EPA — with Pruitt at the helm — has proven.

Ken Cuccinelli is the Director of the FreedomWorks Foundation Regulatory Action Center.

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From: EPA Press Office [press=epa.gov@cmail20.com]
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Sent: 5/24/2018 12:00:19 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

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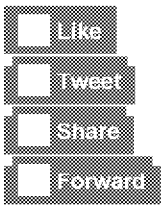

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Message

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Subject: News Articles (For EPA Distribution Only)

GREENWIRE ARTICLES

Senate Dems fire another shot at 'secret science' proposal

Sean Reilly, E&E News reporter

Published: Friday, August 17, 2018

EPA headquarters in Washington. Robin Bravender/E&E News

Nine Senate Democrats are framing an EPA plan to restrict the types of studies that can be used in crafting new regulations as part of a broader pattern of "regulatory capture" by industries the agency is charged with overseeing.

https://www.eenews.net/greenwire/2018/08/17/stories/1060094651

PUBLIC HEALTH

Calif. looks to cancel coffee cancer warnings

Published: Friday, August 17, 2018

California might create an exemption for coffee that would reverse a court decision requiring cancer warnings.

The Los Angeles Superior Court ruled in March that state law requires the warnings because of the presence of the chemical acrylamide, which is a byproduct of roasting coffee.

https://www.eenews.net/greenwire/2018/08/17/stories/1060094607

BNA DAILY ENVIRONMENT REPORT ARTICLES

Walmart to Shed Solvents Linked to Deaths, Birth Defects

By Pat Rizzuto

Posted Aug. 20, 2018, 10:00 AM

Walmart Inc., the world's largest retailer, will stop selling paint strippers containing a solvent linked to more than a dozen deaths and a second solvent that could harm the development of babies in the womb.

Trump's Power-Plant Proposal May Increase U.S. Carbon Pollution

By Jennifer A. Dlouhy

Posted Aug. 20, 2018, 8:33 AM

Donald Trump is poised to replace former President Barack Obama's plan to slash power plant greenhouse gas emissions with a substitute that could actually increase them.

Watch Out Starbucks, Kellogg's: Tougher Warning Mandates Coming

By Julie Steinberg

Posted Aug. 20, 2018, 7:07 AM

Starbuck's, Kellogg's, and General Mills are only a few of the many companies that have found their products targeted under California's chemical warnings law in recent years.

INSIDEEPA.COM ARTICLES

Courts' Rejection Of EPA Rule Delays Poses Test For Wheeler's Agenda

EPA's recent court losses in cases undoing implementation delays for two major Obama-era rules create additional legal complications for acting agency chief Andrew Wheeler's agenda, as he faces new pressures to implement regulations that were previously on hold unless the agency can find a rationale to further delay them.

EPA Receives Conflicting Comments On Proposed Lead Dust Rule Update

EPA's proposal to strengthen its 2001 lead paint dust hazard standards is spurring conflicting reactions, with healthy housing groups, environmentalists and some states urging the agency to significantly tighten its standards for protective measures in some locations, though home builders say more data is necessary to ensure the proposal is viable.

EPA Drops Plan To Weigh First Responders' Asbestos Risk, Citing Legacy Use

EPA has dropped an early plan to consider risks of asbestos exposures to firefighters and other first responders due to its policy of excluding legacy uses from consideration for possible regulation under the revised toxics law, a move that is drawing protest from a group representing the workers and highlights the controversy around the policy decision.

Industry Backs EPA's Plan For Narrow Asbestos Analysis, Sparking Clash

The power industry is supporting EPA's narrow approach for assessing the health risks of exposure to asbestos, especially its decision to preclude legacy uses, setting up a clash with critics who say the agency should broadly assess all risks as part of an effort to ban the mineral.

Experts Say OMB, Not EPA, Should Make Any Cost-Benefit Review Updates

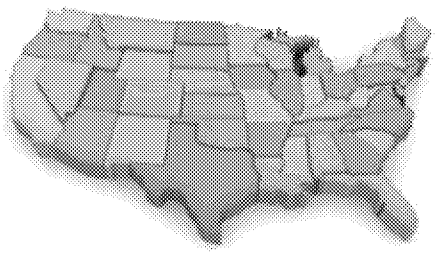
Several experts say the White House Office of Management & Budget (OMB) -- or some other interagency process -- should be responsible for any new policies to establish greater "consistency" in cost benefit analysis, rather

CHEMICAL WATCH ARTICLES

States push for broad TSCA evaluations, despite preemption considerations

Excluded conditions of use face potential state-level action

17 August 2018 / TSCA, United States



State attorney generals have written to the EPA urging it to broaden the scopes of TSCA risk evaluations, even though such an approach could limit their ability to act on those substances. But states are also poised to fill any 'gaps' left from uses omitted from the agency's assessments.

The attorney generals' 3 August letter came in response to the consultation on the agency's 'problem formulations'. These refine the scopes of the assessment the agency is set to conduct on the first ten substances subject to risk evaluation under the law.

Co-signed by attorneys from nearly a dozen states historically active in chemicals management – including California, Vermont and Washington – the letter argues that the scopes reflected in the agency's 'problem formulations' represent an "unlawfully restrictive application of TSCA, [which] ignores that Congress intended for the EPA to assess a chemical in its entirety".

As drafted, the problem formulations would "produce deeply flawed risk evaluations" that would make it impossible for the EPA to fulfil its statutory mandate to protect against unreasonable risks, they say.

And they call on the EPA to issue revised scopes for the risk evaluations to address the agency's "fatally flawed" approach to identifying the conditions of use.

TSCA preemptive effects

The attorney generals' push for more robust assessments comes despite the fact that such an action would, in turn, result in broader preemption of the actions that states can take under the reformed TSCA law.

Outside of certain exemptions (see box), states may not act once the EPA has taken a final action on a substance – either by finalising a risk management rule to address identified risks, or by making an affirmative finding that the substance does not pose a substantial risk.

Crucially, this preemptive effect extends only to the uses of substances that the agency evaluates under its risk evaluations. Any condition of use excluded or missed from its final risk evaluation will then be on the table for states to regulate, if they wish.

Ken Zarker, pollution prevention and regulatory assistance manager at Washington state's Department of Ecology, told Chemical Watch the state is closely monitoring the early evaluations. But with regard to the potential for these to omit certain uses, he said: "We would certainly fill any gaps, as states."

"The more that EPA narrows these scopes, it's going to give the states broader abilities to act where the gaps exist," he said. "We still have that ability, and states can move a lot quicker if we need to."

However, he added that the state would prefer to see "a strong federal system".

Business considerations

Martha Marrapese, a partner with law firm Wiley Rein, told Chemical Watch that this potential for states to act leaves companies with an evaluated substance in an "interesting" position in relation to the uses the EPA includes in its evaluations.

If the EPA evaluates the substance and makes an affirmative finding that it does not pose an unreasonable risk, Ms Marrapese said, then states will be blocked from acting. But for any use the EPA doesn't evaluate, "the states will still have the abilities to regulate themselves, to the extent they're not preempted by other federal laws".

A company might argue that their use of a substance is safe or results in negligible exposure and therefore should be excluded from the assessment, she said. But "the downside to that is if it's not part of EPA's risk evaluation, those companies are still going to be fighting that battle on a state-by-state basis".

"If you believe you have a safe use, it benefits you to have it be part of EPA's risk evaluation", because then states will be preempted from acting, she added.

The problem formulations consultation closed on 16 August. The EPA must finalise its risk evaluations by December 2019.

Preemption: A critical issue

Preemption arose as a critical issue during efforts to negotiate the Lautenberg Act, which amended TSCA in 2016. One of industry's motivations for coming to the negotiating table was to put in place a stronger federal system that would combat the myriad state regulations appearing on chemicals of concern.

TSCA preempts state action on a chemical-specific basis. Final action by EPA on a substance – whether by determining it does not present an unreasonable risk, or by imposing a risk management regulation to address identified risks – blocks states from imposing their own restrictions. This extends only to those uses evaluated by the agency.

There are, however, exemptions. Activities that are not preempted include:

- actions already taken by states before 22 April 2016;
- past or future actions taken under laws that were in effect before 31 August 2003 (which effectively safeguards California's Proposition 65 law);
- information-seeking requirements, such as reporting, monitoring or disclosure rules; and
- most state regulations imposed under water quality, air quality, waste treatment or disposal laws.

States may also seek a waiver to impose restrictions on a substances following final EPA action.

Kelly Franklin

North America editor

Related Articles

- EPA 'narrowing' scope of first ten TSCA risk evaluations
- EPA names first ten chemicals for new TSCA evaluations

Further Information:

- Attorney generals' letter
- TSCA preemption FAQs

US toxics agency releases final profile for two diisocyanates

17 August 2018 / Built environment, Risk assessment, United States

The US Agency for Toxic Substances and Disease Registry has released its final toxicological profile for toluene diisocyanate (TDI) and methylene diphenyl diisocyanate (MDI).

Both substances are used in many polyurethane household products, including furniture cushions, carpet padding and waterproof sealants. Neither occurs naturally in the environment.

In products such as cushions the diisocyanates are cured and, the report says, consumers are unlikely to be exposed through this route.

Exposure to TDI can occur in the air, though, from products such as adhesives, sealants, coatings, paints, craft materials and insulating foam.

The ATSDR profile, which includes a public health statement, says asthma and symptoms of asthma have been observed in some individuals who are particularly sensitive to the substances.

The public health statement points to research by the Department of Health and Human Services that considers TDI as "reasonably anticipated to be a human carcinogen". It also notes that the International Agency for Research on Cancer (Iarc) classifies TDI as possibly carcinogenic to humans.

On MDI, the statement says there is limited data on whether it can cause cancer. It points out that Iarc has found that the substance is not classifiable as carcinogenic to humans.

In July, the EU's human biomonitoring project, HBM4EU, which aims to harmonise the exposure assessment method, added diisocyanates to its second list of priority substances. In March, Echa's Socio-economic Analysis Committee (Seac) adopted final Opinions on restrictions proposed on the use of diisocyanates in the workplace.

Related Articles

- EU's human biomonitoring project finalises second priority list
- Echa's Rac adopts lead shot restriction proposal, CLP dossiers

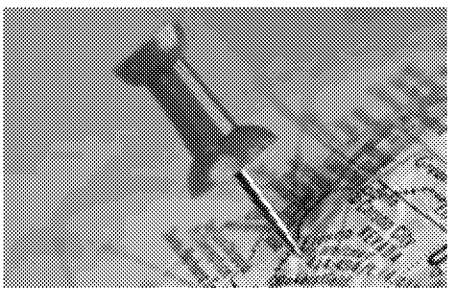
Further Information:

- ATSDR profile

California proposes change to furniture fire safety regulation

Amendment could reduce reliance on flame retardants

17 August 2018 / Built environment, United States



The US state of California is considering an amendment to its flammability regulations, which would eliminate the need for flame retardant use in upholstered furniture designed for public places.

A proposal by the California Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (Bearhfti) would remove all reference to Technical Bulletin (TB) 133 from the California Code of Regulations.

This is a standard for furniture intended for public occupancies that seat 10 people or more. It applies to venues such as restaurants, prisons, hotels, churches. hospitals and care homes.

TB 133 includes an open flame test designed to simulate conditions "typical of arson or incendiary fires or common accidental fires in public buildings", and is typically met through the use of flame retardants.

'Unnecessary health risks'

According to a notice of proposed change by Bearhfti, TB 133 is "a redundant test standard that causes confusion within the industry and presents unnecessary health risks".

The proposed regulatory action is projected "to lower costs of upholstered seating furniture used in public buildings and reduce the need for flame retardants in component materials," the document continues.

Also, it says the action is anticipated to "improve public health by reducing exposure to carcinogenic organohalogen flame retardants".

If the proposal to remove reference to TB 133 is adopted, it would also remove labelling requirements for upholstered seating furniture meeting TB 133.

Manufacturers would instead have to comply with the California upholstered furniture flammability standard, TB 117-2013, which requires a smoulder-resistance test that can more readily be met without the use of flame retardants.

Members of the public are invited to submit comments about the proposal in writing to Bearhfti. A public hearing about the proposed amendment will take place on 17 September.

Industry view

David Panning, technical services director at the Business and Institutional Furniture Manufacturers Association (Bifma), said its members are "very supportive of California repealing the TB 133 regulation".

He added that "the scientific community is very concerned about the use of fire retardant chemicals to meet TB 133" because of the associated health risks.

But the North American Flame Retardant Alliance (Nafra) insists the use of flame retardants is important to ensure the safety of public spaces.

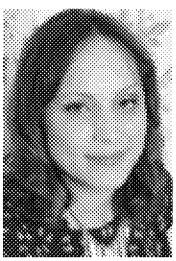
"Fire-related fatalities and injuries associated with upholstered furniture are among the most serious fire problems in the US, and this proposal would reduce the fire safety standard for furniture," a spokesperson told Chemical Watch.

National action

In October last year, the city of San Francisco, California banned the sale of upholstered furniture and children's products containing flame retardant chemicals. The law is due to go into effect in January 2019.

More than a dozen US states have banned some categories of flame retardants and many more are considering legislation to restrict their use.

On a national level, the Consumer Product Safety Commission (CPSC) voted in September last year to ban the use of organohalogen flame retardants in furniture and several other household product categories. The CPSC plans to make a decision next year on whether to adopt California's TB 117-2013 as a national flammability standard for residential upholstered furniture.



Tammy Lovell

Business reporter

Related Articles

- Furniture group to seek 'waiver' from San Francisco flame retardant ban
- US state legislatures look to fill TSCA gaps
- US CPSC investigates possible action against organohalogen flame retardants
- US CPSC plans to act on furniture flammability standard in 2019

Further Information:

- Bearhfti proposal
- TB 133
- TB 117-2013

OTHER ARTICLES

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WSMV Nashville

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WLTX.com

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Gov't may allow new uses for asbestos

Huntington Herald Dispatch

The TSCA requires the EPA to screen potentially **toxic substances** instead of levying bans or restrictions against them. Asbestos has been banned in ...

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Environmental Working Group

Hairdressers, nail technicians and other beauty salon workers face some of the greatest occupational exposures to **toxic chemicals**. A bill moving ...

"Worrisome" levels of lead and arsenic found in baby food

CBS News

Products made with rice fared the worst in tests, but all showed measurable levels of at least one of three **toxic** heavy metals: cadmium, inorganic ...

Examining the toxic history of flame retardants

Marketplace.org

Brancaccio: Now over the years a number of those fire retardant chemicals have been found to be highly **toxic and** in turn, they were taken off the ...

How lead, bromide and flame retardant turned our environment toxic

WVTF

The milk will get to people through soup kitchens **and** food banks. Then, we talk about life in an actual **toxic** environment – we talk to reporter **and** ...

Bipartisan senate bill aims to promote innovation in American sustainable chemistry.

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This bi-partisan bill, follows a similar one in 2015 which aimed to support the spread of a **green chemistry** initiative in the United States and was first ...

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Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 7/17/2018 9:44:04 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy: Spotlight on FERC at Pro summit — Hitching a ride on the 'minibus' — 'Secret science' out in the open

By Kelsey Tamborrino | 07/17/2018 05:43 AM EDT

With help from Emily Holden, Anthony Adragna, Colin Wilhelm and Darius Dixon

SEE YOU THERE: Today's the day — POLITICO Pro is hosting its second annual Pro summit, featuring one-on-one conversations with newsmakers across the policy landscape, including two sessions on energy.

FERC Commissioner Cheryl LaFleur will sit down this afternoon with our own Darius Dixon, before the regulatory body is deadlocked next month following the exit of GOP Commissioner Rob Powelson. LaFleur, a Democrat, has served under presidents from both parties and experienced the agency in almost every configuration — whether it has all five commissioners in place, or just one. There's no shortage of topics to chew over: the potential impact of an Energy Department coal and nuclear rescue plan, the heated rhetoric against states that stand in the way of pipelines, and whether FERC is "on the wrong side of history" when it comes to climate change. Darius' interview with LaFleur starts around 2 p.m.

Also on tap: California Air Resources Board Chairwoman Mary Nichols, Murray Energy CEO Bob Murray and the Council on Foreign Relations' Amy Myers Jaffe will participate in a panel this morning on America's "energy future." Nichols, for one, has been heavily involved in discussions with the Trump administration over car rules that the White House is considering rolling back. Expect questions related to the administration's efforts to pare back regulations and increase oil, gas and coal production — and an in-depth conversation on what that means for free market forces and renewables.

See the full agenda here and watch the livestream here.

WELCOME TO TUESDAY! I'm your host, Kelsey Tamborrino. Citizens' Climate Lobby's Brett Cease was first to correctly identify the two presidents who threw out the first pitch at an All-Star game in D.C.: Franklin D. Roosevelt in 1937 and John F. Kennedy in 1962. For today: Which state or states have just one consonant in its spelling? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

JUST RELEASED: View the latest POLITICO/AARP poll to better understand Arizona voters over 50, a voting bloc poised to shape the midterm election outcome. Get up to speed on priority issues for Hispanic voters age 50+, who will help determine whether Arizona turns blue or stays red.

HITCHING A RIDE ON THE 'MINIBUS': The House Rules Committee late Monday made 70 amendments to the EPA and Interior title of the spending minibus, H.R. 6147 (115). The amendments focus on blocking a host of Obama-era environmental regulations even as the Trump administration is in the process of rolling back many of those. Some of the amendments that caught ME's eye:

— **Diesel emissions grants:** Rep. Gary Palmer's amendment would eliminate the popular bipartisan Diesel Emissions Reduction Grant program used to retrofit diesel engines like those in school buses,

— **WOTUS:** Rep. Don Beyer's amendment would remove language blocking the Obama administration's Waters of the U.S. regulation,

— **Obama-era methane rule:** Rep. Markwayne Mullin's amendment would block enforcement of the Obama-era regulation aimed at curbing methane emissions from new oil and gas sources, which the Trump administration is already reconsidering,

— **Social cost of carbon:** Another amendment from conservatives would bar the use of the social cost of carbon in rulemakings,

— **Trailer efficiency:** Reps. Barry Loudermilk and Morgan Griffith's amendment would bar EPA from applying stricter fuel efficiency and greenhouse gas emissions standards to certain truck trailers,

— **Chesapeake Bay:** Rep. Bob Goodlatte's effort would limit EPA's ability to go after states that miss Chesapeake Bay cleanup milestones,

— **Ozone:** Rep. Glenn Grothman's amendment would block implementation of EPA's 2015 tightened ozone standard,

— **Coal ash:** A Democratic amendment would block the Trump EPA from visiting an Obama-era coal ash regulation,

— **Endangered Species Act riders:** Several measures would bar the administration from issuing or enforcing Endangered Species Act rules relating to species like the lesser prairie chicken and Preble's meadow jumping mouse,

— **Attorney fees:** An amendment from Reps. Jason Smith and Greg Gianforte would block attorney fees from being awarded in any Clean Air Act, Clean Water Act or Endangered Species Act settlement, and,

— **Inspectors general:** Nothing related to former Administrator Scott Pruitt was made in order, but the House will consider an amendment from Rep. Raúl Grijalva that would increase the budget of the Interior Department's inspector general by $2.5 million.

Read the full list of amendments made in order to the measure here.

'SECRET SCIENCE' OUT IN THE OPEN: EPA's controversial proposal to consider only research with publicly available data gets a public hearing at agency headquarters today starting at 8 a.m. Nearly 70 health, medical, academic and science groups — including the American Lung Association, American Heart Association, American Medical Association and American Academy of Pediatrics — oppose the plan, which they say could hamstring public health and environment protections.

EPA's Science Advisory Board voted unanimously to review the proposal, which Pruitt said was meant to bolster transparency. Paul Billings, national senior vice president of advocacy at the American Lung Association, called the rule a "coordinated effort to ignore the science that is inconvenient to the EPA's agenda," and compared it to lobbying efforts by the tobacco industry in the 1990s to exclude studies that showed secondhand smoke could kill.

What's at stake? The proposal could move forward quickly enough to allow EPA to roll back certain air quality standards currently under review. According to the Natural Resources Defense Council, the plan could undercut computer models meant to test chemicals under the new Toxic Substances Control Act and could toss

out landmark studies that relied on personal health records following extraordinary events, including when Hiroshima and Nagasaki victims were tested over time to find out the effects of radiation on humans.

The meeting will run until 8 p.m. or an hour after the last of more than 100 registered speakers has commented. Speakers, aside from many environment and public health groups, include the American Petroleum Institute, the U.S. Chamber of Commerce, the American Chemistry Council, FreedomWorks Foundation and climate science critic Steve Milloy. Dan Byers of the Chamber of Commerce's Global Energy Institute is expected to applaud the agency's efforts and commend EPA for going through the formal public comment and rulemaking process. "It is one thing to be cavalier about transparency principles when their application has little or no import to public policy, but federal rules that impact millions of people and billions of dollars should be held to a higher standard," he is expected to say. Also registered are Reps. Paul Tonko, Suzanne Bonamici and Dan Lipinski. Comments can be submitted until Aug. 16.

Related reading: Competitive Enterprise Institute senior fellow Angela Logomasini looks at the science transparency rule in analysis published today. "The rule is actually far more modest and flexible than depicted by its critics, and its goals are in fact achievable," Logomasini writes. Read it here.

FOR THE RECORD: The House Rules Committee meets at 3 p.m. this afternoon to formulate a rule on an anti-carbon tax resolution, H. Con. Res. 119 (115), that calls a tax on carbon released from fossil fuels "detrimental to the United States economy." The Rules panel will tee up a vote later this week on the resolution, which is led by Majority Whip Steve Scalise and would put a range of lawmakers — most notably the Climate Solutions Caucus — on the record on the issue.

WHERE'S ZINKE? Interior Secretary Ryan Zinke will deliver remarks this morning at the first meeting of the "Made in America" Outdoor Recreation Advisory Committee. The committee is tasked with advising the secretary on "public-private partnerships across all public lands, with the goal of expanding access to and improving infrastructure on public lands and waterways." See the meeting agenda.

AMERICA'S PLEDGE STILL WORKING ON PLEDGES: Michael Bloomberg and California Gov. Jerry Brown, the co-chairs of climate organization "America's Pledge," have unveiled a preview of the report they will release at the Global Climate Action Summit in San Francisco in September, detailing "bottom-up" opportunities for climate action sans federal leadership. The list is familiar: boosting renewables, accelerating coal retirements, retrofitting buildings for energy efficiency, electrifying building energy use, accelerating electric vehicle adoption, phasing out HFCs, preventing methane leaks at the wellhead, reducing methane leaks in cities, reducing emissions from land and starting carbon markets.

Vice Chairman Carl Pope said the group still plans to debut a quantitative analysis outlining what state and local governments are already doing, what they have committed to and what they are keying up. "We have every reason to believe the rest of the world is watching this very closely," Pope said, noting that the U.N.'s top climate official, Patricia Espinosa, mentioned the group and summit by name at the Vatican earlier this month. Read it here.

ESA GETS ITS DAY: Proposed tweaks to the Endangered Species Act will be front and center at a Senate Environment and Public Works hearing this morning. The hearing will feature testimony from Wyoming Gov. Matt Mead, Colorado Parks and Wildlife's Bob Broscheid and Virginia's Secretary of Natural Resources Matthew J. Strickler, and will focus on a discussion draft released by Chairman John Barrasso earlier this month aimed at changing the statute. **If you go:** The hearing kicks off at 9:45 a.m. in 406 Dirksen. Livestream here.

TAKEN BY STORMWATER: The House on Monday passed by voice vote H.R. 3906 (115), the Innovative Stormwater Infrastructure Act of 2017, which would "establish centers of excellence" for stormwater control infrastructure. The legislation, introduced last year by Democratic Rep. Denny Heck, directs EPA to create a

stormwater infrastructure funding task force to make recommendations on the availability of public and private funding for stormwater infrastructure.

DOE ISSUES FIRST TRIBAL LOAN GUARANTEE: The Energy Department will issue its first solicitation for the Tribal Energy Loan Guarantee Program today. The program provides up to $2 billion in partial loan guarantees to support energy development in Native American and Alaska Native communities. According to DOE, today's solicitation marks more than $40 billion in energy infrastructure loans and loan guarantees from DOE's Loan Programs Office in five areas.

HOUSE PANEL TO HOLD GRID HEARING: House Natural Resources will hold a hearing on July 25 on Puerto Rico's electric grid recovery and possible improvements to make it more efficient and resilient to future hurricanes. On top of the devastation caused by Hurricane Maria last year, Puerto Rico's electric utility owes bondholders $9 billion, and most of its leadership departed last week after clashes with Gov. Ricardo Rosselló over executive compensation and political control of the utility, which is quasi-governmental.

MAKING THE GRADE: The Environment America Research & Policy Center is out today with its state-by-state report card, "Renewables on the Rise," which details increases in solar, wind, energy efficiency, electric vehicles and battery storage. The report says the U.S. now produces almost six times as much renewable electricity from wind and solar than it did in 2008. It also found that in March of last year, wind and solar produced 10 percent of the United States' electricity — marking a first. On the state level, the report said California, Arizona, North Carolina, Nevada and Texas saw the greatest total increases from 2008 until 2017 in solar energy generation. See the report here and a state-by-state interactive map here.

YOU DOWN WITH TIP? A bipartisan group of four senators wrote to Energy Secretary Rick Perry on Monday in support of the Western Area Power Administration's Transmission Infrastructure Program, which was axed under the Trump administration's fiscal 2019 budget proposal. "TIP is one of the few federal programs that directly supports new and upgraded electric transmission," according to the letter, signed by Sens. Catherine Cortez Masto, Martin Heinrich, Dean Heller and Cory Gardner.

HOUSE PLANS FLOOD INSURANCE VOTE: The House is planning to vote next week to extend the National Flood Insurance Program, ahead of its July 31 expiration, sources familiar with the matter tell Pro Financial Services' Zachary Warmbrodt. There are already a few options on the table for the program: one from Financial Services Chairman Jeb Hensarling, who has been trying to put together an extension bill that includes reforms, and a new bill introduced by Scalise and Rep. Tom MacArthur that would reauthorize the program through Nov. 30. Read more.

FOR YOUR RADAR: Republican Sen. Chuck Grassley introduced bipartisan legislation on Monday targeting price fixing by OPEC. The bill would amend the Sherman Act to make oil-producing and exporting cartels illegal, and was co-sponsored by Sens. Amy Klobuchar, Mike Lee and Patrick Leahy . "It's long past time to put an end to illegal price fixing by OPEC," Grassley said in a statement. Read the legislation here.

MAIL CALL! National Rural Electric Cooperative Association CEO Jim Matheson sent a letter to the leadership of the Energy and Commerce Environment Subcommittee on Monday in support of legislation to reform the New Source Review permitting program.

— **More than 100 Democrats** signed onto a letter to members of both House and Senate Armed Services committees today to urge them to oppose any provisions to the National Defense Authorization Act that would "have widespread, negative consequences for the conservation of our imperiled wildlife and public lands." Read the letter here.

— **Iowa's congressional delegation** invited acting EPA Administrator Andrew Wheeler to their state to discuss the Renewable Fuel Standard. Read it here.

What role will Hispanic voters over 50 play in Arizona this Fall? Read POLITICO Magazine's new series "The Deciders" which focuses on this powerful voting bloc that could be the determining factor in turning Arizona blue.

QUICK HITS

— "Puerto Ricans return to power grid, but fear for long term," The Associated Press.

— "Oil boom in Southern New Mexico ignites groundwater feud with Texas," Water Deeply.

— "In N.Y., farmers think about what might have been," E&E News.

— "Same agenda, different style, acting EPA head pledges," Bloomberg Environment.

HAPPENING TODAY

8:30 a.m. — POLITICO's Pro Summit, 999 Ninth St. NW.

8:45 a.m. — The United States Institute of Peace discussion on "Wildlife Poaching and Trafficking: Combating a Vital Source of Terrorism," 2301 Constitution Avenue NW.

9 a.m. — The Resilient Puerto Rico Advisory Commission discussion with the authors of the newly released "ReImagina Puerto Rico" report, 14th and F St. NW.

9 a.m. — The National Academy of Sciences' Board on Atmospheric Sciences and Climate meeting to discuss a research agenda for adaptation science, 2101 Constitution Ave. NW.

9:45 a.m. — Senate Environment and Public Works Committee hearing on "The Endangered Species Act Amendments of 2018," 406 Dirksen.

10 a.m. — House Natural Resources Federal Lands Subcommittee hearing on federal land bills, 1324 Longworth.

10 a.m. — The Atlantic Council discussion on "Ready and Resilient," focusing on disaster preparedness, 1030 15th St. NW.

10 a.m. — House Oversight Interior, Energy and Environment Subcommittee hearing on "Tribal Energy Resources: Reducing Barriers to Opportunity," 2247 Rayburn.

10 a.m. — House Science Energy and Environment Subcommittees joint hearing on "The Future of Fossil: Energy Technologies Leading the Way," 2318 Rayburn.

10 a.m. — Senate Energy and Natural Resources Committee hearing on the Interior Department's final list of critical minerals, 366 Dirksen.

12:30 p.m. — The Washington Institute for Near East Policy discussion on "Reimplementing Iran Sanctions: Where, How and How Much?" 1111 19th St. NW.

12:30 p.m. — Sens. Ed Markey and Tom Carper press conference on Supreme Court nominee Brett Kavanaugh, S-115.

1 p.m. — EPA meeting on pesticide health and safety, Rosslyn, Va.

1 p.m. — House Energy and Commerce Environment Subcommittee markup of H.R. 3128 (115), 2322 Rayburn.

3 p.m. — House Rules Committee meets to formulate a rule on H. Con. Res. 119 (115), H-313.

THAT'S ALL FOR ME!

To view online:
https://subscriber.politicopro.com/newsletters/morning-energy/2018/07/spotlight-on-ferc-280874

Stories from POLITICO Pro

House plans vote to keep flood insurance program going Back

By Zachary Warmbrodt | 07/16/2018 06:49 PM EDT

The House is planning to vote next week to extend the National Flood Insurance Program before leaving town ahead of the program's July 31 expiration, sources familiar with the matter said.

House Financial Services Chairman Jeb Hensarling (R-Texas) has been trying to put together an extension bill that includes reforms, sources said. Another option is a new bill introduced by House Majority Whip Steve Scalise (R-La.) and Rep. Tom MacArthur (R-N.J.) that would reauthorize the program through Nov. 30.

In a statement, Scalise said it was important to keep working on a long-term flood insurance reauthorization but that his bill would take concerns about a lapse off the table for the remainder of hurricane season.

While the House has passed a five-year reauthorization and overhaul, the Senate hasn't reached agreement on its own bill amid disputes over how to retool the program. It's unclear if the Senate would be able to pass anything other than a clean, short-term reauthorization at this stage. Sources said Sen. John Kennedy (R-La.) was planning to try to hotline an extension through January.

To view online click here.

Back

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 7/31/2018 2:52:09 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Re: OCSPP-Administrator Cheat Sheet

Can you forward me the other updated sheets?

Sent from my iPhone

On Jul 30, 2018, at 5:38 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

> Troy-
> See attached. Do you need this on 2 separate sheets of paper?
>
> ---
> Nancy B. Beck, Ph.D., DABT
> Deputy Assistant Administrator, OCSPP
> P: 202-564-1273
> M: 202-731-9910
> beck.nancy@epa.gov
>
> **From:** Lyons, Troy
> **Sent:** Monday, July 30, 2018 2:14 PM
> **To:** Wehrum, Bill <Wehrum.Bill@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Wright, Peter <wright.peter@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Breen, Barry <Breen.Barry@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Forsgren, Lee <Forsgren.Lee@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Chancellor, Erin <chancellor.erin@epa.gov>
> **Cc:** Jackson, Ryan <jackson.ryan@epa.gov>; Palich, Christian <palich.christian@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Frye, Tony (Robert) <frye.robert@epa.gov>
> **Subject:** INPUT NEEDED--Administrator Cheat Sheet
> **Importance:** High
>
> Team—the Administrator would like a single paged cheat sheet on the top issues most likely to be asked. To accommodate this request, please provide 1-2 talking points that the Administrator could read verbatim, if needed. **This needs to be completed by COB today so he can review this evening.** Let me know if I have missed any topics.
>
> Please let me know if you have any questions.
>
> OAR
> - CAFE
> - California Waiver--OAR
> - Cross Border
> - Kigali Amendment/Hydrofluorocarbons
> - Small Refinery Exemptions

- New Source Review
- Once In, Always In

OCSPP
- TSCA Implementation
- Methylene Chloride
- Formaldehyde

OLEM
- CCR
- Risk Management Plan

ORD
- Secret Science
- Science Advisory Boards—Conflicts of Interest

OW
- PFAS
- Lead

Troy M. Lyons
Associate Administrator
Office of Congressional & Intergovernmental Relations
U.S. Environmental Protection Agency
202-309-2490 (cell)

<Cheat Sheet OCSPP.7.30.2018.docx>

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 4/23/2018 3:03:35 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt Heads to the Hill • Pompeo, Macron and Merkel • Colorado River Battles

Posted: Apr 23, 2018, 6:30 AM EDT

By Chuck McCutcheon

Scott Pruitt won't be inside his soundproof phone booth, or have bodyguards as a buffer, when he sits down before lawmakers this week.

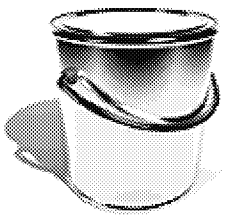
The EPA administrator is scheduled to appear Thursday before the House Energy and Commerce energy panel, then head to the House subcommittee that controls his agency's spending. Pruitt has only made a handful of appearances before Congress, so members of both parties have lots of questions.

EPA Administrator Scott Pruitt speaks during a recent interview. EPA Administrator Scott Pruitt speaks during a recent interview. Photographer: Andrew Harrer/Bloomberg via Getty Images

Among the issues drawing questions: The installation of the $43,000 booth and whether bodyguards went with him to Disneyland and the Rose Bowl.

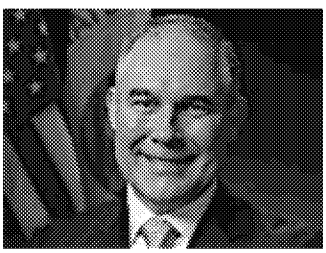
Both have stirred controversy and jump-started investigations—along with Pruitt's unorthodox $50-per-night rental of a Capitol Hill bedroom from a lobbyist, his frequent trips to his home state of Oklahoma, and what one ex-aide has described as a practice of retribution against EPA workers who challenge the administration. Abby Smith is covering.

EPA Lead Paint, Soil Standards Need Work by June: Adviser



The Environmental Protection Agency hasn't conducted extensive reviews of its lead paint and lead-in-soil standards, which a federal court has ordered it to either update or justify by June, an agency adviser said April 19.

Pruitt Moving Again to Change the Way EPA Uses Science (1)



Snapshot

• Pruitt previously told Bloomberg News that agency should rely only on science where data is publicly available

• EPA in 2017 estimated similar open data policy would bar 95 percent of studies it relies on

By Patrick Ambrosio

EPA Administrator Scott Pruitt is taking another step toward changing how the agency uses science.

The White House Office of Management and Budget is reviewing a proposal that aims to strengthen the "transparency and validity" of the science the Environmental Protection Agency uses to support its regulatory decisions, according to

the office's website. OMB's review, typically one of the final steps before a proposal is released for public review, started April 19.

There are no details on what's included in the proposal, but Pruitt told Bloomberg News in March that the EPA should rely on science that is "very objective, very transparent, and very open." He raised concern about third-party research where the underlying data isn't public.

"That's not right," Pruitt said in March. "The methodology and data need to be a part of the official record—the rulemaking—so that you and others can look at it and say, 'Was it wisely done?'"

Researchers and environmental advocates told Bloomberg Environment that such a policy could severely limit the data the agency considers when it regulates everything from drinking water and air quality to pesticides. Some EPA staff agree: The agency in 2017 told the Congressional Budget Office that similar open data requirements would limit usable studies by 95 percent.

"The policy is still being developed," EPA spokesperson Liz Bowman said in an April 20 statement emailed to Bloomberg Environment. "It's important to recognize that Administrator Pruitt believes all Americans deserve transparency, with regard to the science and data that's underpinning regulatory decisions being made by this Agency."

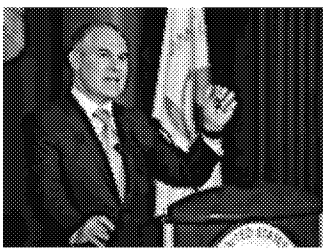
Pruitt's goal is similar to that in legislation (H.R. 1430) that House Science and Technology Committee Chairman Lamar Smith (R-Texas) introduced, which would require the EPA to base its regulatory decisions on data that's publicly available and substantially reproducible.

Last year, Pruitt barred scientists who receive EPA grants from serving on agency advisory panels, citing conflicts of interest. That policy affected many members of the EPA's advisory panels, including a panel that reviews the science backing national air quality standards, who either left or had to relinquish their grants.

To contact the reporter on this story: Patrick Ambrosio in Washington at pambrosio@bloombergenvironment.com

To contact the editor responsible for this story: Rachael Daigle at rdaigle@bloombergenvironment.com

Pruitt's $43,000 Soundproof Phone Booth Started More Modestly



Snapshot

• Agency staff authorized most expensive rush job option

• Higher budgets approved as scale of project mushroomed

By Jennifer A. Dlouhy

In the beginning, it was supposed to be just a secure telephone line.

But over the course of four months last year, that phone line destined for the office of Environmental Protection Agency Administrator Scott Pruitt morphed from a no-more-than $13,500 project into a $43,000 privacy booth, complete with silenced ventilation and "noise-lock" paneling to keep conversations from being overheard, according to documents obtained by Bloomberg News.

The documents, including purchase requisition forms and email correspondence, add another element to the portrait emerging about Pruitt's spending habits at the agency. They also illustrate some staff unease with the purchase as the scale of the project grew and costs mushroomed.

Just one month into the project, on June 28, 2017, Gayle Jefferson, the director of the EPA's facilities management and services division, confided to colleagues: "The secure room for the administrator appears to be taking on a life of its own."

EPA spokesman Jahan Wilcox said that "Administrator Pruitt simply requested a secure phone line but never asked for a soundproof booth, nor did he have knowledge of its purchase."

Role of Career Staff

"As required by law," Wilcox added, "career EPA employees authorized the purchase and installation."

The documents obtained by Bloomberg News do not capture verbal conversations; they contain electronic communication and may be incomplete. From the documents alone, it is impossible to verify the scope of the initial phone line request or know whether Pruitt and other political appointees ever encouraged a more elaborate project.

Pruitt's soundproof phone booth—installed a few floors up from another secure telecommunications center in the same Washington building—is drawing scrutiny from lawmakers, the White House and the EPA's inspector general. Pruitt is already under fire for other spending—including pricey first-class travel—and his unorthodox $50-a-night rental of a bedroom in a Capitol Hill condominium from a lobbyist last year.

Appropriations Law

Earlier this week, the Government Accountability Office concluded the EPA violated an appropriations law by failing to tell Congress about the planned telecommunications booth purchase, since advance notification was required when spending more than $5,000 to furnish or redecorate an agency head's office.

The GAO also said the EPA ran afoul of the Antideficiency Act, a measure prohibiting federal agencies from spending government funds in advance or in excess of an appropriation. Career officials within the EPA's Office of General Counsel had concluded the phone booth purchase—like other approved spending on biometric locks—did not need to be reported to Congress.

The documents obtained by Bloomberg News show the heavy role played by career officials who have purchasing power—and suggest political appointees without the authority to approve acquisitions were less involved.

A July 6, 2017 calendar invite to discuss the status of a "secure communication room for the administrator" included roughly two dozen career EPA employees and one political appointee: former Deputy Chief of Staff Kevin Chmielewski.

Costs Ballooned

EPA officials seeking bids for the project initially estimated a privacy booth would cost $13,500 on a July 24, 2017 requisition form. Another $11,500 was added on Aug. 17, and an additional $570 was included on Aug. 23 as the staff closed in on a final vendor. That $25,570, including a $1,000 after-hours delivery charge, was just for the booth itself;

total costs ballooned to $43,000 after prep work and installation, including leveling a concrete floor to insert the pre-fabricated steel box.

Former Assistant Deputy Chief of Staff Reginald Allen—who had the top career post in the EPA—sent booth costs of $24,570 to Chmielewski on Aug. 23, adding that he was waiting for an estimate for the floor from Jefferson's team. Another email says funding was being handled by Allen's office.

Different Options

At one point, EPA staff considered four different options for the booth purchase, ranging from $20,560 for a standard delivery that could take three months to their ultimate choice: a rush job in less than half the time with a $24,570 price tag.

Chmielewski and Allen did not respond to requests seeking comment. Chmielewski told lawmakers he was put on leave after refusing to retroactively approve first-class travel for one of Pruitt's top aides. And Allen has been reassigned.

The staff realized the project would draw attention on Sept. 27, when an acquisition manager warned Allen: "Just wanted to give you a heads up that the booth made it to the news." While "it is a legal purchase," the manager said, it "will be scrutinized."

Allen responded that the requirement to "speed delivery" came from Chmielewski and Pasquale Perrotta, the special agent in charge of Pruitt's protective detail, who has justified other spending in the name of protecting the administrator. "They must address any questions or concerns," Allen said.

To contact the reporter on this story: Jennifer A. Dlouhy in Washington at jdlouhy1@bloomberg.net

To contact the editor responsible for this story: Jon Morgan at jmorgan97@bloomberg.net

Feds' Plan to End Kids' Lead Exposure Still on Track for Summer

A cross-agency strategy to reduce or even eradicate lead exposure among children is still on track to be released this summer, EPA officials said April 20.

INSIDEEPA.COM ARTICLES

EPA Floats 'Secret Science' Ban Rule, Signaling Possible Internal Fixes

EPA has sent for White House review a proposed rule to increase the transparency of regulatory science, advancing Administrator Scott Pruitt's controversial efforts to ban the use of "secret science" in a move that suggests officials have

addressed at least some internal concerns that such a policy could violate statutory protections of medical privacy and trade secrets.

GREENWIRE ARTICLES

EPA sends 'secret science' plan to White House

Sean Reilly, E&E News reporter

Published: Friday, April 20, 2018

EPA headquarters in Washington. Claudine Hellmuth/E&E News

EPA yesterday sent a proposed rule to the White House Office of Management and Budget with the announced purpose of "strengthening transparency and validity in regulatory science," according to the RegInfo.gov site.

The proposal appears to be a concrete step toward restricting the types of scientific research that EPA officials can use in crafting new regulations. The proposal was not listed on EPA's latest semiannual regulatory agenda, and agency press aides did not respond to an emailed request for more information this morning.

"We need to make sure their [scientists'] data and methodology are published as part of the record," EPA Administrator Scott Pruitt told *The Daily Caller*, a conservative news outlet last month, in an article that the agency later distributed as a news release. "Otherwise, it's not transparent. It's not objectively measured, and that's important."

Wheeler sworn in

Kevin Bogardus, E&E News reporter

Published: Friday, April 20, 2018

EPA Deputy Administrator Andrew Wheeler shakes hands with Administrator Scott Pruitt this morning after being sworn in to the position.

Andrew Wheeler has officially joined EPA as its new No. 2.

Wheeler was sworn in this morning as the agency's deputy administrator.

"Glad to give a warm welcome to Andy Wheeler this morning," Administrator Scott Pruitt said in a tweet today.

Pruitt added the two looked forward to working together to advance President Trump's "agenda of regulatory certainty & environmental stewardship" at EPA.

CHEMICAL WATCH ARTICLES

Turkey adds benzyl cyanide to substances subject to import control

23 April 2018 / Substances of concern, Turkey

Turkey has added phenylacetonitrile (benzyl cyanide) to the list of hazardous chemicals and mixtures subject to import controls.

The substances on the list are deemed harmful to human health and require special permission from the Ministry of Health before they can be imported into the country.

The amendment was published in Turkey's *Official Gazette* on 14 April. It became effective immediately.

Echa says the substance is fatal if inhaled, toxic if swallowed and toxic in contact with skin, according to the classification provided by companies in REACH registrations.

It is used as an intermediate for a variety of compounds, including pharmaceuticals and other types of drugs.

Further Information:

- Official Gazette (in Turkish)
- List of substances subject to import permission (in Turkish)

OTHER ARTICLES

States Are Doing What Scott Pruitt Won't

New York Times

Before President Trump was elected, Massachusetts, California and Maine led the charge, regulating certain toxic substances that the federal government had let slip by. Now Washington State has moved to the fore in this fight. When Stephen Swanson, a retired E.R. doctor, learned that his drinking ...

EPA Pulls Public Documents Regarding Its Transparency Policy

Gizmodo

In an op-ed published in the Hill, Yogin Kothari, a representative for the Center for Science and Democracy at UCS, wrote that the new policy could mean "many of studies that are the foundation of our entire understanding of the public health impacts of pollution and exposure to toxic chemicals would be ...

Zero Out Toxics

State PIRGs

There are more than 80,000 **chemicals** on the market in the United States, used in everything from perfumes **and** household cleaners, to fertilizers **and** industrial solvents. These **chemicals** are created to make our lives better, **and** many of them do. Yet most of them go directly into use without testing their ...

Response to The Home Depot's new strategy to remove toxic chemicals from cleaning products

Safer Chemicals, Healthy Families (press release) (blog)

Today, The Home Depot announced plans to remove harmful chemicals in cleaning products, in an expansion of the company's chemical strategy. The Home Depot will require suppliers to remove nine **toxic chemicals** from cleaning products by the end of 2022, including certain phthalates, parabens, ...

A New Study Found Toxic Chemicals In Kitchen Cabinets, And Here's What You Need To Know

BuzzFeed News

Polychlorinated biphenyls (PCBs) are **chemicals** that were once used in the manufacture of insulation, electrical equipment, **and** other items but are no longer used because they are carcinogens. They were banned in the 1970s, **and** they tend to be found in Superfund sites, or those areas identified by ...

After The Governor's Veto, The Fate of Vermont's Toxic Substances Bill

Vermont Public Radio

Live call-in discussion: New regulations for **toxic substances**—and a new agency to enforce them—passed both the House and Senate in April, but the bill was vetoed by Gov. Scott. Now lawmakers are working on a possible veto override. We're looking at what the bill could mean for Vermont, the ...

Gov. Scott's veto of toxic chemicals bill will stand or fall in the VT House

BurlingtonFreePress.com

MONTPELIER - The Vermont Senate has voted to override the governor's veto of a **toxic chemicals** bill, setting up a decisive vote in the House of Representatives. Scott vetoed the bill Monday evening, fearing that it would "jeopardize jobs and make Vermont less competitive for businesses." With a vote ...

MINNESOTA

May 15, 2018

The Honorable E. Scott Pruitt, Administrator
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Mail Code 1101A
Washington, D.C. 20460

Re: Comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018 at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Pruitt:

The Minnesota Pollution Control Agency (MPCA) and Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science," published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259. This proposed rule to "strengthen transparency" does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and it will threaten the lives of real people. EPA should withdraw this dangerous proposal.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are appalled by the specious and brazen attack on health sciences research and the field of epidemiology. The proposed rule was clearly designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, or soil. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research – and to create suspicion significant enough to deter future use of health-based studies in regulatory decision-making. EPA's proposal flagrantly ignores the reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields.

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analysis would effectively breach confidentiality requirements upheld by public and private research through Institutional Review Boards (IRB). It is well documented that privacy assurances are essential to including people in health studies.

From a risk assessment perspective, not including epidemiology studies in regulatory science is not sound or prudent. Laboratory, toxicology, and epidemiology are complementary and necessary pieces of understanding and quantifying effects of a pollutant on human health. Excluding evidence from one of these three essential disciplines threatens the science basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in an impossible situation of relying primarily on animal models or in-vivo models that cannot be directly extrapolated to human dose-response estimates.

Minnesota supports open data access and is a national leader in science and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data available, providing technical assistance for using data, and engaging partners across communities and research institutions

around effective dissemination and data utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state IRBs.

Based on the lack of meaningful information and articulated or demonstrated need for the proposed rule, EPA has not made the case for a new regulation at 40 CFR Part 30.

The promulgation of this proposed rule would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision-making. As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. The EPA should immediately announce that it is withdrawing this proposal.

Our agencies will be submitting additional, substantive comments to the rulemaking record.

Sincerely,

John Linc Stine, Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, Minnesota 55155

Jan Malcolm, Commissioner
Minnesota Department of Health
625 Robert Street North, Box 64975
St. Paul, Minnesota 55155

Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 6/15/2018 9:44:23 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy, presented by the National Rural Electric Cooperative Association: Where in the world is Rick Perry? — Pressure mounts to call Pruitt before EPW — BLM to hold ANWR hearing

By Kelsey Tamborrino | 06/15/2018 05:42 AM EDT

With help from Alex Guillén

WHERE IN THE WORLD IS RICK PERRY? The Energy secretary will confer with his G-20 counterparts today in Bariloche, Argentina, while he attends the second meeting of the Energy Transitions Working Group. Perry will participate in ministerial sessions and other bilateral meetings to discuss international energy challenges and solutions, according to DOE. The G-20 has described today's confab as discussions of "public policies to help promote transitions towards more flexible, more transparent and cleaner energy systems."

Much like the G-7 of last week, the summit will close with all nations signing onto a joint communique that outlines the energy chiefs' agreements. (You can watch the press conference here .) Since the agenda is prioritizing, among other things, "the lowering of inefficient subsidies to fossil fuels," ME is guessing Perry's not going to be any happier than President Donald Trump was in Canada last week given his push to prop up struggling coal power plants in the U.S. For his part, Perry has pitched Trump's "energy dominance" commitment before on an international stage, including ramping up natural gas and oil exports. ME will also be watching to see how Perry handles issues related to climate change.

The Paris climate agreement cast a shadow over last year's G-20 summit, where the president isolated himself from other nations on the issue. Just last week, Trump said the U.S. would not sign onto the G-7 communique in Canada because of trade concerns. And of course Trump has already promised to pull the U.S. out of the Paris accord, so the U.S. instead would only commit to "strengthen the world's collective energy security, including through policies that facilitates open, diverse, transparent, liquid and secure global markets for all energy sources."

IT'S FINALLY FRIDAY! I'm your host Kelsey Tamborrino, and Entergy's Rob Hall was the first to identify all four baseball teams former Kentucky Sen. Jim Bunning played for: the Detroit Tigers, Philadelphia Phillies, Pittsburgh Pirates and Los Angeles Dodgers. Now for something completely different: What was the name of the first pet cow former President William Howard Taft brought with him to the White House? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

POLITICO will be reporting from inside the World Gas Conference June 25 - June 29. Sign up now for our pop-up conference newsletter to receive on-the-ground insights and information every afternoon from POLITICO Pro Energy Editor Matt Daily.

Join Pro subscribers, expert reporters and key decision-makers from the executive branch, federal agencies and Congress for a full day of incisive policy conversations on July 17. Speakers include: Rep. Joe Crowley (D-N.Y.), Chairman, House Democratic Caucus, Kevin McAleenan, Commissioner, U.S. Customs and Border Patrol, and others. Register today.

WOTUS TO OMB TODAY: EPA Administrator Scott Pruitt will send the Waters of the U.S. rewrite to the Office of Management and Budget today, the administrator confirmed in a tweet. "In keeping w/ @POTUS's promise, we have stopped the 2015 #WOTUS rule & I just announced to folks in Lincoln that a much more reasonable #WOTUS rule will be sent to OMB tomorrow," he said Thursday. "Time to provide farmers & ranchers nationwide w/ regulatory certainty!" Pruitt discussed the new WOTUS rule at a roundtable discussion with Nebraska farmers on Thursday, where he said the agency will release "a back to the basics" rule that doesn't reinterpret the Clean Water Act, according to a reporter from the Lincoln Journal Star who attended.

WILL HE OR WON'T HE? Several GOP senators are pressing for an oversight hearing for Pruitt, Pro's Anthony Adragna reports. Pressure is mounting for the Environment and Public Works Committee to call on the administrator to discuss his ever-growing number of ethics scandals. On Thursday, three more Republicans — Shelley Moore Capito (W.Va.), Roger Wicker (Miss.) and Dan Sullivan (Alaska) — echoed Jim Inhofe and Joni Ernst's call for Pruitt to return to their committee for the first time since January.

"The policies that the administrator has moved forward on have really reaped a lot of benefits in terms of job creation in my state on the energy side, but it just seems like things keep cropping up, so I would agree with Sen. Inhofe," Capito told POLITICO. Chairman John Barrasso told Anthony, however, he still had "no immediate plans" to call Pruitt back before his committee. Read more.

BARRASSO WANTS MORE MONEY FOR EPA IG: The Senate Appropriations Committee on Thursday voted for a bill that would keep funding for EPA Inspector General Arthur Elkins at $50 million next year, but Barrasso says he will push for more money. "The EPA's Inspector General requested $62 million," Barrasso told ME in a statement. "I'd like to get as close as possible to that amount. I will continue to work with the Senate Appropriations Committee to get the Inspector General the funding he needs." Elkins said earlier this year that his current budget simply isn't cutting it — and that was before his office opened many of its ongoing probes into Pruitt. The Senate bill could hit the floor sometime this summer, which would be the next opportunity to amend it.

THE UNION PERSPECTIVE: John O'Grady, the president of AFGE Council #238 that represents more than 8,000 EPA workers, told reporters this week the administration is "just beginning to start the real attacks on the unions," citing recent executive orders weakening the influence of government unions and making it easier for agencies to fire civil servants. Asked about Pruitt, O'Grady said people within the agency are "disgusted" by the administrator, and the "almost daily" drip of scandals that would get any one else fired. "It's discouraging that the person that's supposed to be leading the agency that is dedicated to protecting human health and the environment is a person that apparently lacks basic ethical values," he said. "He is making a laughingstock out of his own party as far as I'm concerned and certainly out of this country."

WHITE HOUSE MOVING ON AUTO REGS: The White House Office of Information and Regulatory Affairs will meet with the Alliance of Automobile Manufacturers and the California Air Resources Board as part of the next round of discussions on fuel efficiency standards, Reuters reports. Officials will meet with the automakers trade group and CARB separately before unveiling the administration's proposal to reverse rules aimed at increasing fuel efficiency, participants told the news outlet. The plan is expected to be made available for public comment later in June or July, and point toward freezing requirements at 2020 levels. Read more.

NOMS: Trump said Thursday he intends to make Dan Simmons the permanent head of the Energy Department's energy efficiency and renewable energy office, where he's been for more than a year already. Simmons became EERE's principal deputy assistant secretary on May 1,2017, after working on Trump's DOE transition and beachhead teams, Pro's Darius Dixon reports.

BLM'S FRIDAY HAPPY HOUR? Those wishing to speak today at Bureau of Land Management's scoping meeting on drilling lease sales in the Arctic National Wildlife Refuge will have to face the luck of the draw — and probably skip the rest of their Friday night plans.

The final public meeting on the environmental impact statement for oil exploration on the coastal plain of ANWR kicks off at 4:30 p.m. at the National Housing Center. The meeting with begin with a brief presentation, with speakers set to speak at 5 p.m. and general public comments running from 6:30 until 9 p.m. The public comment, BLM said , will be chosen at random. "We anticipate there will be more speakers than time available for public testimony," said acting BLM Alaska State Director Karen Mouritsen in a statement, justifying that a random drawing would ensure "we hear from a sampling of views from all who attend." The agency also noted it will accept public comment through other means up until Tuesday. The agency wouldn't say whether it has taken this approach to public comment before.

Expect some protests: Subhankar Banerjee, a professor at the University of New Mexico, said he will attend today's meeting, after signing onto a letter this week with fellow academics that called attention to the biological, cultural and climate impacts of drilling in ANWR. Having spent more than 20 years studying the area, he told ME that the particular area of ANWR is one of the most biologically diverse nurseries in the world. BLM's scoping process is "absolutely unreal," Banerjee said, and he pointed out that although BLM held various meetings in Alaska on the lease sales, today's meeting is the only one in the contiguous U.S. "This timeline is inappropriate," he said. "Who is going to show up on a Friday evening?"

— **Gwich'in leaders and conservationists will hold a rally** at 4 p.m. outside of the hearing, where Alaska Wilderness League's Kristen Miller said 150 to 200 people are expected to attend. Speakers at the rally will include League of Conservation Voters' Gene Karpinski and Union of Concerned Scientists' Joel Clement, among others.

RELATED TIMELINE: The Energy Information Administration said Thursday development of ANWR would increase U.S. crude oil production after 2030, based on three resource estimate values. "In all three cases, production from ANWR does not start until 2031 because of the time needed to acquire leases, explore, and develop the required production infrastructure," EIA said.

DEMOCRATS CALL OUT MOUNTAINTOP STUDY: Eight Democratic senators signed a letter asking Interior Secretary Ryan Zinke why a National Academies of Sciences, Engineering and Medicines study on the health effects of mountaintop removal mining was stopped. Earlier this week , Interior's Office of Inspector General found that "officials were unable to provide specific criteria, used for their determination whether to allow or cease certain grants and cooperative agreements" on the study. In Thursday's letter, the senators call on Zinke to explain the reasoning behind ending the study, as well as provide an accounting of the taxpayer money spent. Read it here.

APPROVAL NEEDED: Guidelines posted to the U.S. Geological Survey and obtained by The Washington Post show that scientists at the agency were told to submit their presentation titles for review by DOI in order to get approval to attend two major conferences. The Post writes: "The USGS's Office of Administration told employees they will have to provide a detailed 'attendee justification' when applying for travel approval for the annual meetings of the American Geophysical Union in Washington and the Geological Society of America in Indianapolis later this year." Read more.

COURT VACATES LEASES IN SANTA FE FOREST: The U.S. District Court for the District of New Mexico on Thursday vacated oil and gas leases in the Santa Fe National Forest for BLM's failure "to quantify and analyze the impacts of downstream greenhouse gas emissions on the environment." The federal court sent

the leases back to the BLM and U.S. Forest Service to perform further analysis of the impacts of oil and gas drilling to the forest, it said. Read the opinion here.

MAIL CALL! NAAQS IT OUT: Democratic Reps. Don Beyer and Marcy Kaptur led a letter from 71 Democrats to Pruitt expressing concern over a May memorandum on the National Ambient Air Quality Standards process. The Democrats urged Pruitt "to withdraw the improper charge to [the Clean Air Scientific Advisory Committee] at once, and to make clear that CASAC — and EPA — will remain focused exclusively on the adverse public health effects that the Clean Air Act and a unanimous Supreme Court confirm are the only relevant statutory considerations during the health standard-setting processes." Read it here.

— **The ranking members** of the Homeland Security, Transportation, Natural Resources and Energy and Commerce committees joined Thursday to send a letter to FEMA Administrator Brock Long on his agency's decision to end the Army Corps of Engineers' mission to help rebuild the grid in Puerto Rico. "FEMA's decision to scale back the Federal presence in Puerto Rico is troubling given that approximately 10,000 Americans still lack power, eight months after the storm," they write. Read it here.

— **More than 30 green groups signed onto** to two letters opposing a draft bill currently being floated in the House that would penalize coastal states that prohibit offshore drilling. Read the letters here and here.

NATURE CONSERVANCY JOINS IN: The Nature Conservancy announced Thursday it has joined the Carbon Capture Coalition as a member, recognizing in a statement that "a wide range of technologies must be developed and deployed to achieve greenhouse gas emission reductions necessary to avoid the worst impacts of climate change." The Carbon Capture Coalition was co-founded by the the Center for Climate and Energy Solutions and the Great Plains Institute in 2011 to advocate for carbon capture, use and storage.

MOVERS/SHAKERS: White House assistant press secretary Kelly Love, who handled issues related to energy and EPA, will depart today to join the Energy Department, two officials told Bloomberg. Love also handled media questions related to agriculture, legislative affairs and the Justice Department, and handled media for Donald Trump Jr., Ivanka Trump and Eric Trump during the campaign, Bloomberg reports. Read more.

QUICK HITS

— Study: Climate change is moving fish around faster than laws can handle, The Washington Post.

— Yellowstone superintendent officially learned of dismissal through press release, The Hill.

— Trump's pick to lead weather agency spent 30 years fighting it, Bloomberg Businessweek.

— In possible roadblock for Keystone XL, pipeline opponents gift land to Ponca, Omaha World-Herald.

HAPPENING TODAY

8:15 a.m. — Securing America's Energy Future forum on its report titled "America's Workforce and the Self-Driving Future," 805 21st Street NW

10:00 a.m. — The Center for Strategic and International Studies discussion on Energy Department priorities, 1616 Rhode Island Avenue NW

12:00 p.m. — The Global America Business Institute discussion on spent fuel management in Sweden, 1001 Connecticut Avenue NW

CORRECTION: The June 14 edition of Morning Energy misidentified what state former Sen. Jim Bunning represented. He represented Kentucky.

THAT'S ALL FOR ME!

To view online:
https://subscriber.politicopro.com/newsletters/morning-energy/2018/06/where-in-the-world-is-rick-perry-251907

Stories from POLITICO Pro

Trump splits with other G-20 leaders on climate change Back

By Andrew Restuccia | 07/08/2017 10:13 AM EDT

President Donald Trump emerged from the G-20 summit in Germany isolated from every other major economy on climate change, but the White House nonetheless scored small victories during the meeting.

After a tense round of negotiations, G-20 nations on Saturday reached a compromise on climate change, the last remaining issue of contention at the summit. Every country except the United States declared that the Paris climate change agreement is "irreversible" and must be implemented "swiftly." The U.S., on the other hand, declared its intention to pull out of the 2015 deal, which has won the backing of nearly 200 nations.

Several countries, including France, had objected to the United States' insistence on mentioning fossil fuels in the G-20's joint communique, leading to an eleventh-hour round of talks.

In the end, the United States appeared to win that fight, keeping the reference to fossil fuels, while pairing it with a call to use renewable energy.

"The United States of America states it will endeavor to work closely with other countries to help them access and use fossil fuels more cleanly and efficiently and help deploy renewable and other clean energy sources, given the importance of energy access and security in their nationally-determined contributions," the joint communique says.

Administration officials hailed the language as a victory, with one telling POLITICO the U.S. "scored big."

Supporters of the Paris climate agreement disagreed.

"It's nearly unprecedented to have text in a document like this one referring to what only one country believes. In that respect, it's a vacuous victory for the U.S., since it only confirms what everyone already knew they believe," said former State Department climate change adviser Andrew Light. "If anything, it only indicates the knots this administration will tie itself into in order to try to simultaneously appear to be appeasing their base and not alienating the rest of the world."

The United States also used the G-20 communique to underscore its intention to withdraw from the Paris climate deal and scrap former President Barack Obama's domestic emissions reduction plan (known in United

Nations parlance as a "nationally determined contribution"), while stressing that it hopes to continue working with other countries.

"The United States of America announced it will immediately cease the implementation of its current nationally-determined contribution and affirms its strong commitment to an approach that lowers emissions while supporting economic growth and improving energy security needs," the text says.

Foreign diplomats hope this language leaves room for the United States to remain in or rejoin the Paris deal if Trump writes a new domestic climate plan that reflects his priorities.

The 19 other G-20 nations all underscored their support for the Paris agreement and endorsed a broad German-backed climate and energy plan, which includes a detailed road map for reducing emissions.

The unity is a coup for German Chancellor Angela Merkel, who sought to minimize disagreements among the rest of the G-20 amid U.S. opposition to the Paris agreement. There had been some speculation that Saudi Arabia and Turkey might object to certain portions of the climate language, but Merkel and other leaders worked to ensure they were on board.

Still, that language was weakened slightly in the final negotiations, as part of what one diplomat called a "tit-for-tat" with the United States. A previous draft version of the text said countries "agree" that the Paris deal is "irreversible." The final version uses less firm language, a seemingly minor tweak that caught the attention of some U.S. officials and foreign diplomats.

"The Leaders of the other G20 members state that the Paris Agreement is irreversible," the communique says.

G-20 countries similarly insisted that the United States use the word "state" to characterize its position, worrying that stronger language could imply broader agreement among other nations.

The U.S. has been an outsider on climate change at international talks since Trump took office.

At the May G-7 meeting in Italy, the U.S. declined to join other countries in backing the Paris deal, saying it was in the process of reviewing its policies. After Trump's June announcement that he intends to withdraw from the Paris agreement, the U.S. position was relegated to a footnote in a joint statement released after a G-7 environment ministers meeting in Germany last month.

David Herszenhorn contributed to this report.

To view online click here.

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GOP pressure mounts for Pruitt oversight hearing Back

By Anthony Adragna | 06/14/2018 05:18 PM EDT

Several Senate Republicans — including the chamber's second in command — voiced support Thursday for bringing EPA Administrator Scott Pruitt before the Environment and Public Works Committee for an oversight hearing to discuss his ever-growing number of ethics scandals.

Three more EPW Republicans — Shelley Moore Capito (W.Va.), Roger Wicker (Miss.) and Dan Sullivan (Alaska) — joined their colleagues Jim Inhofe (Okla.) and Joni Ernst (Iowa) in pressing for Pruitt to return to their committee for the first time since January. Their comments add pressure on Chairman John Barrasso (R-Wyo.) to request that Pruitt make another appearance amid a stream of scandals.

News emerged Wednesday that Pruitt had pressed his staff to ask GOP donors to help find a job for his wife, Marlyn, who later secured a position at a conservative legal group — news that prompted some conservatives to call for his ouster.

"The policies that the administrator has moved forward on have really reaped a lot of benefits in terms of job creation in my state on the energy side, but it just seems like things keep cropping up, so I would agree with Sen. Inhofe," Capito told POLITICO.

"I'm always happy with oversight opportunities," Sullivan said.

But Barrasso told POLITICO he had "no immediate plans" to call Pruitt back.

Congressional Republicans have expressed concern for months about Pruitt's conduct, but they have stopped short of calling for his resignation, deferring to President Donald Trump. Meanwhile, Democrats on the panel have repeatedly demanded Barrasso call Pruitt to testify.

White House press secretary Sarah Huckabee Sanders said Thursday "certainly we have some areas of concern in some of these allegations" but declined further comment on whether the latest revelation about Pruitt had affected the administration's thoughts on his fate.

Majority Whip John Cornyn (R-Texas) told POLITICO Pruitt's future rests with the president, but he said he favored holding an oversight hearing.

"The drip drip drip is not helpful — at all," he said.

Lisa Murkowski (R-Alaska), who oversees the Appropriations subcommittee responsible for funding EPA, also said an oversight hearing was appropriate given the continuing revelations.

"You all keep asking me questions about him," she told POLITICO. "I don't have the answers for him. I think he needs to answer."

The calls for Pruitt's appearance come one day after leading conservatives, including Fox News host Laura Ingraham and National Review, called for his resignation. Inhofe, a longtime ally of the EPA chief, told Ingraham on her radio show Wednesday the allegations "upset me as much as they upset you," and he later urged Barrasso to hold a hearing to address the issues.

Pruitt has also drawn rebukes from Ernst and Chuck Grassley (R-Iowa) for his moves to excuse several refineries from complying with biofuels blending requirements under the Renewable Fuel Standard.

"I support Sen. @JimInhofe's call for a hearing on EPA Administrator Pruitt's scandals; and I continue to urge the President to take a hard look at Mr. Pruitt's actions - as I do not feel that Mr. Pruitt is serving @RealDonaldTrump's best interests," Ernst added later in a tweet.

Not all EPW Republicans backed the call for Pruitt's appearance, though several said they would support such a move if Barrasso pursued it.

"If the chairman says that we should do that, then I would be supportive," Mike Rounds (R-S.D.) told POLITICO.

Darius Dixon contributed to this report.

To view online click here.

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Trump issues orders making it easier to fire federal employees Back

By Lorraine Woellert | 05/25/2018 05:10 PM EDT

President Donald Trump on Friday issued a series of executive orders to weaken the influence of government unions and make it easier for agencies to fire civil servants.

The orders will standardize agency rules to make it easier and quicker to remove poorly performing employees. They also direct federal agencies to renegotiate their labor contracts and cap the amount of paid time that workers can take off to conduct union-related business.

"The president is fulfilling his promise to promote more efficient government by reforming our civil service rules," Andrew Bremberg, director of the president's Domestic Policy Council, told reporters. "These executive orders will make it easier for agencies to remove poor-performing employees and ensure that taxpayer dollars are more efficiently used."

The changes could save taxpayers more than $100 million a year, the White House estimated. It referenced a 2015 Government Accountability Office report that found it can take a year or more to dismiss a permanent federal employee.

The largest federal employee union condemned Friday's orders.

"This is more than union busting — it's democracy busting," said J. David Cox Sr., president of the American Federation of Government Employees. "This administration seems hellbent on replacing a civil service that works for all taxpayers with a political service that serves at its whim."

In addition to hemming in union power, the executive orders could be abused to reduce accountability or punish whistleblowers, said Nick Schwellenbach, director of investigations at the nonprofit Project on Government Oversight.

"Weakening civil service protection laws would make the government less effective and put us all at risk, " he said. "It would impede Congress's ability to conduct oversight of the executive branch: Congress's best sources of information are the employees inside agencies, and without robust protections and due process, more sources will remain silent."

The executive orders are Trump's latest salvo against the government workforce, which he has promised to reform as part of his "drain the swamp" agenda.

They direct agencies to charge rent to employees who use federal office space for union activity and to stop covering travel expenses for non-agency business.

Preference given to long-tenured workers will be eliminated. The common practice of agency gag orders, in which managers promise to keep silent about employees in exchange for their resignations, will be eliminated. Civil servants whose performance isn't up to par will get 30 days to show improvements.

Agencies will be required to report disciplinary activity to the Office of Personnel Management for publication. They are also directed to negotiate new contracts with unions, which also will be made public. Unions will be charged for the use of agency office space.

The use of "official time" — legally sanctioned time off for labor-related activities — will be capped at 25 percent of an employee's working hours.

Republicans on the House Oversight and Government Reform Committee found this week that more than 12,500 employees took advantage of official time in 2017. The Department of Veterans Affairs was among the worst offenders, the House panel found. There, 472 employees spent 100 percent of their working hours on labor-management-related business in fiscal 2017, according to the GOP report. Those employees included a VA nurse anesthetist and dentist each making more than $190,000 a year.

The moves are sure to be challenged by labor groups and Democrats, who have accused the administration of targeting labor for political purposes.

Meanwhile, worker complaints to the Federal Labor Relations Authority are piling up because the agency has been without a presidentially appointed general counsel since November. The vacancy has prevented labor complaints cases from
being prosecuted.

A senior administration official said on Friday that the White House had no announcement to make on the labor relations appointment.

To view online click here.

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DOE beachhead member lands senior EERE post Back

By Darius Dixon | 05/01/2017 05:30 PM EDT

The Institute for Energy Research's Daniel Simmons will take up a leading post at the Department of Energy as the acting assistant secretary for the Office of Energy Efficiency and Renewable Energy, the agency said in an email to staff today.

DOE said Simmons, a former vice president for policy at the libertarian-leaning IER, would take the role of principal deputy assistant secretary for the office effective today. However, without an EERE assistant secretary who has been nominated and confirmed by the Senate, Simmons can only hold the position on a temporary basis.

DOE confirmed Simmons' appointment.

Simmons was a member of President Donald Trump's transition and beachhead teams at DOE. Before joining IER, he directed the Natural Resources Task Force at the American Legislative Exchange Council.

Steven Chalk, who had served in the position for the past few months, will now return to his role as the deputy assistant secretary for operations, according to the email.

To view online click here.

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White House to tap Simmons as permanent EERE head Back

By Darius Dixon | 06/14/2018 05:39 PM EDT

President Donald Trump intends to make Dan Simmons the permanent head of the Energy Department's energy efficiency and renewable energy office, after more than a year as its top official.

The White House announced it plans to nominate Simmons to be the assistant secretary for EERE, a division that often takes a backseat to other offices under Republican administration. EERE is one of the largest accounts within the agency and its top job is one of the few remaining vacancies among the brass at DOE. Simmons became EERE's principal deputy assistant secretary on May 1, 2017, after working on Trump's DOE transition and beachhead teams.

Before joining the administration, Simmons was the vice president for policy at the libertarian-leaning Institute for Energy Research, which regularly attacked the Obama administration's renewable energy programs. He also directed the Natural Resources Task Force at the American Legislative Exchange Council.

WHAT'S NEXT: Simmons' nomination falls to the Senate Energy and Natural Resources Committee.

To view online click here.

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Pruitt changes NAAQS review to consider 'adverse' effects of standards Back

By Alex Guillén | 05/10/2018 10:13 AM EDT

EPA Administrator Scott Pruitt today directed the agency to change the review process for a critical air quality program to include the potential "adverse" effects of tighter standards.

In a memo signed Wednesday, Pruitt directed the Clean Air Scientific Advisory Committee, which advises on National Ambient Air Quality Standards issues, to provide advice on background pollution concentrations and the "adverse public health, welfare, social, economic or energy effects" from setting and achieving NAAQS standards.

The Supreme Court has previously ruled that EPA cannot consider implementation costs when setting NAAQS standards. Pruitt's memo argues that such information, even if not used to set a standard, can provide "important policy context for the public, co-regulators and EPA."

Pruitt also committed EPA to finish reviews of two controversial standards before the end of President Donald Trump's first term.

Even as EPA continues internal deliberations over revising the 2015 ozone standard, Pruitt committed the agency to meeting the October 2020 deadline to again review the standard. He also directed EPA to complete its review of the particulate matter standard by December 2020.

The memo also:

— Calls for "more efficient ways" to conduct the scientific and policy assessments that underlie NAAQS reviews;

— Requests a "clearer distinction" between the scientific conclusions and the "wider range of policy concerns" that Pruitt considers in setting standards;

— Urges CASAC members who disagree with the panel's consensus to "share their own individual opinions;" and

— Advises EPA to issue implementation rules and guidance concurrent with NAAQS revisions.

WHAT'S NEXT: The memo directs EPA to begin work on the next ozone review in order to complete it by October 2020.

To view online click here.

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Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 4/23/2018 9:43:21 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy: Where do biofuels stand? — This week: Pruitt faces the Hill — Macron heads to Washington

By Kelsey Tamborrino | 04/23/2018 05:42 AM EDT

With help from Eric Wolff and Annie Snider

YOU CAN'T ALWAYS GET WHAT YOU WANT: Despite efforts by President Donald Trump to settle a long-running dispute between ethanol backers and the refining industry, progress on a biofuels deal has stalled. Instead, the administration has taken a piecemeal approach to the policy, pushing for an expanded market for higher blends of ethanol, while handing out exemptions to the Renewable Fuels Standard to small refiners.

Trump, for his part, has huddled multiple times with members of his Cabinet, industry and lawmakers from both corn belt and oil states, Pro's Eric Wolff reports. But so far, there's been little progress in striking a grand deal. At odds are the independent refiners, who say they feel financial stress from the RFS, and the agriculture sector, which is anxious to expand the market for corn ethanol.

Trump has promised to allow year-round sales of 15 percent ethanol blends of gasoline, while EPA Administrator Scott Pruitt has so far granted more than two dozen temporary waivers to small refineries that exempt them from the mandate requiring them to blend ethanol with gasoline. "After 18 months of pursuing various regulatory forms of relief and a handful of Oval Office confabs, the merchant refiners ended up with [an increase in E15] taking even more market share away from them in return for some small refiner hardship waivers — and some of them did not even get that," one oil refining source told Eric.

And Pruitt's controversies stemming from his first-class flights, security spending and condo rental from a lobbyist, have left the EPA chief unable to make an aggressive case for instituting price caps many refiners want on the biofuel credits, according to an administration source. Read more here.

Democrats weigh in: House Energy and Commerce ranking member Frank Pallone and Agriculture ranking member Collin Peterson sent this letter to the president on Friday, expressing concern with the waivers issued by Pruitt to small refineries, writing it "undermines the goal of the RFS program, creates uncertainty and economic hardship in the agricultural community, and gives unfair advantage to specific facilities within the refining sector."

GOOD MONDAY MORNING! I'm your host Kelsey Tamborrino, and Entergy's Rob Hall was first to correctly answer that former Senate Majority Leader Robert Taft's father served as a Supreme Court chief justice. For today: Who was the first woman to be awarded the Medal of Honor? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

POLITICO Space is our new weekly briefing on the policies and personalities shaping the second space age. Sign up **today.**

ICYMI: Check out the event videos and highlights from last Tuesday's event on how private businesses can address clean energy and build a more sustainable future.

PRUITT HEADS TO THE HILL: Thursday's the day: Pruitt is scheduled to face questions from two House committees for the first time since his swirling scandals emerged in March. He'll appear before both the House Appropriations Committee and the Energy and Commerce Committee to discuss his agency's budget request for fiscal 2019, but of course lawmakers are planning to take Pruitt to task over his ethics and spending issues. "Members are going to have questions about how things are going at the EPA and how the money is being spent," E&C Chairman Greg Walden told POLITICO last week. "And we will. We should. He'll have to answer those."

Not least on the list of questions: POLITICO's Theo Meyer and Eliana Johnson were first to report this weekend that the lobbyist, J. Steven Hart, whose wife rented a $50-per-night condo to Pruitt, also lobbied the agency while Pruitt was leading it, according to a Friday filing by his firm. That news comes despite the denials from both Hart and Pruitt that the lobbyist did not have any business before the agency. Hart announced his resignation from his lobbying firm Williams & Jensen hours before the disclosure was published. He was already planning to retire in November, but moved up his departure in the wake of the revelation that his wife had been Pruitt's landlord.

An EPA official acknowledged on Saturday that Pruitt had met with Hart, who attended a meeting with a former meat-processing executive concerned about Trump's proposal to cut spending on a Chesapeake Bay cleanup program. But the official argued that the meeting didn't meet the definition of lobbying. The disclosure, meanwhile, says Hart lobbied the EPA on issues "relating to support for EPA Chesapeake Bay Programs." A spokeswoman for House Oversight Chairman Trey Gowdy, who is already probing the administrator, told POLITICO that "the Committee has already been looking into this matter." Read more.

The hits keep coming: The Associated Press reported on Friday that state records show how, as Oklahoma's attorney general, Pruitt ordered investigations agents from his office to work as his driver and bodyguard. And a separate report from The New York Times probed how Pruitt bought a historic house in Oklahoma from a top lobbyist with the help of a shell company.

— **Another Republican called on Pruitt to resign** this weekend, marking at least four current Republican lawmakers to do so. "Yes EPA Administrator Scott Pruitt should resign. Wrong fit from start for agency dedicated to protecting our environment," New Jersey Rep. Frank LoBiondo tweeted . "#EarthDay2018 reinforces our need to promote pristine planet via clean air & water, leaving it better for future generations. Requires leadership & balance."

NOW THAT'S A MISTAKE: Three days after releasing a raft of communications between top EPA personnel to the Union of Concerned Scientists under the Freedom of Information Act, the agency removed them from its electronic library Friday. Among the documents were emails POLITICO cited on Thursday that show political officials developing a new scientific transparency policy were more concerned with the impact it could have on the agency's ability to consider industry data when reviewing pesticides and toxic chemicals for safety than they were about potentially excluding studies on the effect of pollution on public health, as many scientists have warned. EPA sent the policy, based on legislation from House Science Chairman Lamar Smith (R-Texas), to the White House for interagency review Thursday.

EPA did not respond to requests for comment over the weekend, but Yogin Kothari with UCS said the agency told him it accidentally released documents with private information and privileged attorney-client communications. His group removed emails it considered to fit that description and posted the rest on its website.

XCEL NOT SO INTO MARKETS AFTER ALL: Colorado utility Xcel Energy blew a hole in Southwest Power Pool's plans for a western power market when the company announced late Friday it had dropped out of the Mountain West Transmission Group. SPP had been working with the informal group of power providers for months to try and join the power market — and SPP had advanced the effort as recently as last month. Xcel

didn't respond to a request for comment, but the press release said there were "limited benefits" in the effort and "increasingly uncertain costs."

Perhaps most intriguing to ME is the company's point that "Xcel now sees few opportunities for westward expansion of the RTO which might have added to the value proposition." SPP faces competition from both California's already established energy-imbalance market that includes utilities in the Pacific Northwest and Nevada, and a nascent joint project between eastern market operator PJM Interconnection and western reliability manager PEAK. Xcel's press release did not say if it had engaged with either of these other projects.

MR. MACRON HEADS TO WASHINGTON: French President Emmanuel Macron makes his first official visit to Washington this week, where he'll meet with the president and deliver an address to a joint meeting of Congress. Macron and his wife will be hosted by the president and first lady at a private dinner tonight and the two leaders will participate in a bilateral meeting on Tuesday.

Officially, the two heads of state are set to discuss ongoing issues in Syria, the Iran deal and trade tensions. But keep an ear out for climate mentions, too. Macron has been critical of Trump's announcement that he would remove the U.S. from the Paris climate agreement.

Ahead of his meeting with Trump, Macron appeared on "Fox News Sunday," where he was asked whether he believes Trump will serve his full term. "I never wonder that," Macron said. "I mean, I work with him because both of us are very much at the service of our country in both side. And for me, that's why — even when we have some disagreements on climate and on some issues, I think the most important thing is to — I mean, just to remind that we are at the service of our people, that's our legitimacy."

FROM BLOOMBERG WITH LOVE: Special envoy to the U.N. for climate action Michael Bloomberg pledged to help cover the U.S. financial commitment to the Paris climate accord on Sunday. Appearing on CBS, the former New York City mayor announced he would foot the $4.5 million bill to the U.N. Climate Change Secretariat under the 2015 agreement that was struck by former President Barack Obama.

"America made a commitment. And as an American, if the government's not going to do it, we all have a responsibility, and I'm able to do it," he said on CBS. "So yes, I'm going to send them a check for the monies that America had promised to the organization." Bloomberg will also make more funding available should the U.S. government fail to produce funds for its share of the U.N. climate budget in 2019, according to a press release announcing the action.

READY FOR TAKEOFF: Rep. Jim Bridenstine will be sworn-in at 2:30 p.m. today as the new NASA administrator. After the swearing-in ceremony, Vice President Mike Pence and Bridenstine will speak live with three NASA astronauts currently living on the International Space Station.

MAIL CALL! Senate Democrats sent a series of letters Friday, calling on the administration and agency heads to share documents related to the Koch brothers' role in influencing policy in the Trump era. The letters cite specific actions for which the Koch network has taken credit, including shrinking national monuments, exiting the Paris climate change agreement and streamlining of infrastructure permitting. "Americans have a right to know if special interests are unduly influencing public policy decisions that have profound implications for public health, the environment, and the economy," the senators write. The letters, led by Sen. Sheldon Whitehouse, come before Senate floor speeches this week from Democrats that are expected to detail the influence of the Koch brothers network. Read the letter to the White House here, EPA here and Interior here.

IN CELEBRATION OF EARTH DAY: The president touted his administration's rollback of "unnecessary and harmful regulations," and pointed toward a "market-driven economy" as an essential tool in environmental protection. "A healthy environment and a strong economy go hand in hand," a White House presidential message said. "We know that it is impossible for humans to flourish without clean air, land, and water. We also

know that a strong, market-driven economy is essential to protecting these resources." Trump said for that reason, his administration is "dedicated to removing unnecessary and harmful regulations that restrain economic growth and make it more difficult for local communities to prosper and to choose the best solutions for their environment."

REPORT OUT ON DOE BUDGET: The Information Technology and Innovation Foundation is out with a new report today analyzing the Energy Department's budget for research, development and demonstration. The report details how the administration's current budget proposal for fiscal 2019 would "impose the largest single-year decrease" in DOE history. "R&D spending as a share of sales in the U.S. energy industry is only 0.4 percent, compared with 8.5 percent in aerospace and defense, 9.8 percent in computers and electronics, and 2.4 percent in the automotive industry," the report finds. Read it here.

MOVER, SHAKER: Holly Burke last week joined the League of Conservation Voters as communications coordinator. She previously worked for American Bridge.

— **Jennifer Talhelm,** formerly communications director for Sen. Tom Udall, is moving to the Western Resource Advocates and will be based in Santa Fe.

QUICK HITS

— She tried to report on climate change. Sinclair told her to be more "balanced," BuzzFeed.

— Oil is fast approaching $70. Is the economy ready for it? The Wall Street Journal.

— EPA sources: Pruitt aide tried to back-date departure after congressional interview request, CNN.

— Environmental review for mine project expected this week, Associated Press.

— America's nuclear headache: old plutonium with nowhere to go, Reuters.

— Perched on a platform high in a tree, a 61-year-old woman fights a gas pipeline, The Washington Post.

HAPPENING THIS WEEK

MONDAY

11:30 a.m. — Verizon discussion on "Celebrating Earth Day: The Power of Next-Gen Networks to Advance Environmental Sustainability," 1300 I Street NW

TUESDAY

8:00 a.m. — American Fuel & Petrochemical Manufacturers holds security conference, New Orleans

10:00 a.m. — Senate Energy and Natural Resources Committee hearing on the president's proposed budget request for FY 2019 for the Forest Service, 366 Dirksen

10:00 a.m. — Senate Foreign Relations Committee hearing on nominations, including Jackie Wolcott to be representative to the International Atomic Energy Agency, 419 Dirksen

10:00 a.m. — The Bipartisan Policy Center webcast "Can America's Infrastructure Withstand the Next Natural Disasters? Lessons Learned from Previous Disasters."

3:00 p.m. — Woodrow Wilson Center book launch discussion with author Barry Rabe on pricing carbon, 1300 Pennsylvania Ave NW

5:00 p.m. — Johns Hopkins University's Energy, Resources and Environment presentation on "Cities as Innovation Centers: Investing in Resilient Infrastructure," 1619 Massachusetts Avenue NW

WEDNESDAY

10:00 a.m. — Senate Commerce Committee hearing on "Enhancing the Marine Mammal Protection Act," 253 Russell

11:30 a.m. — The World Resources Institute forum on "activism for energy," 10 G Street NE

12:30 p.m. — Olympians brief Congress about impact of climate change on winter sports, hosted by Sens. Michael Bennet and Susan Collins, 538 Dirksen

2:00 p.m. — Resources for the Future webinar on "What Research Says on Key Fracking Debate Issues."

2:00 p.m. — House Natural Resources Committee hearing on "The Weaponization of the National Environmental Policy Act and the Implications of Environmental Lawfare," 1324 Longworth

3:30 p.m. — Bloomberg Government and the Norwegian-American Chamber of Commerce conversation on "Investing In A Sustainable Energy Future," New York City

6:30 p.m. — The Carnegie Institution for Science lecture on the sustainable use of the ocean, 1530 P Street NW

THURSDAY

8:00 a.m. — Water Leaders summit on "Building an Innovative Future for Water Policy and Technology in America," 215 Capitol Visitors Center

8:30 a.m. — George Mason University's Center for Energy Science and Policy symposium on "Energy-Water Nexus," Fairfax, Va.

9:00 a.m. — Colorado State University hosts symposium on "Water in the West," Denver

10:00 a.m. — The U.S. Energy Association forum on "fostering the deployment of CCUS technologies," 1300 Pennsylvania Ave NW

10:00 a.m. — The House Energy and Commerce Committee hearing on EPA's budget request, 2323 Rayburn

10:00 a.m. — House Natural Resources Oversight Subcommittee hearing on "Examining the Critical Importance of Offshore Energy Revenue Sharing for Gulf Producing States," 1324 Longworth

10:00 a.m. — The Center for Strategic and International Studies' Energy and National Security Program discussion on "Challenges to Ukrainian Energy Reform and European Energy Security," 1616 Rhode Island Avenue NW

11:30 a.m. — The Atlantic Council discussion on "From an Oil Company to an Energy Company," 1030 15th Street NW

1:30 p.m. — Information Technology and Innovation Foundation release on "Closing the Innovation Gap in Grid-Scale Energy Storage," 1101 K Street NW

2:00 p.m. — House Appropriations Interior, Environment, and Related Agencies Subcommittee hearing on EPA's fiscal 2019 budget, 2007 Rayburn

2:00 p.m. — House Natural Resources Committee hearing on H.R. 5317 (115) and H.R. 211 (115), 1324 Longworth

2:00 p.m. — Senate Appropriations Energy and Water Development Subcommittee hearing on the Nuclear Regulatory Commission's proposed budget for FY 2019, 430 Dirksen

2:30 p.m. — The Center for a New American Security event on how lower oil prices have reshaped geopolitical calculations for U.S. policymakers, 1152 15th St NW

FRIDAY

12:00 p.m. — Women's Council on Energy and the Environment discussion on wholesale electricity pricing, 888 First Street NE

12:00 p.m. — The Nuclear Information and Resource Service, and U.S. Climate Action Network discussion on "Climate Justice and Nuclear Power in South Africa," 1200 G Street NW

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Failure to strike biofuels deal opens door for smaller ethanol moves Back

By Eric Wolff | 04/23/2018 05:01 AM EDT

President Donald Trump's long-sought biofuels deal between the agricultural and refining industries appears to be turning into a piecemeal policy cobbled together through EPA that expands the market for corn ethanol while granting exemptions from the program to many small oil processors.

Trump has huddled several times with members of his Cabinet, refining and ethanol industry players, and lawmakers from both corn-belt and oil states. But so far, there's been little progress in striking a grand deal that would relieve the financial pain that some independent refiners say the Renewable Fuel Standard is causing them while acceding to agriculture-sector pressure to expand the market for corn ethanol.

Instead, Trump has promised to allow year-round sales of 15 percent ethanol blends of gasoline while EPA Administrator Scott Pruitt has handed out more than two dozen temporary waivers to small refineries that exempt them from the mandate requiring them to blend ethanol with gasoline.

"After 18 months of pursuing various regulatory forms of relief and a handful of Oval Office confabs, the merchant refiners ended up with [an increase in E15] taking even more market share away from them in return for some small refiner hardship waivers — and some of them did not even get that," said a source with an oil refining company.

For over a year, refiners have urged the administration to put a cap on the price of the biofuel credits that refiners must buy to meet their RFS compliance levels. But the move has been sharply opposed by ethanol and corn interests, as well as Sen. Chuck Grassley (R-Iowa), who as recently as last month called a potential cap "CATASTROPHIC to ethanol."

But the prices for biofuel credits, called Renewable Identification Numbers, have fallen since Pruitt's EPA began issuing at least 25 compliance waivers. Although that's angered biofuels supporters who complain it has sapped demand for ethanol, they see the administration's plan to drop the Clean Air Act rules that have barred E15 sales in the summer in some states as a boon.

"Right now we're going to have anywhere from a billion- to a billion and a half-[gallon] reduction in [ethanol] demand because of [RFS] waivers given so far," Sen. Mike Rounds (R-S.D.) told POLITICO. "I think we're moving in the right direction, but we want to make sure we get the [E15] waiver in place."

At a meeting with Midwestern senators and governors April 12, Trump announced his plan to expand E15 sales. But Trump also said there were efforts to set a transition period for the two years "where we will have a little bit of complexity," an apparent reference to refiners' worries that an increase in the number of RINs from higher E15 sales won't help push down prices for the credits in the near term.

The expansion of E15 sales came after an early April meeting at the White House, where Agriculture Secretary Sonny Perdue urged Trump to give corn farmers something to offset the ethanol demand drop they were seeing from the refinery compliance waivers, as well as the decline expected because of China's retaliatory import tariffs put in place after Trump announced his trade penalties, according to an administration source. The Washington Post reported Trump spent much of the meeting discussing the controversies around Pruitt's condo rental from a lobbyist and heavy spending on first-class travel and round-the-clock security.

Trump's discussion of Pruitt's controversies left the EPA chief unable to make an aggressive case for instituting price caps on RINs, according to an administration source, and have put him in a generally weakened position inside the White House.

And that may have killed the effort to establish RIN price caps, and given traction to the piecemeal EPA actions on E15 and the temporary compliance waivers, according to both administration and industry sources.

"[The oil industry] got what they wanted with the small refinery waivers, so we should get what we want," said Rob Walther, vice president of federal affairs for the ethanol producer POET.

Refiners, who over the last several months have sought and received RFS waivers for the 2016 and 2017 compliance years, are now expected to be pushing for the same exemptions for 2018 before they even know what their final liability for the year is.

Separately, a debate has grown over how EPA has been able to issue so many waivers to refiners this year. Though an EPA spokeswoman says the agency continued to use the same process it had under the Obama EPA to grant those exceptions, oil and ethanol industry sources acknowledge it has made crucial changes that make it far easier to get out from under the biofuel mandates.

In particular, EPA is relying on report language congressional appropriators added to 2016 and 2017 government funding bills that called on EPA to loosen its requirements for determining if a refinery should be awarded a waiver. EPA has also softened its definition of what constitutes economic hardship for a refinery as a result of a ruling from the U.S. Court of Appeals for the 10th Circuit last year.

That decision, in the case of *Sinclair Wyoming Refining v. EPA*, said the agency's test for defining economic hardship as whether a refiner was about to be pushed into bankruptcy had been too severe.

EPA has also taken a more aggressive interpretation of the law, saying it would no longer grant only partial waivers. Instead, the agency is now granting full-volume waivers to qualifying small refineries, according to an industry attorney.

The American Petroleum Institute, which represents the biggest oil companies, has opposed the waivers, and ethanol producers are furious at the use of the congressional report language to loosen the standards for receiving them. Monte Shaw, executive director of the Iowa Renewable Fuels Association, said his group has asked allies on the Appropriations Committee to consider writing their own language into future appropriations reports reversing the previous guidance.

Other groups think EPA is relying too much on that congressional guidance that is not included in the law.

"The report language does not override the plain reading of the statute," said Bob Dinneen, CEO of the Renewable Fuels Association. "While the court's decision in *Sinclair* might suggest EPA views these waivers differently, EPA has turned 180 degrees in its interpretation of the statute, and essentially now requires no demonstration of economic hardship. That's not what either the statute or the court required."

EPA staff has begun work trying to figure out how to best implement the expansion of E15 sales, which corn growers see as pivotal for the program's near future. But ethanol producers and their allies are looking ahead to the long term, in which E25 and E30 provide the octane for smaller, high-efficiency engines that get far higher fuel efficiency than current models.

"We have to move to the point to emphasize the need for octane, for these small engines that become more important in meeting CAFE standards in coming years," Rounds said. "That's where ethanol really shines."

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Lobbyist whose wife rented to Pruitt lobbied EPA despite denials Back

By Theodoric Meyer and Eliana Johnson | 04/20/2018 06:43 PM EDT

The prominent lobbyist whose wife rented a condominium to Environmental Protection Agency Administrator Scott Pruitt lobbied the agency while Pruitt was leading it, contrary to his and Pruitt's public denials that he had any business before the agency, according to a Friday filing by his firm.

The disclosure from the lobbying firm Williams & Jensen contradicts Pruitt's public statement last month that the lobbyist, J. Steven Hart, had no clients with business before the EPA, and came hours after Hart's resignation from the firm.

An EPA official acknowledged on Saturday that Pruitt had met with Hart, who attended a meeting with a former meat processing executive concerned about President Donald Trump's proposal to cut spending on a Chesapeake Bay cleanup program. But the official argued that the meeting didn't meet the definition of lobbying.

A second EPA official, agency spokesman Jahan Wilcox, told POLITICO: "We have no knowledge of any facts that precipitated Williams & Jensen electing to make this filing."

The disclosure is the latest sign of one-time allies distancing themselves from Pruitt, whose job is in jeopardy because of multiple investigations into his stewardship of the agency, ranging from spending on a 20-person security team and first-class travel to the installation of costly office furniture and a soundproof phone booth. The Government Accountability Office said earlier this week that the purchase of the booth, which cost $43,000, violated federal law . And the staff of House Oversight Chairman Trey Gowdy (R-S.C.) has interviewed a former EPA political appointee who alleges that Pruitt lied about not knowing about steep raises given to two of his top aides.

When asked late Friday about Hart's lobbying activities, a Gowdy spokeswoman told POLITICO that 'the Committee has already been looking into this matter.'"

Sen. Sheldon Whitehouse (D-R.I.) said in a statement Saturday that any evidence of deception about Pruitt's relationship with the lobbyist-turned-landlord would bode ill for the EPA administrator.

"It doesn't get much swampier than an agency head getting a sweetheart deal on rent from a lobbyist with business before his agency, but someone lying about it afterwards does make it worse," Whitehouse said. "The laundry list of Pruitt scandals grows."

Hart announced he would resign from Williams & Jensen hours before the firm filed a disclosure showing that he lobbied the EPA for Smithfield Foods in the first quarter of 2017. While Hart, the chairman and former chief executive of the firm, has disputed that the contact he had with Pruitt and Pruitt's chief of staff, Ryan Jackson, constituted lobbying activity, the disclosure indicates otherwise.

Hart lobbied the EPA on issues "relating to support for EPA Chesapeake Bay Programs," according to the disclosure.

Pruitt told Fox News earlier this month that "Hart has no clients that have business before this agency."

Smithfield paid Williams & Jensen, which has lobbied for the company for years, $70,000 to lobby on a variety of matters in the first quarter, according to the disclosure filing. Hart also lobbied Congress on trade, agriculture and food safety issues on Smithfield's behalf during the first quarter, alongside other Williams & Jensen lobbyists.

But Smithfield said Hart's lobbying of the EPA "was not undertaken at the direction of or on behalf of Smithfield Foods."

"These activities were conducted at the request of a then former executive and current Smithfield Foundation board member, Dennis Treacy, in his personal capacity," the company said in a statement. "Mr. Treacy is associated with several environmental organizations and is a member of the Chesapeake Bay Commission."

Treacy had been Smithfield's chief sustainability officer, as well as president of the nonprofit Smithfield Foundation, and before that had led Virginia's Department of Environmental Quality.

The first EPA official, who spoke on condition of anonymity, said Pruitt and Jackson, his chief of staff, met with Treacy and Hart on July 11 for 20 minutes in Pruitt's office. That's backed up by a chain of agency emails obtained by POLITICO, which show Treacy requesting a meeting in May to discuss his "focused and unique view of environmental protection" with Pruitt, and one finally being scheduled for July 11.

On July 10, Hart wrote to Jackson that he wanted to attend the meeting at Treacy's request. Hart added that Treacy "is a good guy and can be trusted. He is coming in as the business rep on the Chesapeake Bay Foundation — another of your controversies."

But the disclosure filed by Williams & Jensen indicates that Hart's lobbying work took place in the first three months of this year, not in 2017.

The official said Hart set up the meeting as a "personal introduction" but that Treacy used a Smithfield email address, which may have prompted Williams & Jensen to consider the meeting lobbying activity on behalf of Smithfield. Treacy wanted to talk about the president's proposed budget cuts to EPA's spending on Chesapeake Bay, the subject of one of the nation's premier ecosystem restoration projects, the official said.

The official said Pruitt discussed his meeting with Hart with EPA staff before going on Fox News for an interview this month, where Pruitt maintained that Hart had no clients with business before the agency. But "it has been clear in [Pruitt's] mind for months now this was a personal introduction of an individual who was supportive of the administration, who wanted to meet the administrator."

Smithfield Foods has had a tangled history with Chesapeake Bay: In 1997, a federal judge slapped the company with a record $12.6 million fine for violating the Clean Water Act by dumping hog waste into a bay tributary. But Smithfield is now listed as a corporate partner of the nonprofit Alliance for the Chesapeake Bay.

Pruitt's rental of the Capitol Hill condo — a relative bargain at $50 a night — had attracted criticism even before the filing because Hart has lobbied on energy issues in the past. Hart is also a past political donor to Pruitt, contributing a total of $4,366 in cash and in-kind services to the former Oklahoma attorney general's campaigns and leadership PAC.

Pruitt's lease originally had J. Steven Hart's name printed on it as the landlord, but someone crossed it out and wrote in the name of his wife, Vicki. Public records show Vicki Hart's name on both the mortgage and deed. (Vicki Hart is also a lobbyist but works primarily on health care issues.)

Hart was already planning to retire in November but moved up his departure in the wake of the revelation that his wife has been Pruitt's landlord.

"Considering the last couple of weeks, I think it is easier on my family and the firm to expedite my departure," Hart wrote on Friday afternoon in an email to family and friends that was obtained by POLITICO.

Williams & Jensen confirmed Hart's departure.

"Mr. Hart informed the firm of his decision to resign today," the firm said in a statement on Friday. "We are grateful to Steve for his 35 years of service and we wish him and his family well in all of their future endeavors."

Hart did not respond to a request for comment. But he was sharply critical of the news coverage of the Pruitt scandal in the email he sent on Friday.

"As you know, these days I am no more an energy lobbyist than I am an astronaut," Hart wrote. "But, why let the facts get in the way of a good story?"

After leaving the firm, Hart wrote that he was "looking forward to devoting myself to an independent legal practice, some strategic business counseling for a few clients, golf, and shooting (not in that order)."

Alex Guillén and Emily Holden contributed to this report.

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Third Republican calls on Pruitt to resign Back

By Alex Guillén | 04/05/2018 03:34 PM EDT

Rep. Elise Stefanik (R-N.Y.) today called on EPA Administrator Scott Pruitt to resign, becoming at least the third Republican to do so even as more conservative lawmakers come to Pruitt's defense.

"I'm going to make news today," Stefanik said at a town hall meeting in South Glens Falls, about 45 miles north of Albany, according to The Saratogian. "I think Scott Pruitt should resign. I fundamentally disagree with how Pruitt has handled the EPA."

Reps. Carlos Curbelo and Ileana Ros-Lehtinen, both Florida Republicans, earlier this week called for Pruitt's ouster, as have a number of Democrats. Pruitt is facing increased scrutiny for ethics issues including the $50-per-night rent he paid to rent space in a condo from a lobbyist last year.

Meanwhile, conservative Republicans like Sens. Rand Paul (R-Ky.) and Ted Cruz (R-Texas) have come to Pruitt's defense today.

"Why do Obama and his media cronies want so badly to drive @EPAScottPruitt out of office?" tweeted Cruz.

Pruitt "is likely the bravest and most conservative member of Trump's cabinet," tweeted Paul. "We need him to help @realDonaldTrump drain the regulatory swamp."

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EPA emails show industry worries slowed new science policy Back

By Annie Snider | 04/19/2018 05:01 PM EDT

EPA's rollout of a controversial new transparency policy that would severely restrict the scientific research the agency can rely on when drafting new regulations has been slowed down by political officials' fears that it could have major unintended consequences for chemical makers, according to newly released EPA documents.

The issue of scientific transparency has been high on the agenda of House Science Chairman Lamar Smith (R-Texas), who has found strong support from EPA Administrator Scott Pruitt — much to the consternation of public health advocates and green groups, who view the effort as backdoor attack on the agency's ability to enact environmental regulations.

Since Pruitt announced plans for the new policy last month, researchers and public health proponents have raised alarms that it could restrict the agency's ability to consider a broad swath of data about the effects of pollution on human health. But documents released under the Freedom of Information Act show that top EPA officials are more worried the new restrictions would prevent the agency from considering industry studies that frequently support their efforts to justify less stringent regulations.

Emails between EPA officials obtained by the Union of Concerned Scientists show that Nancy Beck, the top political official in the agency's chemicals office who came to the agency after serving as a key expert for the chemical industry's lead lobbying group, voiced major concerns after she received a draft of the not-yet-released policy on Jan. 31.

The new scientific transparency directive is expected to require that the raw data for all studies EPA relies on be publicly available, and that the studies be peer-reviewed. But Beck said these requirements would exclude a great deal of industry data about pesticides and toxic chemicals that her office considers when determining whether a substance is safe or must be restricted.

It costs companies "millions of dollars to do these studies," Beck wrote in an email to Richard Yamada, the political official in EPA's office of research and development who is spearheading work on the new scientific policy and is also a former staffer for the House Science Committee chairman.

"These data will be extremely valuable, extremely high quality, and NOT published," Beck wrote. "The directive needs to be revised."

Moreover, much of this data, Beck noted, is considered proprietary by companies. It is dubbed confidential business information, and even though EPA can consider it as part of its regulatory review, the data cannot legally be made public.

Yamada replied to thank Beck for the heads up. "Yes, thanks this is helpful - didn't know about the intricacies of CBI," he wrote. "We will need to thread this one real tight!"

The term "confidential business information" primarily applies to industry information. That data is separate from the personal medical information that public health researchers worry could block consideration of their work.

Yogin Kothari, a lobbyist for the Union of Concerned Scientists, said the emails show the Trump administration's EPA has been "trying to stack the deck in favor of the industries they're supposed to be regulating."

"They want to potentially create exemptions for industry, but if you look at this entire set of documents ... you will see that there's not a single consideration for the impacts on public health data, on long-term health studies, on studies that EPA does after public health disasters like the BP oil spill," he said.

EPA spokeswoman Liz Bowman emphasized the policy is not yet finalized.

"These discussions are part of the deliberative process; the policy is still being developed. It's important to understand; however, that any standards for protecting [confidential business information] would be the same for all stakeholders," she said in a statement.

The emails indicate Pruitt wanted the new science policy rolled out at the end of February, and teased his plans in an interview with conservative outlet The Daily Caller in mid-March. But the agency has yet to finalize the policy.

The transparency directive has its origins in legislation introduced by Smith during the Obama administration, that had the backing of a number of industry groups, including the American Chemistry Council. The House Science Committee chairman frequently charged that the Obama EPA used "secret science" to justify "costly new regulations."

Although versions of the measure were approved by the House multiple times, the Senate never took it up. CBO estimated that one version of Smith's legislation would cost EPA $250 million a year, at least in the initial years, and a leaked staff response to questions from the budget office said a later version would be even more costly, would endanger confidential medical and business information, and "would prevent EPA from using the best available science."

But Smith found an ally in Pruitt. The emails indicate that Smith met with Pruitt in early January and show that Pruitt's staff quickly began working on a directive to "internally implement" the legislation.

Industry's backing for the new scientific approach began to waiver under the Trump administration, though. When a top American Chemistry Council scientist testified before Smith's committee in February 2017, she emphasized the need to protect industry information if the transparency initiative moved forward.

"One of the things that we do need to take into consideration as making that data publicly available is that there are adequate protections for confidential business information to ensure that we keep innovation and competitiveness available for the marketplace," Kimberly White told the committee.

Industry has historically claimed that a wide range of information about chemicals, ranging from the processes by which they are produced, to the locations of manufacturing plants, to their very identities, must be kept confidential in order to keep competitors from learning trade secrets. Environmental and public health advocates argue that industry claims this exemption in many cases where it's not necessary and that it often keeps important health and safety information from public view.

The issue was a key point of debate when Congress considered a major overhaul of the nation's primary chemical safety law passed 2016 and has reemerged as Pruitt's EPA sets about implementing the law.

Asked for comment on EPA's new effort to implement the scientific transparency approach internally, American Chemistry Council spokesman Scott Openshaw said the group looks forward to reviewing the directive once it's finalized.

"It is critical that any final directive properly protect confidential business information and competitive intelligence," he said in a statement.

The internal emails show that EPA political staff were particularly attuned to this concern. In a Feb. 23 email to colleagues, Beck forwarded language from a 2005 White House document that laid out narrow exemptions from its requirement that all "important scientific information" disseminated by the federal government go through peer review.

"[Y]ou may need to tweak but hopefully there is something helpful here that can be borrowed/adopted," she wrote.

Richard Denison, lead senior scientist for the Environmental Defense Fund, said that EPA's access to industry data is indeed important to its ability to review the safety of new chemicals and pesticides, but said the internal EPA communications show that Pruitt's EPA wants to "have their cake and eat it too" with the new directive.

"They're trying to force peer review studies done by academic scientists to disclose every last detail, while at the same time allowing industry studies to be kept private or aspects of those to still be kept private," he said.

He pointed out that the concerns Beck raised about the burden the new policy would place on industry are the very same ones that the CBO report said the policy would place on EPA.

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France's Macron arrives for 'celebration' of unlikely friendship with Trump Back

By Nicholas Vinocur and Michael Crowley | 04/22/2018 09:45 PM EDT

PARIS — French President Emmanuel Macron will receive full state honors in Washington this week, nine months after he rolled out a literal red carpet for Donald Trump on Paris' Avenue des Champs Elysées.

The three-day visit is likely to feature more displays of public affection between two leaders who talk on the phone constantly and closely coordinated recent airstrikes against Syria. Despite the U.S president's enormous unpopularity in his country, Macron virtually never criticizes Trump in in public and calls him a "friend." Trump in turn reportedly even scribbled a love note to the 40-year-old French president last July.

This week's visit will be "something of a celebration of the relationship," a senior Trump administration official said.

Few would have predicted such talk just after Macron's May 2017 election defeat of the nationalist insurgent Marine LePen, whom Trump implied he supported. Macron's dark-horse win was seen as a rebuke to the western nationalist movement of which Trump has become a symbol. And while the French adored President Barack Obama as a suave intellectual, Trump is seen as the embodiment of a gauche American.

But rather than denounce Trump as many French politicians have, Macron has sought to win Trump over with flattering words. In an interview with "Fox News Sunday," Macron stressed his similarities with Trump, saying both he and the president could be called a "maverick" whose election had been unexpected.

The two men hardly see eye to eye on policy, and are expected to debate the Iran nuclear deal, Syria and trade policy, among other sensitive topics.

But Macron and Trump have worked closely together as Paris takes a larger leadership role on international issues — at a time when Britain is sidelined by political chaos and a weakened German Chancellor Angela Merkel's relationship with Trump is cool at best.

"Macron has become Trump's main European interlocutor when it comes to addressing international crises," Alexandra de Hoop Scheffer, senior transatlantic fellow at the German Marshall Fund, wrote in a recent policy paper.

Macron and Trump will share a private dinner Monday evening, followed by a bilateral meeting early Tuesday. They'll then meet with Cabinet members before a state dinner at the White House. On Wednesday, Macron will address a joint session of Congress.

In their private talks, the two men are likely to focus on security issues, including a fast-approaching decision point for the Iran nuclear deal. French officials say they share some of Trump's concerns about the July 2015 pact brokered by President Barack Obama, but are urging Trump not to abandon the agreement in mid-May, when Trump has threatened to reimpose sanctions on Tehran.

Macron has sought common ground with Trump by saying the current deal is flawed and that he might be willing to crack down on Iran's ballistic missile program. But Trump wants much stronger measures that French officials worry could abrogate the deal entirely. A Trump official said the deal would be "a major topic of discussion" during Macron's visit.

The official also said the two leaders "will discuss, probably in some detail, the way ahead in Syria."

In a televised debate last week, Macron said he had changed Trump's mind on the U.S. presence in war-torn Syria: "President Trump said the USA's will is to disengage from Syria. We convinced him that it was necessary to stay," the French leader said.

The White House quickly denied that characterization, and Macron later said he never meant the countries should maintain an indefinite military presence in the country.

But on Sunday, Macron told Fox News that he would urge international cooperation during his address to Congress, warning that Iran would benefit from a U.S. and European abandonment of Syria. "We are very much attached to the same values, and especially liberty and peace," Macron said of America and France.

Trade will also be on the agenda, after Macron and Merkel — who's due to fly into Washington on April 27, a few days after Macron leaves — both vowed to tell the U.S. president that Europe would not stand for his recent steel tariffs. U.S. officials may in turn complain to Macron's entourage about a French-led proposal to slap a 3-percent tax on U.S. internet giants.

Despite the menu of issue differences, officials on both sides sought to lower expectations for specific results from the meeting.

"It's largely symbolic," an aide to Macron said.

"I think what the President would like to hear from President Macron is his counsel and his point of view and his perspective," said the Trump official. "Whether we will actually solve, or come to closure, or a full detailed agreement on some of the issues that we've touched on is difficult to say at this remove."

As they work together internationally, Trump and Macron are both fending off political threats at home. A year into his presidency, the French president's sheen as a political prodigy and savior of European liberalism has been dulled by grinding rail strikes and sagging poll numbers.

Macron wants Trump to stand at his side as the European Union's soon-to-be sole military power with a permanent seat on the United Nations Security Council, nuclear capability and the will to intervene where others will not.

The April 14 strike on Syria's chemical facilities bolstered the burgeoning Franco-American relationship, French officials say. Macron and Trump spoke repeatedly during the crisis — and no fewer than seven times over the past month, according to accounts from the Elysée presidential palace.

While Britain also joined the strikes, Merkel barely featured in the Syrian discussions. Characteristically for intervention-averse Germany, she did not order participation in the strikes, commenting on them after the fact as "necessary and appropriate."

Once the missiles had hit their targets, Macron seized on a chance to drive home his point: While others may waver, France remains a red-blooded beacon of Western power. Paris had intervened in Syria for the "honor of the international community," he told the European Parliament in Strasbourg

One outstanding question about the Macron-Trump relationship that fascinates commentators in Europe: Does the French president really like Trump, or is he just "playing him"?

European commentators suggested as much last summer when, during Trump's visit to Paris, Macron mimicked his guest's signature thumbs-up move to TV cameras.

There may be no definitive answer. Macron is a one-time stage actor who loves to quote classical French playwrights from memory and, as he told a pair of French interviewers last weekend, has "no friends."

Quizzed about Macron's apparent affection for Trump, the French president's aides say he has concluded that befriending Trump and avoiding any direct criticism of the U.S. president that could inflame his temper are the best ways of keeping Trump — and the United States — on his nation's side.

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Message

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As-it-happens update - April 21, 2018

NEWS

Trump's EPA wants to stamp out 'secret science.' Internal emails show it is harder than expected

Science Magazine

The emails also reveal that an **EPA** political appointee — a former chemical industry executive — raised concerns about the science overhaul. Nancy **Beck**, deputy assistant administrator of **EPA's** chemicals office, raised pointed concerns about what a secret science policy would mean for both pesticide ...

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Sent: 5/11/2018 2:03:13 PM

To: Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Bodine, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2cc6086fcc44c3be6b5d32b262d983-Bodine, Sus]; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Cory, Preston (Katherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd80b15f6d04a3ba11fc8ca3c85bc50-Cory, Kathe]; Daniell, Kelsi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd867173479344b3bda202b3004ff830-Daniell, Ke]; Ferguson, Lincoln [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08cd7f82606244de96b61b96681c46de-Ferguson, L]; Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]; Frye, Tony (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58c08abdfc1b4129a10456b78e6fc2e1-Frye, Rober]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Hanson, Paige (Catherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95adc1b2ac3b40ab9dc591801d594df8-Hanson, Cat]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Kelly, Albert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08576e43795149e5a3f9669726dd044c-Kelly, Albe]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Letendre, Daisy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b691cccca6264ae09df7054c7f1019cb-Letendre, D]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; McMurray, Forrest [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=344246fb2cb643bfab4f92fe016566e2-McMurray, F]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]; Rodrick, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6515dbe46dae466da53c8a3aa3be8cc2-Rodrick, Ch]; Ross, David P [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=119cd8b52dd14305a84863124ad6d8a6-Ross, David]; Shimmin, Kaitlyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=becb3f33f9a14acd8112d898cc7853c6-Shimmin, Ka]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Wheeler, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17a1669ef5b54fba8cb457845308787e-Wheeler, An]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]

Subject: EPA News Highlights 5.11.18

Attachments: EPA News Highlights 5.11.18.docx

EPA News Highlights 5.11.18

The Washington Post: Many Mocked This Scott Pruitt Proposal. They Should Have Read It First.

When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science." But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

The Washington Examiner: EPA Won't Redo Obama's Report On Risks From Deadly Paint Stripper

The Environmental Protection Agency announced Thursday that it would not seek to redo an Obama administration report that listed the numerous health risks from exposure to the paint stripper chemical methylene chloride. The EPA is "not re-evaluating the paint stripping uses of methylene chloride and is relying on its previous risk assessments," the agency announced. The paint stripping chemical has caused dozens of deaths, and environmentalists have called on EPA Administrator Scott Pruitt to ban the substance as a public health concern. The agency also said it plans to finish the regulatory process for the chemical that started under the Obama administration in 2016. It expects to send a final determination on the chemical "shortly" to the Office of Management and Budget for review.

The Associated Press: Action 'shortly' on solvent after Pruitt and families meet

The Environmental Protection Agency is promising quick action on new restrictions for a widely sold solvent used for paint stripping. Thursday's announcement comes after EPA administrator Scott Pruitt met with families of men who died after using products with the compound methylene chloride. The Obama administration in its last days proposed banning most consumer sales of methylene chloride. Lawmakers last month accused Pruitt of putting the rule on hold. Pruitt met Tuesday with families of a 31-year-old man and 21-year-old man who died after using paint-strippers.

The Washington Post: Mothers Lobbied Scott Pruitt To Ban A Toxic Chemical. Two Days Later, EPA Signaled It Would.

Environmental Protection Agency chief Scott Pruitt has met with few environmental groups throughout his tenure. More often, he has conferred with industry representatives. But this week, the EPA chief agreed to meet with a different sort of lobbyist: the mothers of two men who died from exposure to paint strippers containing a toxic chemical. The result: Two days later, the EPA signaled on Thursday it will follow through on an Obama-era proposal to ban paint strippers containing a toxic chemical — leaving Democratic lawmakers, environmental groups and the families of victims cautiously optimistic they won Pruitt over, Brady Dennis and I reported Thursday.

Politico: Pruitt changes NAAQS review to consider 'adverse' effects of standards

EPA Administrator Scott Pruitt today directed the agency to change the review process for a critical air quality program to include the potential "adverse" effects of tighter standards. In a memo signed Wednesday, Pruitt directed the Clean Air Scientific Advisory Committee, which advises on National Ambient Air Quality Standards issues, to provide advice on

background pollution concentrations and the "adverse public health, welfare, social, economic or energy effects" from setting and achieving NAAQS standards. The Supreme Court has previously ruled that EPA cannot consider implementation costs whGasen setting NAAQS standards. Pruitt's memo argues that such information, even if not used to set a standard, can provide "important policy context for the public, co-regulators and EPA."

Oil & Gas Journal: Pruitt Signs Memo Outlining NAAQS 'Back To Basics' Review Process

US Environmental Protection Agency Administrator E. Scott Pruitt signed a memorandum describing a "back to basics" process for reviewing the federal Clean Air Act's National Ambient Air Quality Standards (NAAQS). The memo assures that EPA and its independent science advisors take a transparent, efficient, and timely approach, he said on May 10. The memo's principles will reform the process for setting NAAQS in a manner consistent with cooperative federalism and the rule of law, Pruitt maintained. "Getting EPA and its advisors back on track with CAA requirements, statutory deadlines, and the issuance of timely implementation rules will assure that we continue the dramatic improvement in air quality across our country," he said.

National News Highlights 5.11.18

The New York Times: Israel And Iran, Newly Emboldened, Exchange Blows In Syria Face-Off

The tense shadow war between Iran and Israel burst into the open early Thursday as Israeli warplanes struck dozens of Iranian military targets inside Syria. It was a furious response to what Israel called an Iranian rocket attack launched from Syrian territory just hours earlier. The cross-border exchanges — the most serious assaults from each side in their face-off over Iran's presence in Syria — took place a little more than a day after the United States withdrew from the Iran nuclear agreement. Israel's defense minister said that Israeli warplanes had destroyed "nearly all" of Iran's military infrastructure in Syria after Iran launched 20 rockets at Israeli-held territory, none reaching their targets. Iran struck shortly after President Trump pulled out of the nuclear agreement, raising speculation that it no longer felt constrained by the possibility that the Americans might scrap the deal if Iran attacked Israel.

The Associated Press: Trump's High-Risk Doctrine? Swing For The Bleacher Seats

The way President Donald Trump sees it, why go for a solid single when you can swing for a home run? Trump's upcoming summit with North Korea's Kim Jong Un is only the latest example of the president's go-big strategy. From tax reform to international trade to foreign policy, Trump has pursued a high-risk, high-reward approach that advisers say can help produce results on longstanding problems — and that critics warn could trigger dangerous repercussions all the way from a trade war to global conflict. Drawn to big moments and bigger headlines, Trump views the North Korea summit as a legacy-maker for him, believing that the combustible combination of his bombast and charm already has led to warmer relations between North and South. As he welcomed home three Americans who had been detained in North Korea, Trump early Thursday used a televised, middle-of-the-night ceremony to play up both his statecraft and stagecraft.

TRUMP TWEETS

The Washington Post

https://www.washingtonpost.com/opinions/many-mocked-this-scott-pruitt-proposal-they-should-have-read-it-first/2018/05/10/31baba9a-53c2-11e8-abd8-265bd07a9859_story.html?noredirect=on&utm_term=.f7bcbc0a1887

Many Mocked This Scott Pruitt Proposal. They Should Have Read It First.

By Robert Hahn, 5/10/18

When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science."

But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

Critics typically argue that the proposed regulation would suppress research that contains confidential medical records and therefore scientists could not share underlying data publicly for privacy reasons. Such restrictions, these critics say, would have excluded landmark research, such as Harvard University's "Six Cities" study, which suggested that reducing fine particles in the air would dramatically improve human health and helped lead to more stringent regulation of fine particles in the United States.

These concerns are likely the result of rhetoric surrounding the rule. Pruitt describes the regulation as an attempt to end "secret science" at the agency. Conservatives have long prioritized the need for making all data and statistical models used in regulatory decision-making available for independent scrutiny, with the intent to limit the use of studies that cannot be replicated. Breitbart went even further, characterizing the action as "a massive victory for both Pruitt and President Trump in their war on the Green Blob."

But it appears that few defenders or opponents of the proposal have actually read the proposed EPA regulation, which is only seven pages long. Both sides distort the regulatory text.

Here's what the rule would actually do. First, it would require the EPA to identify studies that are used in making regulatory decisions. Second, it would encourage studies to be made publicly available "to the extent practicable." Third, it would define "publicly available" by listing examples of information that could be used for validation, such as underlying data, models, computer code and protocols. Fourth, the proposal recognizes not all data can be openly accessible in the public domain and that restricted access to some data may be necessary. Fifth, it would direct the EPA to work with third parties, including universities and private firms, to make information available to the extent reasonable. Sixth, it would encourage the use of efforts to de-identify data sets to create public-use data files that would simultaneously help protect privacy and promote transparency. Seventh, the proposal outlines an exemption process when compliance is "impracticable." Finally, it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

Here's what the EPA's rule wouldn't do: nullify existing environmental regulations, disregard existing research, violate confidentiality protections, jeopardize privacy or undermine the peer-review process.

The costs of compliance with EPA regulations are substantial. A draft report from the White House Office of Management and Budget suggests that significant EPA regulations imposed costs ranging from $54 billion to $65 billion over the past decade. These rules also realize substantial public-health and environmental benefits estimated to range from $196 billion to $706 billion over the decade.

Given the stakes for both the cost of compliance with EPA regulations and the real risks that pollution poses to public health and the environment, this rule should be read closely by critics and supporters for what it actually says. Just as transparency in science and evidence are essential, so, too, are intellectual honesty and accurate policy communication.

Taking steps to increase access to data, with strong privacy protections, is how society will continue to make scientific and economic progress and ensure that evidence in rule-making is sound. The EPA's proposed rule follows principles laid out in 2017 by the bipartisan Commission on Evidence-Based Policymaking — humility, transparency, privacy, capacity and rigor — and moves us toward providing greater access to scientific data while protecting individual privacy.

Instead of throwing stones, the scientific community should come together to offer practical suggestions to make the rule better. For example, the rule should recognize the incentives for scientists to produce new research. Scientists need to have time to produce and take credit for their research findings. Thus, there will inevitably be a trade-off between the production of new insights and the sharing of data with others, including regulators.

The EPA should also establish use restrictions and a secure data infrastructure so that confidential business and personal data are adequately protected. Finally, it should set procedures to evaluate the effectiveness of this rule. Done right, this could improve government policy not only in the United States but also around the world.

It's still hard to tell how this rule will affect EPA decisions, but one thing is clear: The rule will make the evidence by which we make policy decisions more transparent. The policy might not be perfect, but its benefits will likely far outweigh its costs.

Robert Hahn is a visiting professor at Oxford University's Smith School of Enterprise and the Environment and a non-resident senior fellow at the Brookings Institution. He recently served as a commissioner on the U.S. Commission on Evidence-Based Policymaking.

The Washington Examiner

https://www.washingtonexaminer.com/policy/energy/epa-wont-redo-obamas-report-on-risks-from-deadly-paint-stripper

EPA Won't Redo Obama's Report On Risks From Deadly Paint Stripper

By John Siciliano, 5/10/18

The Environmental Protection Agency announced Thursday that it would not seek to redo an Obama administration report that listed the numerous health risks from exposure to the paint stripper chemical methylene chloride.

The EPA is "not re-evaluating the paint stripping uses of methylene chloride and is relying on its previous risk assessments," the agency announced.

The paint stripping chemical has caused dozens of deaths, and environmentalists have called on EPA Administrator Scott Pruitt to ban the substance as a public health concern.

The agency also said it plans to finish the regulatory process for the chemical that started under the Obama administration in 2016. It expects to send a final determination on the chemical "shortly" to the Office of Management and Budget for review.

Pruitt recently met with the parents of children who died from exposure to the chemical solvent. Wendy Hartley and Cindy Wynne met with Pruitt a few days before Thursday's announcement.

Hartley and Wynne said they were disappointed that the visit was not followed by a commitment to ban the substance.

But Senate Democrats said Thursday's announcement should be greeted with optimism that the EPA is moving ahead with a ban on the chemical.

Sen. Tom Carper of Delaware, the top Democrat on the Senate Environment and Public Works Committee, took the announcement to mean that the EPA "intends to finalize a ban on methylene chloride."

Carper, an outspoken critic of Pruitt, said the announcement "is welcome news, especially after the agency previously delayed finalization of this proposed ban indefinitely."

Nevertheless, Carper is "encouraged" that the EPA is relying on the Obama-era risk assessments, which "clearly and scientifically showed just how threatening products containing methylene chloride could be to people's health and safety."

However, "just like a law doesn't mean much if it is not enforced, intentions to finalize a ban on a deadly chemical don't mean much if that chemical stays on the shelves," he added.

The Associated Press

https://apnews.com/6cb39378fdbc4586a00cd3d48f02abbe/Action-'shortly'-on-solvent-after-Pruitt-and-families-meet

Action 'shortly' on solvent after Pruitt and families meet

5/10/18

WASHINGTON (AP) — The Environmental Protection Agency is promising quick action on new restrictions for a widely sold solvent used for paint stripping.

Thursday's announcement comes after EPA administrator Scott Pruitt met with families of men who died after using products with the compound methylene chloride.

The Obama administration in its last days proposed banning most consumer sales of methylene chloride. Lawmakers last month accused Pruitt of putting the rule on hold. Pruitt met Tuesday with families of a 31-year-old man and 21-year-old man who died after using paint-strippers.

The EPA said Thursday it would act "shortly" to put the new regulation on the books.

Activist Liz Hitchcock said she and other campaigners against methylene chloride welcome the announcement. Hitchcock says she will watch the final wording of the rule closely.

The Washington Post

https://www.washingtonpost.com/news/powerpost/paloma/daily-202/2018/05/11/daily-202-trump-reassures-anxious-hawks-that-he-s-willing-to-walk-away-from-north-korea-talks/5af4bf9530fb042588799475/

Mothers Lobbied Scott Pruitt To Ban A Toxic Chemical. Two Days Later, EPA Signaled It Would.

By James Hohmann, 5/11/18

Environmental Protection Agency chief Scott Pruitt has met with few environmental groups throughout his tenure. More often, he has conferred with industry representatives.

But this week, the EPA chief agreed to meet with a different sort of lobbyist: the mothers of two men who died from exposure to paint strippers containing a toxic chemical.

The result: Two days later, the EPA signaled on Thursday it will follow through on an Obama-era proposal to ban paint strippers containing a toxic chemical — leaving Democratic lawmakers, environmental groups and the families of victims cautiously optimistic they won Pruitt over, Brady Dennis and I reported Thursday.

"I wanted to use Kevin's story to try to save more lives," one of the mothers, Wendy Hartley, told The Washington Post in an interview. Her son Kevin Hartley was a trained contractor who died last year at age 21 while refinishing a bathtub with White Lightning Low Odor Stripper near Nashville.

"We do not need any more lives lost due to this," Hartley said. "And if I could tell Kevin's story and get someone to listen to it and do something about, then I was willing to tell his story."

Since taking office, Pruitt has been laser-focused on undoing environmental and safety rules proposed by President Barack Obama's administration. But the EPA's announcement that it "intends to finalize" a proposed ban on certain uses of the chemical, called methylene chloride, would be an exception.

The chemical, used by professional contractors and do-it-yourselfers to remove paint, has been linked to dozens of deaths – including 12 people between 2000 and 2011 who specialize in refinishing bathtubs, according to a Centers for Disease Control and Prevention report.

The EPA first proposed banning the use of methylene chloride in paint and coating removal products in the waning days of Obama's second term. A year earlier, Congress had granted the EPA new powers to restrict the use of that and other chemicals in an amendment to the 1976 Toxic Substances Control Act, the nation's main chemical safety law.

But in December, the Pruitt's EPA indefinitely postponed bans on certain uses of methylene chloride and two other deadly chemicals often found in consumer products. For a time, it seemed like the ban was headed to the trash bin, along with many other Obama-era rules after President Trump's election.

That delay in December kicked off an effort to salvage it. Several Democratic lawmakers asked Pruitt about the chemical and urged him to ban it in a pair of hearings on Capitol Hill last month. Rep. Frank Pallone (D-N.Y.) asked Pruitt if he had anything to say to the people whose family members died given the lack of EPA action.

Pruitt didn't directly address that question, but he made clear that the agency hadn't abandoned its evaluation of the chemical's safety. "There has been no decision at this time," he said at the April 26 hearing.

That did little to satisfy Pallone. "Look, you say you're going to do something, but these chemicals are still on the shelves, and they make a mockery of [chemical reform] legislation that this committee works so hard on," Pallone said. "And it makes a mockery of EPA. You have the power immediately to get this chemical off the shelves. And you're not doing it. And you should do it."

The lobbying effort also continued behind the scenes. After the hearings, the Environmental Defense Fund contacted Pruitt's office on behalf of the families of Kevin Hartley and and Drew Wynne, 31, was running a cold-brew coffee business in Charleston, S.C., when he died last year while stripping paint from the floor of a walk-in refrigerator using a product called Goof Off.

The group asked for a meeting with the administrator and the EPA agreed. So this past Tuesday morning, Wendy Hartley, along with Cindy Wynne and her other son Brian Wynne, met Pruitt and several of his aides at his office in EPA headquarters.

The families brought with them photographs and the death certificates of the two men, and explained to Pruitt what happened to them.

Pruitt "was very attentive to us," Cindy Wynne told The Post in an interview earlier this week before the EPA's announcement. "He was somewhat surprised when we showed him the cans from Lowe's," where her son had purchased the paint stripper.

Her son, Brian, asked Pruitt if he agreed that methylene chloride was a problem. Pruitt responded, "I do."
But when pressed on whether he would finalize the ban, the administrator did not make a commitment, the family members said.

"We all have the same sense that for a moment there, we felt like there was positive momentum," Brian Wynne said. "And then that went out of the room pretty quickly when he was steadfast against the word 'ban.'"

In an interview after the announcement Thursday, the brother said he was now "cautiously optimistic" that Pruitt would follow through.

"This is a positive development," Brian Wynne said. "It was a surprising one. We certainly didn't see this coming in our meeting with Administrator Pruitt. But we're certainly encouraged by this sign that he seems ready to take action."
Public health and environmental groups also reserved full-throated cheers until the rule's language is made public and submitted to the White House's Office of Management and Budget, which the EPA said will happen "shortly." Sarah Vogel, EDF's vice president for health, urged the EPA to "move quickly to implement a ban, and that includes ensuring necessary administrative procedures are followed to guarantee a permanent ban and that these products are promptly removed from store shelves."

The EPA said the "meeting with the families was constructive."

"It provided the families the opportunity to share with Administrator Pruitt the circumstances in each of their cases and the Administrator the opportunity to hear directly from them," Wilcox said. "There was an exchange of ideas, and we appreciate EDF reaching out to request the meeting."

Politico

https://subscriber.politicopro.com/energy/whiteboard/2018/05/pruitt-changes-naaqs-review-to-consider-adverse-effects-of-standards-1193678

Pruitt changes NAAQS review to consider 'adverse' effects of standards
By Alex Guillen, 5/10/18, 10:13 AM

EPA Administrator Scott Pruitt today directed the agency to change the review process for a critical air quality program to include the potential "adverse" effects of tighter standards.

In a memo signed Wednesday, Pruitt directed the Clean Air Scientific Advisory Committee, which advises on National Ambient Air Quality Standards issues, to provide advice on background pollution concentrations and the "adverse public health, welfare, social, economic or energy effects" from setting and achieving NAAQS standards.

The Supreme Court has previously ruled that EPA cannot consider implementation costs when setting NAAQS standards. Pruitt's memo argues that such information, even if not used to set a standard, can provide "important policy context for the public, co-regulators and EPA."

Pruitt also committed EPA to finish reviews of two controversial standards before the end of President Donald Trump's first term.

Even as EPA continues internal deliberations over revising the 2015 ozone standard, Pruitt committed the agency to meeting the October 2020 deadline to again review the standard. He also directed EPA to complete its review of the particulate matter standard by December 2020.

The memo also:

— Calls for "more efficient ways" to conduct the scientific and policy assessments that underlie NAAQS reviews;

— Requests a "clearer distinction" between the scientific conclusions and the "wider range of policy concerns" that Pruitt considers in setting standards;

— Urges CASAC members who disagree with the panel's consensus to "share their own individual opinions;" and

— Advises EPA to issue implementation rules and guidance concurrent with NAAQS revisions.

WHAT'S NEXT: The memo directs EPA to begin work on the next ozone review in order to complete it by October 2020.

Oil & Gas Journal

https://www.ogj.com/articles/2018/05/pruitt-signs-memo-outlining-naaqs-back-to-basics-review-process.html

Pruitt Signs Memo Outlining NAAQS 'Back To Basics' Review Process
By Nick Snow, 5/10/18

US Environmental Protection Agency Administrator E. Scott Pruitt signed a memorandum describing a "back to basics" process for reviewing the federal Clean Air Act's National Ambient Air Quality Standards (NAAQS). The memo assures that EPA and its independent science advisors take a transparent, efficient, and timely approach, he said on May 10.

The memo's principles will reform the process for setting NAAQS in a manner consistent with cooperative federalism and the rule of law, Pruitt maintained. "Getting EPA and its advisors back on track with CAA requirements, statutory

deadlines, and the issuance of timely implementation rules will assure that we continue the dramatic improvement in air quality across our country," he said.

The reforms advance initiatives President Donald J. Trump set out in an April 12 memorandum directing Pruitt to take specific actions to ensure efficient and cost-effective NAAQS implementation, including permitting decisions for new and expanded manufacturing facilities and with respect to the Regional Haze Program.

EPA said that Pruitt's memo commits it to begin the next review of the ground-level ozone NAAQS so it can finalize any revisions by the October 2020 deadline under the CAA. It also requires that the agency complete its review of the particulate matter NAAQS by December 2020.

Responding to Pruitt's announcement, an American Petroleum Institute official noted that US ozone concentrations have fallen 17% since 2005, partly due to the oil and gas industry's investments to improve the environmental performance of its products, facilities, and operations.

"We look forward to continuing this progress in achieving our shared goals of protecting public health and the environment and meeting the nation's energy needs," API Regulatory and Scientific Affairs Senior Director Howard J. Feldman said.

Manufacturers applaud EPA for recognizing the problems that have plagued past air quality determinations and for taking strong steps to correct them, observed Ross Eisenberg, the National Association of Manufacturers VP for Energy Resources. "We hope today's announcement leads to better, more effective regulations and improved air quality," he said.

The New York Times

https://www.nytimes.com/2018/05/10/world/middleeast/israel-iran-syria-military.html

Israel And Iran, Newly Emboldened, Exchange Blows In Syria Face-Off

By Isabel Kershner and David M. Halbfinger, 5/10/18

JERUSALEM — The tense shadow war between Iran and Israel burst into the open early Thursday as Israeli warplanes struck dozens of Iranian military targets inside Syria. It was a furious response to what Israel called an Iranian rocket attack launched from Syrian territory just hours earlier.

The cross-border exchanges — the most serious assaults from each side in their face-off over Iran's presence in Syria — took place a little more than a day after the United States withdrew from the Iran nuclear agreement.

Israel's defense minister said that Israeli warplanes had destroyed "nearly all" of Iran's military infrastructure in Syria after Iran launched 20 rockets at Israeli-held territory, none reaching their targets.

Iran struck shortly after President Trump pulled out of the nuclear agreement, raising speculation that it no longer felt constrained by the possibility that the Americans might scrap the deal if Iran attacked Israel.

Israel appeared newly emboldened as well, partly because of what seemed like extraordinary latitude from Russia, Syria's most important ally, allowing the Israelis to act against Iran's military assets in Syria.

Moscow did not condemn Israel's strikes, as it had in the past, instead calling on Israel and Iran to resolve their differences diplomatically.

And Prime Minister Benjamin Netanyahu of Israel, who spent 10 hours with President Vladimir V. Putin of Russia on Wednesday, told his cabinet on Thursday that he had persuaded the Russians to delay the sale of advanced weapons to Syria.

Russia and Iran have been allies in the Syrian war, defending President Bashar al-Assad. But as the war appears to be winding down, some analysts say the aims of Russia and Iran are diverging: Moscow prefers a strong secular central government in Syria, while Tehran prefers a weaker government that would allow Iran-backed militias free rein.

Israel has conducted scores of strikes on Iran and its allies inside Syria, rarely acknowledging them publicly. But before Thursday, Iran had not retaliated, seemingly handcuffed while it awaited Mr. Trump's decision on the nuclear accord.

Even so, the Iranians have plenty to lose if the conflict continues to grow. They still seem determined to preserve the nuclear accord despite renewed American sanctions. The accord also includes Russia, China, Britain, France, Germany and the European Union.

"We see now that Netanyahu feels that Iran's capacities in Syria are vulnerable, that he can target them, that Iran's capacities to strike back are weakened — he took out some of these capacities, probably less than he claims — and that Iran has no significant way to react without risking itself," said Ofer Zalzberg, an analyst at the International Crisis Group.

Israel made it clear on Thursday that its planning for the airstrikes had been known internally as "Chess," and it looked in the aftermath as though Iran might have been baited into a trap on the Syrian game board.

Iran's rocket attack against Israel came after what appeared to have been an Israeli missile strike against a village in the Syrian Golan Heights late on Wednesday.

Early on Thursday, Iranian forces fired about 20 Grad and Fajr-5 rockets at the Israeli-controlled Golan Heights, targeting forward positions of the Israeli military, according to an Israeli military spokesman. The barrage was launched under the command of the Quds Force of the Islamic Revolutionary Guards Corps and used Iranian weapons, said the Israeli spokesman, Lt. Col. Jonathan Conricus.

Four of the rockets were intercepted by Israel's Iron Dome antimissile defense system, and the rest fell short of the Israeli-controlled territory, the military said. Indeed, by Thursday morning, Israeli life returned to routine in the Golan Heights, with children going to school.

Still, the rocket attack was a significant escalation in Iran's maneuvers in the Middle East. Though Israel has hit Iranian forces in Syria with a number of deadly airstrikes, Tehran had been restrained in hitting back, until now.

"Iran had to make a point: that it can respond, even if it's a weak response," said Joshua M. Landis, a Syria expert and director of the Center of Middle East Studies at the University of Oklahoma. "But it also revealed a weakness: Those rockets don't have any brains."

Israel said its response struck a severe blow to Iran's military capacity in Syria. In a statement, the military said the targets included what it described as Iranian intelligence sites; a logistics headquarters belonging to the Quds Force; military compounds; munition storage warehouses of the Quds Force at Damascus International Airport; intelligence systems associated with those forces; and military posts and munitions in the buffer zone between the Syrian Golan Heights and the Israeli-occupied portion.

"If there is rain on our side, there will be a flood on their side," Israel's defense minister, Avigdor Lieberman, said Thursday morning in remarks broadcast from a policy conference in Herzliya, near Tel Aviv. "I hope we have finished with this round and that everybody understood."

In all, at least 23 people were killed in the strikes, according to the Syrian Observatory for Human Rights, a Britain-based monitoring group. The Syrian Army, by contrast, said that three people had died. Israel reported no casualties on its side.

Israel said it had no intention of further escalation, and analysts looking for clues to Iran's potential response noted that its news media was largely ignoring the overnight hostilities, focusing instead on the nuclear deal. The English-language report on the airstrikes from Iran's Fars news agency made no mention of Iranian involvement.

In a sign of international concern that the conflict could escalate, however, Britain, France, Germany and Russia were quick to call for calm. "We proceed from the fact that all issues should be solved through dialogue," the Russian foreign minister, Sergey V. Lavrov, said at a news conference.

The White House condemned the missile attack on Israel, saying in a statement that it strongly supported "Israel's right to act in self-defense" and called on Iran "to take no further provocative steps."

It also inflicted new financial pain on Iran on Thursday. The Treasury Department said it had teamed with the United Arab Emirates to disrupt an Iranian currency exchange network that transferred millions of dollars, in coordination with Iran's central bank, to the Islamic Revolutionary Guards Corps. "We are intent on cutting off I.R.G.C. revenue streams wherever their source and whatever their destination," Treasury Secretary Steven Mnuchin said in a statement.

Iran has taken advantage of the chaos in Syria to build a substantial military infrastructure there. It has built and trained large militias with thousands of fighters and sent advisers from its Revolutionary Guards Corps to Syrian military bases.

Mr. Netanyahu said this week that the Revolutionary Guards had moved advanced weapons to Syria, including ground-to-ground missiles, weaponized drones and Iranian antiaircraft batteries that he said would threaten Israel's military jets.

Israel's political and security establishment has been unified and vocal in vowing to thwart Iran's efforts to entrench itself militarily across Israel's northern frontier and to build what Israeli and American officials refer to as a land corridor from Iran, through Iraq and Syria, to Lebanon.

Israel had warned Tehran that it would respond to any attack. Israel also broadcast warnings to Syria, saying that allowing Iranian entrenchment in its territory put Mr. Assad's government at risk.

The tensions between Iran and Israel have been complicated further by Mr. Trump's withdrawal from the nuclear agreement on Tuesday.

Israel had railed against the agreement, and Mr. Trump had campaigned on the promise of withdrawing from it, but European countries and many analysts had seen it as a crucial element holding back Iran and Israel, implacable foes, from all-out conflict.

As Mr. Trump announced his decision, Israel put its troops on "high alert," called up reservists, set up Iron Dome batteries and instructed the authorities in the Golan Heights to prepare public bomb shelters after detecting what it said was irregular activity by Iranian forces.

Israel's strikes early Thursday were some of the country's largest aerial operations in decades across the Syrian frontier, and by far the broadest direct attack yet on Iranian assets. "This was an operation we prepared for, and were not surprised by," Colonel Conricus said.

Israel said Russia had been informed before the overnight attack.

In recent years, Iran has helped Hezbollah, the Iranian-backed force in Lebanon, amass a huge arsenal of rockets it can use against Israel as a deterrent against Israeli strikes on Iran's nuclear program.

Israel has carried out scores of strikes against what it says are advanced weapons and convoys destined for Hezbollah. But since February, when Israel intercepted what it later called an armed Iranian drone that had penetrated its airspace

from Syria, setting off a day of heated cross-border exchanges, Israel's efforts appear to have been more focused on Iranian assets in Syria.

"Israel doesn't want another Hezbollah inside Syria, it doesn't want another Lebanon," said Andrew J. Tabler, a Syria scholar at the Washington Institute for Near East Policy. "The Israelis think they can surgically strike and not create a wider conflict. They think that Assad, working with the Russians, will have an incentive not to respond."

The Associated Press

https://apnews.com/22f986def6eb42c0b8c035ca4b0d7f95

Trump's High-Risk Doctrine? Swing For The Bleacher Seats

By Catherine Lucey, Jonathan Lemire, and Ken Thomas, 5/10/18

WASHINGTON (AP) — The way President Donald Trump sees it, why go for a solid single when you can swing for a home run?

Trump's upcoming summit with North Korea's Kim Jong Un is only the latest example of the president's go-big strategy. From tax reform to international trade to foreign policy, Trump has pursued a high-risk, high-reward approach that advisers say can help produce results on longstanding problems — and that critics warn could trigger dangerous repercussions all the way from a trade war to global conflict.

Drawn to big moments and bigger headlines, Trump views the North Korea summit as a legacy-maker for him, believing that the combustible combination of his bombast and charm already has led to warmer relations between North and South. As he welcomed home three Americans who had been detained in North Korea, Trump early Thursday used a televised, middle-of-the-night ceremony to play up both his statecraft and stagecraft.

"I think you probably broke the all-time, in history, television rating for three o'clock in the morning," Trump told reporters on the tarmac at Joint Base Andrews.

Trump has also played the disruptor's role in recent weeks and months by withdrawing the U.S. from the Iran nuclear deal, imposing sweeping tariffs on allies and announcing he's moving the U.S. embassy in Israel to Jerusalem, which is claimed by both Israelis and Palestinians.

It's all a sharp contrast to his play-it-safe predecessor.

"You hit singles, you hit doubles; every once in a while we may be able to hit a home run," President Barack Obama said of his own foreign policy. "But we steadily advance the interests of the American people and our partnership with folks around the world."

Not all of Trump's attention-grabbing gambits have worked — and the potential risks going forward are daunting.

His push to overturn Obama's landmark health care law ended in a humiliating defeat for the Republicans. His decision to impose new tariffs on steel and aluminum imports has left global markets in a state of flux and unnerved some of America's closest allies about the potential for a trade war. And his withdrawal from the international nuclear agreement with Iran, with strong support from Israel, has escalated tensions in the already volatile region.

Critics say Trump sometimes focuses on bold gestures first — and fallout later.

For now, scoring a diplomatic win with Pyongyang has become Trump's top focus.

His outside-the-box approach to North Korea — complete with ominous taunts of raining "fire and fury" on the North while belittling its leader as "Little Rocket Man" — alarmed many global capitals and much of Washington's national security establishment, increasing worries about nuclear war.

But Trump believes it brought Kim to the negotiating table, with a summit between the two men now set for June 12 in Singapore.

Trump told one confidant that he now believes a deal with North Korea, rather than in the Middle East, could be his historic victory. White House officials also believe that a triumph on the Korean Peninsula — something that has eluded the United States for generations — could bolster Trump's approval ratings, help inoculate him against the investigations swirling around him and maybe even trickle down to help Republicans in this fall's midterm elections.

While some White House aides characterized Trump's moves as evidence of bold thinking, there is also concern that he has little sense of the potential repercussions from some of his big moves, believing that if things don't work out, that he can always just reverse course.

In the early months of his administration, Trump latched on to the belief that he could be the president to bring peace to the Middle East. Fond of the idea of making history, the president told advisers he was driven to accomplish something that his predecessors could not and believed that his negotiating skills and strong relationship with Israeli Prime Minister Benjamin Netanyahu could lead to the unprecedented achievement, according to four White House officials and outside advisers.

At one moment last spring, Trump mused in the Oval Office that he wouldn't even require a second term to settle things in the region, according to two people familiar with the exchange but not authorized to speak publicly about private conversations.

Though he did break with tradition to move the U.S. embassy to Jerusalem, the White House plan bogged down and the divide between Israelis and Palestinians seems as intractable as ever, prompting Trump's attention shift to North Korea. Warned by Obama days after his election that the threat posed by Pyongyang could define his presidency, Trump answered Kim's threats with bellicose warnings of his own and rallied an international pressure campaign against North Korea.

Some Republicans have suggested his efforts should bring him the Nobel Peace Prize, an idea Trump clearly savored at a recent rally in Michigan when the crowd chanted "Nobel." Asked about the chatter in the Oval Office this week, Trump said: "I want to get peace. It's the main thing. We want to get peace. That was a big problem, and I think it's going to work out well."

Then he added his catchall caveat: "We'll see."

Long before he was president, the onetime New York real estate developer and reality television star often spoke about the benefits of acting boldly. In "The Art of the Deal," he put it this way: "I like thinking big. I always have. To me it's very simple: if you're going to be thinking anyway, you might as well think big."

Trump appears to have embraced the "Great Man" theory of history, believing that individuals more than circumstances or trends alter the course of events. In his 2016 GOP convention speech, he famously declared "I alone can fix it," in referencing the nation's problems.

Trump and his team also believe that his bold tactics have the added benefit for Trump of overshadowing the threats his administration faces from the ongoing Russia probe and the legal web surrounding his personal attorney, Michael Cohen, and porn actress Stormy Daniels.

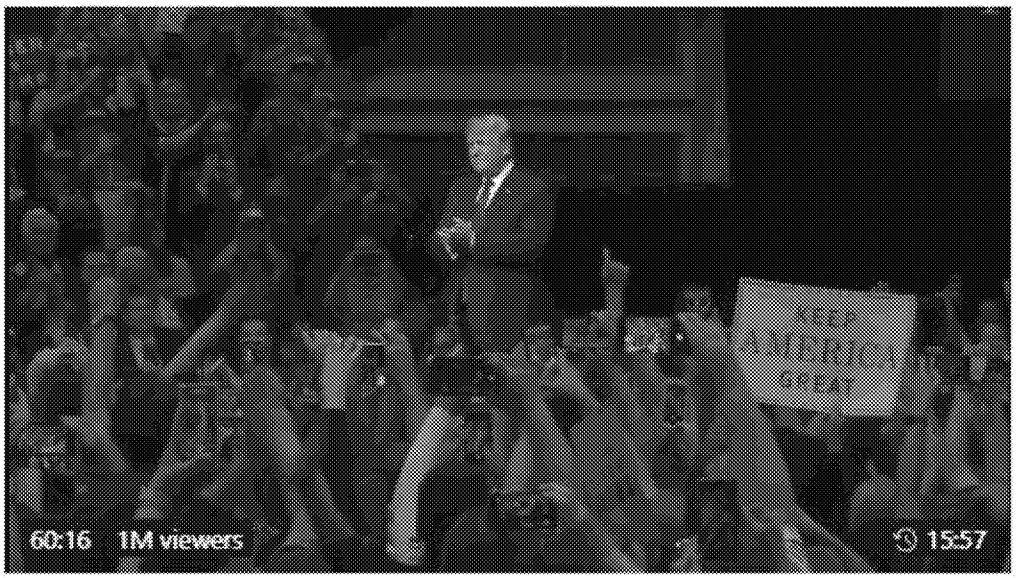
Rice University presidential historian Douglas Brinkley said Trump's diplomacy with North Korea is a "high-risk game."

"But if he pulls off the denuclearization of the North Korean Peninsula, it will be the landmark achievement," said Brinkley. "It's Trump's big going-to-China moment."

TRUMP TWEETS

Donald J. Trump @realDonaldTrump · 13h

Thank you Indiana! #MAGA



President Trump and VP Pence Hold a Rally in Indiana

Fox News @FoxNews

8.8K 13K 56K

Donald J. Trump @realDonaldTrump · 23h

The highly anticipated meeting between Kim Jong Un and myself will take place in Singapore on June 12th. We will both try to make it a very special moment for World Peace!

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EPA News Highlights 5.11.18

The Washington Post: Many Mocked This Scott Pruitt Proposal. They Should Have Read It First.
When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science." But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

The Washington Examiner: EPA Won't Redo Obama's Report On Risks From Deadly Paint Stripper
The Environmental Protection Agency announced Thursday that it would not seek to redo an Obama administration report that listed the numerous health risks from exposure to the paint stripper chemical methylene chloride. The EPA is "not re-evaluating the paint stripping uses of methylene chloride and is relying on its previous risk assessments," the agency announced. The paint stripping chemical has caused dozens of deaths, and environmentalists have called on EPA Administrator Scott Pruitt to ban the substance as a public health concern. The agency also said it plans to finish the regulatory process for the chemical that started under the Obama administration in 2016. It expects to send a final determination on the chemical "shortly" to the Office of Management and Budget for review.

The Associated Press: Action 'shortly' on solvent after Pruitt and families meet
The Environmental Protection Agency is promising quick action on new restrictions for a widely sold solvent used for paint stripping. Thursday's announcement comes after EPA administrator Scott Pruitt met with families of men who died after using products with the compound methylene chloride. The Obama administration in its last days proposed banning most consumer sales of methylene chloride. Lawmakers last month accused Pruitt of putting the rule on hold. Pruitt met Tuesday with families of a 31-year-old man and 21-year-old man who died after using paint-strippers.

The Washington Post: Mothers Lobbied Scott Pruitt To Ban A Toxic Chemical. Two Days Later, EPA Signaled It Would.
Environmental Protection Agency chief Scott Pruitt has met with few environmental groups throughout his tenure. More often, he has conferred with industry representatives. But this week, the EPA chief agreed to meet with a different sort of lobbyist: the mothers of two men who died from exposure to paint strippers containing a toxic chemical. The result: Two days later, the EPA signaled on Thursday it will follow through on an Obama-era proposal to ban paint strippers containing a toxic chemical — leaving Democratic lawmakers, environmental groups and the families of victims cautiously optimistic they won Pruitt over, Brady Dennis and I reported Thursday.

Politico: Pruitt changes NAAQS review to consider 'adverse' effects of standards
EPA Administrator Scott Pruitt today directed the agency to change the review process for a critical air quality program to include the potential "adverse" effects of tighter standards. In a memo signed Wednesday, Pruitt directed the Clean Air Scientific Advisory Committee, which advises on National Ambient Air Quality Standards issues, to provide advice on background pollution concentrations and the "adverse public health, welfare, social, economic or energy effects" from setting and achieving NAAQS standards. The Supreme Court has previously ruled that EPA cannot consider implementation costs whGasen setting NAAQS standards. Pruitt's memo argues that such information, even if not used to set a standard, can provide "important policy context for the public, co-regulators and EPA."

Oil & Gas Journal: Pruitt Signs Memo Outlining NAAQS 'Back To Basics' Review Process
US Environmental Protection Agency Administrator E. Scott Pruitt signed a memorandum describing a "back to basics" process for reviewing the federal Clean Air Act's National Ambient Air Quality Standards (NAAQS). The memo assures that EPA and its independent science advisors take a transparent, efficient, and timely approach, he said on May 10. The memo's principles will reform the process for setting NAAQS in a manner consistent with cooperative federalism and the rule of law, Pruitt maintained. "Getting EPA and its advisors back on track with CAA requirements, statutory deadlines,

and the issuance of timely implementation rules will assure that we continue the dramatic improvement in air quality across our country," he said.

National News Highlights 5.11.18

The New York Times: Israel And Iran, Newly Emboldened, Exchange Blows In Syria Face-Off
The tense shadow war between Iran and Israel burst into the open early Thursday as Israeli warplanes struck dozens of Iranian military targets inside Syria. It was a furious response to what Israel called an Iranian rocket attack launched from Syrian territory just hours earlier. The cross-border exchanges — the most serious assaults from each side in their face-off over Iran's presence in Syria — took place a little more than a day after the United States withdrew from the Iran nuclear agreement. Israel's defense minister said that Israeli warplanes had destroyed "nearly all" of Iran's military infrastructure in Syria after Iran launched 20 rockets at Israeli-held territory, none reaching their targets. Iran struck shortly after President Trump pulled out of the nuclear agreement, raising speculation that it no longer felt constrained by the possibility that the Americans might scrap the deal if Iran attacked Israel.

The Associated Press: Trump's High-Risk Doctrine? Swing For The Bleacher Seats
The way President Donald Trump sees it, why go for a solid single when you can swing for a home run? Trump's upcoming summit with North Korea's Kim Jong Un is only the latest example of the president's go-big strategy. From tax reform to international trade to foreign policy, Trump has pursued a high-risk, high-reward approach that advisers say can help produce results on longstanding problems — and that critics warn could trigger dangerous repercussions all the way from a trade war to global conflict. Drawn to big moments and bigger headlines, Trump views the North Korea summit as a legacy-maker for him, believing that the combustible combination of his bombast and charm already has led to warmer relations between North and South. As he welcomed home three Americans who had been detained in North Korea, Trump early Thursday used a televised, middle-of-the-night ceremony to play up both his statecraft and stagecraft.

TRUMP TWEETS

The Washington Post
https://www.washingtonpost.com/opinions/many-mocked-this-scott-pruitt-proposal-they-should-have-read-it-first/2018/05/10/31baba9a-53c2-11e8-abd8-265bd07a9859_story.html?noredirect=on&utm_term=.f7bcbc0a1887
Many Mocked This Scott Pruitt Proposal. They Should Have Read It First.
By Robert Hahn, 5/10/18

When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science."

But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

Critics typically argue that the proposed regulation would suppress research that contains confidential medical records and therefore scientists could not share underlying data publicly for privacy reasons. Such restrictions, these critics say, would have excluded landmark research, such as Harvard University's "Six Cities" study, which suggested that reducing fine particles in the air would dramatically improve human health and helped lead to more stringent regulation of fine particles in the United States.

These concerns are likely the result of rhetoric surrounding the rule. Pruitt describes the regulation as an attempt to end "secret science" at the agency. Conservatives have long prioritized the need for making all data and statistical models

used in regulatory decision-making available for independent scrutiny, with the intent to limit the use of studies that cannot be replicated. Breitbart went even further, characterizing the action as "a massive victory for both Pruitt and President Trump in their war on the Green Blob."

But it appears that few defenders or opponents of the proposal have actually read the proposed EPA regulation, which is only seven pages long. Both sides distort the regulatory text.

Here's what the rule would actually do. First, it would require the EPA to identify studies that are used in making regulatory decisions. Second, it would encourage studies to be made publicly available "to the extent practicable." Third, it would define "publicly available" by listing examples of information that could be used for validation, such as underlying data, models, computer code and protocols. Fourth, the proposal recognizes not all data can be openly accessible in the public domain and that restricted access to some data may be necessary. Fifth, it would direct the EPA to work with third parties, including universities and private firms, to make information available to the extent reasonable. Sixth, it would encourage the use of efforts to de-identify data sets to create public-use data files that would simultaneously help protect privacy and promote transparency. Seventh, the proposal outlines an exemption process when compliance is "impracticable." Finally, it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

Here's what the EPA's rule wouldn't do: nullify existing environmental regulations, disregard existing research, violate confidentiality protections, jeopardize privacy or undermine the peer-review process.

The costs of compliance with EPA regulations are substantial. A draft report from the White House Office of Management and Budget suggests that significant EPA regulations imposed costs ranging from $54 billion to $65 billion over the past decade. These rules also realize substantial public-health and environmental benefits estimated to range from $196 billion to $706 billion over the decade.

Given the stakes for both the cost of compliance with EPA regulations and the real risks that pollution poses to public health and the environment, this rule should be read closely by critics and supporters for what it actually says. Just as transparency in science and evidence are essential, so, too, are intellectual honesty and accurate policy communication.

Taking steps to increase access to data, with strong privacy protections, is how society will continue to make scientific and economic progress and ensure that evidence in rule-making is sound. The EPA's proposed rule follows principles laid out in 2017 by the bipartisan Commission on Evidence-Based Policymaking — humility, transparency, privacy, capacity and rigor — and moves us toward providing greater access to scientific data while protecting individual privacy.

Instead of throwing stones, the scientific community should come together to offer practical suggestions to make the rule better. For example, the rule should recognize the incentives for scientists to produce new research. Scientists need to have time to produce and take credit for their research findings. Thus, there will inevitably be a trade-off between the production of new insights and the sharing of data with others, including regulators.

The EPA should also establish use restrictions and a secure data infrastructure so that confidential business and personal data are adequately protected. Finally, it should set procedures to evaluate the effectiveness of this rule. Done right, this could improve government policy not only in the United States but also around the world.

It's still hard to tell how this rule will affect EPA decisions, but one thing is clear: The rule will make the evidence by which we make policy decisions more transparent. The policy might not be perfect, but its benefits will likely far outweigh its costs.

Robert Hahn is a visiting professor at Oxford University's Smith School of Enterprise and the Environment and a non-resident senior fellow at the Brookings Institution. He recently served as a commissioner on the U.S. Commission on Evidence-Based Policymaking.

The Washington Examiner

https://www.washingtonexaminer.com/policy/energy/epa-wont-redo-obamas-report-on-risks-from-deadly-paint-stripper

EPA Won't Redo Obama's Report On Risks From Deadly Paint Stripper

By John Siciliano, 5/10/18

The Environmental Protection Agency announced Thursday that it would not seek to redo an Obama administration report that listed the numerous health risks from exposure to the paint stripper chemical methylene chloride.

The EPA is "not re-evaluating the paint stripping uses of methylene chloride and is relying on its previous risk assessments," the agency announced.

The paint stripping chemical has caused dozens of deaths, and environmentalists have called on EPA Administrator Scott Pruitt to ban the substance as a public health concern.

The agency also said it plans to finish the regulatory process for the chemical that started under the Obama administration in 2016. It expects to send a final determination on the chemical "shortly" to the Office of Management and Budget for review.

Pruitt recently met with the parents of children who died from exposure to the chemical solvent. Wendy Hartley and Cindy Wynne met with Pruitt a few days before Thursday's announcement.

Hartley and Wynne said they were disappointed that the visit was not followed by a commitment to ban the substance.

But Senate Democrats said Thursday's announcement should be greeted with optimism that the EPA is moving ahead with a ban on the chemical.

Sen. Tom Carper of Delaware, the top Democrat on the Senate Environment and Public Works Committee, took the announcement to mean that the EPA "intends to finalize a ban on methylene chloride."

Carper, an outspoken critic of Pruitt, said the announcement "is welcome news, especially after the agency previously delayed finalization of this proposed ban indefinitely."

Nevertheless, Carper is "encouraged" that the EPA is relying on the Obama-era risk assessments, which "clearly and scientifically showed just how threatening products containing methylene chloride could be to people's health and safety."

However, "just like a law doesn't mean much if it is not enforced, intentions to finalize a ban on a deadly chemical don't mean much if that chemical stays on the shelves," he added.

The Associated Press

https://apnews.com/6cb39378fdbc4586a00cd3d48f02abbe/Action-'shortly'-on-solvent-after-Pruitt-and-families-meet

Action 'shortly' on solvent after Pruitt and families meet

5/10/18

WASHINGTON (AP) — The Environmental Protection Agency is promising quick action on new restrictions for a widely sold solvent used for paint stripping.

Thursday's announcement comes after EPA administrator Scott Pruitt met with families of men who died after using products with the compound methylene chloride.

The Obama administration in its last days proposed banning most consumer sales of methylene chloride. Lawmakers last month accused Pruitt of putting the rule on hold. Pruitt met Tuesday with families of a 31-year-old man and 21-year-old man who died after using paint-strippers.

The EPA said Thursday it would act "shortly" to put the new regulation on the books.

Activist Liz Hitchcock said she and other campaigners against methylene chloride welcome the announcement. Hitchcock says she will watch the final wording of the rule closely.

The Washington Post

https://www.washingtonpost.com/news/powerpost/paloma/daily-202/2018/05/11/daily-202-trump-reassures-anxious-hawks-that-he-s-willing-to-walk-away-from-north-korea-talks/5af4bf9530fb042588799475/

Mothers Lobbied Scott Pruitt To Ban A Toxic Chemical. Two Days Later, EPA Signaled It Would.

By James Hohmann, 5/11/18

Environmental Protection Agency chief Scott Pruitt has met with few environmental groups throughout his tenure. More often, he has conferred with industry representatives.

But this week, the EPA chief agreed to meet with a different sort of lobbyist: the mothers of two men who died from exposure to paint strippers containing a toxic chemical.

The result: Two days later, the EPA signaled on Thursday it will follow through on an Obama-era proposal to ban paint strippers containing a toxic chemical — leaving Democratic lawmakers, environmental groups and the families of victims cautiously optimistic they won Pruitt over, Brady Dennis and I reported Thursday.

"I wanted to use Kevin's story to try to save more lives," one of the mothers, Wendy Hartley, told The Washington Post in an interview. Her son Kevin Hartley was a trained contractor who died last year at age 21 while refinishing a bathtub with White Lightning Low Odor Stripper near Nashville.

"We do not need any more lives lost due to this," Hartley said. "And if I could tell Kevin's story and get someone to listen to it and do something about, then I was willing to tell his story."

Since taking office, Pruitt has been laser-focused on undoing environmental and safety rules proposed by President Barack Obama's administration. But the EPA's announcement that it "intends to finalize" a proposed ban on certain uses of the chemical, called methylene chloride, would be an exception.

The chemical, used by professional contractors and do-it-yourselfers to remove paint, has been linked to dozens of deaths – including 12 people between 2000 and 2011 who specialize in refinishing bathtubs, according to a Centers for Disease Control and Prevention report.

The EPA first proposed banning the use of methylene chloride in paint and coating removal products in the waning days of Obama's second term. A year earlier, Congress had granted the EPA new powers to restrict the use of that and other chemicals in an amendment to the 1976 Toxic Substances Control Act, the nation's main chemical safety law.

But in December, the Pruitt's EPA indefinitely postponed bans on certain uses of methylene chloride and two other deadly chemicals often found in consumer products. For a time, it seemed like the ban was headed to the trash bin, along with many other Obama-era rules after President Trump's election.

That delay in December kicked off an effort to salvage it. Several Democratic lawmakers asked Pruitt about the chemical and urged him to ban it in a pair of hearings on Capitol Hill last month. Rep. Frank Pallone (D-N.Y.) asked Pruitt if he had anything to say to the people whose family members died given the lack of EPA action.

Pruitt didn't directly address that question, but he made clear that the agency hadn't abandoned its evaluation of the chemical's safety. "There has been no decision at this time," he said at the April 26 hearing.

That did little to satisfy Pallone. "Look, you say you're going to do something, but these chemicals are still on the shelves, and they make a mockery of [chemical reform] legislation that this committee works so hard on," Pallone said. "And it makes a mockery of EPA. You have the power immediately to get this chemical off the shelves. And you're not doing it. And you should do it."

The lobbying effort also continued behind the scenes. After the hearings, the Environmental Defense Fund contacted Pruitt's office on behalf of the families of Kevin Hartley and and Drew Wynne, 31, was running a cold-brew coffee business in Charleston, S.C., when he died last year while stripping paint from the floor of a walk-in refrigerator using a product called Goof Off.

The group asked for a meeting with the administrator and the EPA agreed. So this past Tuesday morning, Wendy Hartley, along with Cindy Wynne and her other son Brian Wynne, met Pruitt and several of his aides at his office in EPA headquarters.

The families brought with them photographs and the death certificates of the two men, and explained to Pruitt what happened to them.

Pruitt "was very attentive to us," Cindy Wynne told The Post in an interview earlier this week before the EPA's announcement. "He was somewhat surprised when we showed him the cans from Lowe's," where her son had purchased the paint stripper.

Her son, Brian, asked Pruitt if he agreed that methylene chloride was a problem. Pruitt responded, "I do."
But when pressed on whether he would finalize the ban, the administrator did not make a commitment, the family members said.

"We all have the same sense that for a moment there, we felt like there was positive momentum," Brian Wynne said. "And then that went out of the room pretty quickly when he was steadfast against the word 'ban.'"

In an interview after the announcement Thursday, the brother said he was now "cautiously optimistic" that Pruitt would follow through.

"This is a positive development," Brian Wynne said. "It was a surprising one. We certainly didn't see this coming in our meeting with Administrator Pruitt. But we're certainly encouraged by this sign that he seems ready to take action."
Public health and environmental groups also reserved full-throated cheers until the rule's language is made public and submitted to the White House's Office of Management and Budget, which the EPA said will happen "shortly." Sarah Vogel, EDF's vice president for health, urged the EPA to "move quickly to implement a ban, and that includes ensuring necessary administrative procedures are followed to guarantee a permanent ban and that these products are promptly removed from store shelves."

The EPA said the "meeting with the families was constructive."

"It provided the families the opportunity to share with Administrator Pruitt the circumstances in each of their cases and the Administrator the opportunity to hear directly from them," Wilcox said. "There was an exchange of ideas, and we appreciate EDF reaching out to request the meeting."

Politico

https://subscriber.politicopro.com/energy/whiteboard/2018/05/pruitt-changes-naaqs-review-to-consider-adverse-effects-of-standards-1193678

Pruitt changes NAAQS review to consider 'adverse' effects of standards

By Alex Guillen, 5/10/18, 10:13 AM

EPA Administrator Scott Pruitt today directed the agency to change the review process for a critical air quality program to include the potential "adverse" effects of tighter standards.

In a memo signed Wednesday, Pruitt directed the Clean Air Scientific Advisory Committee, which advises on National Ambient Air Quality Standards issues, to provide advice on background pollution concentrations and the "adverse public health, welfare, social, economic or energy effects" from setting and achieving NAAQS standards.

The Supreme Court has previously ruled that EPA cannot consider implementation costs when setting NAAQS standards. Pruitt's memo argues that such information, even if not used to set a standard, can provide "important policy context for the public, co-regulators and EPA."

Pruitt also committed EPA to finish reviews of two controversial standards before the end of President Donald Trump's first term.

Even as EPA continues internal deliberations over revising the 2015 ozone standard, Pruitt committed the agency to meeting the October 2020 deadline to again review the standard. He also directed EPA to complete its review of the particulate matter standard by December 2020.

The memo also:

— Calls for "more efficient ways" to conduct the scientific and policy assessments that underlie NAAQS reviews;

— Requests a "clearer distinction" between the scientific conclusions and the "wider range of policy concerns" that Pruitt considers in setting standards;

— Urges CASAC members who disagree with the panel's consensus to "share their own individual opinions;" and

— Advises EPA to issue implementation rules and guidance concurrent with NAAQS revisions.

WHAT'S NEXT: The memo directs EPA to begin work on the next ozone review in order to complete it by October 2020.

Oil & Gas Journal

https://www.ogj.com/articles/2018/05/pruitt-signs-memo-outlining-naaqs-back-to-basics-review-process.html

Pruitt Signs Memo Outlining NAAQS 'Back To Basics' Review Process

By Nick Snow, 5/10/18

US Environmental Protection Agency Administrator E. Scott Pruitt signed a memorandum describing a "back to basics" process for reviewing the federal Clean Air Act's National Ambient Air Quality Standards (NAAQS). The memo assures that EPA and its independent science advisors take a transparent, efficient, and timely approach, he said on May 10.

The memo's principles will reform the process for setting NAAQS in a manner consistent with cooperative federalism and the rule of law, Pruitt maintained. "Getting EPA and its advisors back on track with CAA requirements, statutory deadlines, and the issuance of timely implementation rules will assure that we continue the dramatic improvement in air quality across our country," he said.

The reforms advance initiatives President Donald J. Trump set out in an April 12 memorandum directing Pruitt to take specific actions to ensure efficient and cost-effective NAAQS implementation, including permitting decisions for new and expanded manufacturing facilities and with respect to the Regional Haze Program.

EPA said that Pruitt's memo commits it to begin the next review of the ground-level ozone NAAQS so it can finalize any revisions by the October 2020 deadline under the CAA. It also requires that the agency complete its review of the particulate matter NAAQS by December 2020.

Responding to Pruitt's announcement, an American Petroleum Institute official noted that US ozone concentrations have fallen 17% since 2005, partly due to the oil and gas industry's investments to improve the environmental performance of its products, facilities, and operations.

"We look forward to continuing this progress in achieving our shared goals of protecting public health and the environment and meeting the nation's energy needs," API Regulatory and Scientific Affairs Senior Director Howard J. Feldman said.

Manufacturers applaud EPA for recognizing the problems that have plagued past air quality determinations and for taking strong steps to correct them, observed Ross Eisenberg, the National Association of Manufacturers VP for Energy Resources. "We hope today's announcement leads to better, more effective regulations and improved air quality," he said.

The New York Times

https://www.nytimes.com/2018/05/10/world/middleeast/israel-iran-syria-military.html

Israel And Iran, Newly Emboldened, Exchange Blows In Syria Face-Off

By Isabel Kershner and David M. Halbfinger, 5/10/18

JERUSALEM — The tense shadow war between Iran and Israel burst into the open early Thursday as Israeli warplanes struck dozens of Iranian military targets inside Syria. It was a furious response to what Israel called an Iranian rocket attack launched from Syrian territory just hours earlier.

The cross-border exchanges — the most serious assaults from each side in their face-off over Iran's presence in Syria — took place a little more than a day after the United States withdrew from the Iran nuclear agreement.

Israel's defense minister said that Israeli warplanes had destroyed "nearly all" of Iran's military infrastructure in Syria after Iran launched 20 rockets at Israeli-held territory, none reaching their targets.

Iran struck shortly after President Trump pulled out of the nuclear agreement, raising speculation that it no longer felt constrained by the possibility that the Americans might scrap the deal if Iran attacked Israel.

Israel appeared newly emboldened as well, partly because of what seemed like extraordinary latitude from Russia, Syria's most important ally, allowing the Israelis to act against Iran's military assets in Syria.

Moscow did not condemn Israel's strikes, as it had in the past, instead calling on Israel and Iran to resolve their differences diplomatically.

And Prime Minister Benjamin Netanyahu of Israel, who spent 10 hours with President Vladimir V. Putin of Russia on Wednesday, told his cabinet on Thursday that he had persuaded the Russians to delay the sale of advanced weapons to Syria.

Russia and Iran have been allies in the Syrian war, defending President Bashar al-Assad. But as the war appears to be winding down, some analysts say the aims of Russia and Iran are diverging: Moscow prefers a strong secular central government in Syria, while Tehran prefers a weaker government that would allow Iran-backed militias free rein.

Israel has conducted scores of strikes on Iran and its allies inside Syria, rarely acknowledging them publicly. But before Thursday, Iran had not retaliated, seemingly handcuffed while it awaited Mr. Trump's decision on the nuclear accord.

Even so, the Iranians have plenty to lose if the conflict continues to grow. They still seem determined to preserve the nuclear accord despite renewed American sanctions. The accord also includes Russia, China, Britain, France, Germany and the European Union.

"We see now that Netanyahu feels that Iran's capacities in Syria are vulnerable, that he can target them, that Iran's capacities to strike back are weakened — he took out some of these capacities, probably less than he claims — and that Iran has no significant way to react without risking itself," said Ofer Zalzberg, an analyst at the International Crisis Group.

Israel made it clear on Thursday that its planning for the airstrikes had been known internally as "Chess," and it looked in the aftermath as though Iran might have been baited into a trap on the Syrian game board.

Iran's rocket attack against Israel came after what appeared to have been an Israeli missile strike against a village in the Syrian Golan Heights late on Wednesday.

Early on Thursday, Iranian forces fired about 20 Grad and Fajr-5 rockets at the Israeli-controlled Golan Heights, targeting forward positions of the Israeli military, according to an Israeli military spokesman. The barrage was launched under the command of the Quds Force of the Islamic Revolutionary Guards Corps and used Iranian weapons, said the Israeli spokesman, Lt. Col. Jonathan Conricus.

Four of the rockets were intercepted by Israel's Iron Dome antimissile defense system, and the rest fell short of the Israeli-controlled territory, the military said. Indeed, by Thursday morning, Israeli life returned to routine in the Golan Heights, with children going to school.

Still, the rocket attack was a significant escalation in Iran's maneuvers in the Middle East. Though Israel has hit Iranian forces in Syria with a number of deadly airstrikes, Tehran had been restrained in hitting back, until now.

"Iran had to make a point: that it can respond, even if it's a weak response," said Joshua M. Landis, a Syria expert and director of the Center of Middle East Studies at the University of Oklahoma. "But it also revealed a weakness: Those rockets don't have any brains."

Israel said its response struck a severe blow to Iran's military capacity in Syria. In a statement, the military said the targets included what it described as Iranian intelligence sites; a logistics headquarters belonging to the Quds Force; military compounds; munition storage warehouses of the Quds Force at Damascus International Airport; intelligence systems associated with those forces; and military posts and munitions in the buffer zone between the Syrian Golan Heights and the Israeli-occupied portion.

"If there is rain on our side, there will be a flood on their side," Israel's defense minister, Avigdor Lieberman, said Thursday morning in remarks broadcast from a policy conference in Herzliya, near Tel Aviv. "I hope we have finished with this round and that everybody understood."

In all, at least 23 people were killed in the strikes, according to the Syrian Observatory for Human Rights, a Britain-based monitoring group. The Syrian Army, by contrast, said that three people had died. Israel reported no casualties on its side.

Israel said it had no intention of further escalation, and analysts looking for clues to Iran's potential response noted that its news media was largely ignoring the overnight hostilities, focusing instead on the nuclear deal. The English-language report on the airstrikes from Iran's Fars news agency made no mention of Iranian involvement.

In a sign of international concern that the conflict could escalate, however, Britain, France, Germany and Russia were quick to call for calm. "We proceed from the fact that all issues should be solved through dialogue," the Russian foreign minister, Sergey V. Lavrov, said at a news conference.

The White House condemned the missile attack on Israel, saying in a statement that it strongly supported "Israel's right to act in self-defense" and called on Iran "to take no further provocative steps."

It also inflicted new financial pain on Iran on Thursday. The Treasury Department said it had teamed with the United Arab Emirates to disrupt an Iranian currency exchange network that transferred millions of dollars, in coordination with Iran's central bank, to the Islamic Revolutionary Guards Corps. "We are intent on cutting off I.R.G.C. revenue streams wherever their source and whatever their destination," Treasury Secretary Steven Mnuchin said in a statement.

Iran has taken advantage of the chaos in Syria to build a substantial military infrastructure there. It has built and trained large militias with thousands of fighters and sent advisers from its Revolutionary Guards Corps to Syrian military bases.

Mr. Netanyahu said this week that the Revolutionary Guards had moved advanced weapons to Syria, including ground-to-ground missiles, weaponized drones and Iranian antiaircraft batteries that he said would threaten Israel's military jets.

Israel's political and security establishment has been unified and vocal in vowing to thwart Iran's efforts to entrench itself militarily across Israel's northern frontier and to build what Israeli and American officials refer to as a land corridor from Iran, through Iraq and Syria, to Lebanon.

Israel had warned Tehran that it would respond to any attack. Israel also broadcast warnings to Syria, saying that allowing Iranian entrenchment in its territory put Mr. Assad's government at risk.

The tensions between Iran and Israel have been complicated further by Mr. Trump's withdrawal from the nuclear agreement on Tuesday.

Israel had railed against the agreement, and Mr. Trump had campaigned on the promise of withdrawing from it, but European countries and many analysts had seen it as a crucial element holding back Iran and Israel, implacable foes, from all-out conflict.

As Mr. Trump announced his decision, Israel put its troops on "high alert," called up reservists, set up Iron Dome batteries and instructed the authorities in the Golan Heights to prepare public bomb shelters after detecting what it said was irregular activity by Iranian forces.

Israel's strikes early Thursday were some of the country's largest aerial operations in decades across the Syrian frontier, and by far the broadest direct attack yet on Iranian assets. "This was an operation we prepared for, and were not surprised by," Colonel Conricus said.

Israel said Russia had been informed before the overnight attack.

In recent years, Iran has helped Hezbollah, the Iranian-backed force in Lebanon, amass a huge arsenal of rockets it can use against Israel as a deterrent against Israeli strikes on Iran's nuclear program.

Israel has carried out scores of strikes against what it says are advanced weapons and convoys destined for Hezbollah. But since February, when Israel intercepted what it later called an armed Iranian drone that had penetrated its airspace from Syria, setting off a day of heated cross-border exchanges, Israel's efforts appear to have been more focused on Iranian assets in Syria.

"Israel doesn't want another Hezbollah inside Syria, it doesn't want another Lebanon," said Andrew J. Tabler, a Syria scholar at the Washington Institute for Near East Policy. "The Israelis think they can surgically strike and not create a wider conflict. They think that Assad, working with the Russians, will have an incentive not to respond."

The Associated Press

https://apnews.com/22f986def6eb42c0b8c035ca4b0d7f95

Trump's High-Risk Doctrine? Swing For The Bleacher Seats

By Catherine Lucey, Jonathan Lemire, and Ken Thomas, 5/10/18

WASHINGTON (AP) — The way President Donald Trump sees it, why go for a solid single when you can swing for a home run?

Trump's upcoming summit with North Korea's Kim Jong Un is only the latest example of the president's go-big strategy. From tax reform to international trade to foreign policy, Trump has pursued a high-risk, high-reward approach that advisers say can help produce results on longstanding problems — and that critics warn could trigger dangerous repercussions all the way from a trade war to global conflict.

Drawn to big moments and bigger headlines, Trump views the North Korea summit as a legacy-maker for him, believing that the combustible combination of his bombast and charm already has led to warmer relations between North and South. As he welcomed home three Americans who had been detained in North Korea, Trump early Thursday used a televised, middle-of-the-night ceremony to play up both his statecraft and stagecraft.

"I think you probably broke the all-time, in history, television rating for three o'clock in the morning," Trump told reporters on the tarmac at Joint Base Andrews.

Trump has also played the disruptor's role in recent weeks and months by withdrawing the U.S. from the Iran nuclear deal, imposing sweeping tariffs on allies and announcing he's moving the U.S. embassy in Israel to Jerusalem, which is claimed by both Israelis and Palestinians.

It's all a sharp contrast to his play-it-safe predecessor.

"You hit singles, you hit doubles; every once in a while we may be able to hit a home run," President Barack Obama said of his own foreign policy. "But we steadily advance the interests of the American people and our partnership with folks around the world."

Not all of Trump's attention-grabbing gambits have worked — and the potential risks going forward are daunting.

His push to overturn Obama's landmark health care law ended in a humiliating defeat for the Republicans. His decision to impose new tariffs on steel and aluminum imports has left global markets in a state of flux and unnerved some of America's closest allies about the potential for a trade war. And his withdrawal from the international nuclear agreement with Iran, with strong support from Israel, has escalated tensions in the already volatile region.

Critics say Trump sometimes focuses on bold gestures first — and fallout later.

For now, scoring a diplomatic win with Pyongyang has become Trump's top focus.

His outside-the-box approach to North Korea — complete with ominous taunts of raining "fire and fury" on the North while belittling its leader as "Little Rocket Man" — alarmed many global capitals and much of Washington's national security establishment, increasing worries about nuclear war.

But Trump believes it brought Kim to the negotiating table, with a summit between the two men now set for June 12 in Singapore.

Trump told one confidant that he now believes a deal with North Korea, rather than in the Middle East, could be his historic victory. White House officials also believe that a triumph on the Korean Peninsula — something that has eluded the United States for generations — could bolster Trump's approval ratings, help inoculate him against the investigations swirling around him and maybe even trickle down to help Republicans in this fall's midterm elections.

While some White House aides characterized Trump's moves as evidence of bold thinking, there is also concern that he has little sense of the potential repercussions from some of his big moves, believing that if things don't work out, that he can always just reverse course.

In the early months of his administration, Trump latched on to the belief that he could be the president to bring peace to the Middle East. Fond of the idea of making history, the president told advisers he was driven to accomplish something that his predecessors could not and believed that his negotiating skills and strong relationship with Israeli Prime Minister Benjamin Netanyahu could lead to the unprecedented achievement, according to four White House officials and outside advisers.

At one moment last spring, Trump mused in the Oval Office that he wouldn't even require a second term to settle things in the region, according to two people familiar with the exchange but not authorized to speak publicly about private conversations.

Though he did break with tradition to move the U.S. embassy to Jerusalem, the White House plan bogged down and the divide between Israelis and Palestinians seems as intractable as ever, prompting Trump's attention shift to North Korea. Warned by Obama days after his election that the threat posed by Pyongyang could define his presidency, Trump answered Kim's threats with bellicose warnings of his own and rallied an international pressure campaign against North Korea.

Some Republicans have suggested his efforts should bring him the Nobel Peace Prize, an idea Trump clearly savored at a recent rally in Michigan when the crowd chanted "Nobel." Asked about the chatter in the Oval Office this week, Trump said: "I want to get peace. It's the main thing. We want to get peace. That was a big problem, and I think it's going to work out well."

Then he added his catchall caveat: "We'll see."

Long before he was president, the onetime New York real estate developer and reality television star often spoke about the benefits of acting boldly. In "The Art of the Deal," he put it this way: "I like thinking big. I always have. To me it's very simple: if you're going to be thinking anyway, you might as well think big."

Trump appears to have embraced the "Great Man" theory of history, believing that individuals more than circumstances or trends alter the course of events. In his 2016 GOP convention speech, he famously declared "I alone can fix it," in referencing the nation's problems.

Trump and his team also believe that his bold tactics have the added benefit for Trump of overshadowing the threats his administration faces from the ongoing Russia probe and the legal web surrounding his personal attorney, Michael Cohen, and porn actress Stormy Daniels.

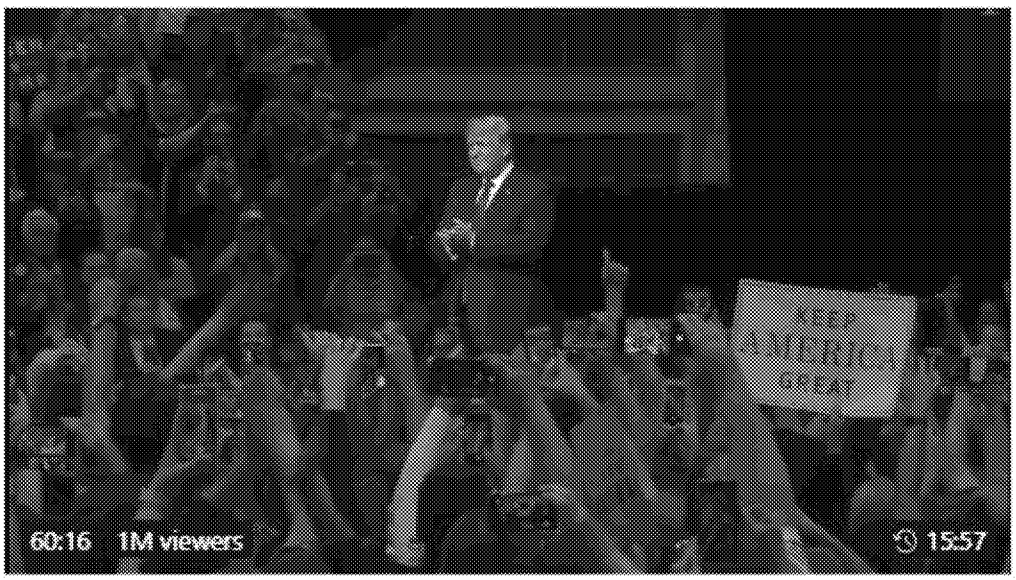
Rice University presidential historian Douglas Brinkley said Trump's diplomacy with North Korea is a "high-risk game."

"But if he pulls off the denuclearization of the North Korean Peninsula, it will be the landmark achievement," said Brinkley. "It's Trump's big going-to-China moment."

TRUMP TWEETS

Donald J. Trump @realDonaldTrump · 13h

Thank you Indiana! #MAGA



President Trump and VP Pence Hold a Rally in Indiana

Fox News @FoxNews

8.8K 13K 56K

Donald J. Trump @realDonaldTrump · 23h

The highly anticipated meeting between Kim Jong Un and myself will take place in Singapore on June 12th. We will both try to make it a very special moment for World Peace!

21K 57K 202K

Message

From: Johnson, Laura-S [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DEA46EDADAA04F2C847D3245F8F5847C-LJOHNS06]

Sent: 4/24/2018 9:17:01 PM

To: Brennan, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=78caa4c8d91743c887c1bb5dc8cdb369-Thomas Brennan]; Johnston, Khanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ee74eeb7ad744e58f6dbf7d2f20243b-Johnston, Khanna]; Benjamin-Sirmons, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4439dd0e4bc4593827fac14083b749f-DBENJA02]; Rogers, JoanB [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03eb3fb61a3348a1b160fd67a66a4c1c-JCrawfor]; Showman, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a5d6e83fbf5499e93cc6b41090245b2-jshowman]; Vizian, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb2401bf8d4f441dbf27f21e122be2c5-Vizian, Donna]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33d96ae800cf43a3911d94a7130b6c41-Wehrum, Wil]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Shaw, Betsy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31ca1476a7674825a131cb2c0d6c88c8-BShaw03]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Wise, Louise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf7be035da4b45a3a7d45c84c9f4b4a3-LWise]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Bodine, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2cc6086fcc44c3be6b5d32b262d983-Bodine, Sus]; Starfield, Lawrence [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a89d6cd217d4254a5879abecb3f314e-Starfield, Lawrence]; Traylor, Patrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6d06c6b766c4b4b8bfdf6b0fea4b998-Traylor, Pa]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Nishida, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65e465e683c54e1b825f1bad32dcb099-Nishida, Jane]; Cherry, Katrina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eff58fe613b7474987b56083cb518d69-Cherry, Katrina]; Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]; Cook, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=394f5dede6184bc083cf9390e49a192c-Cook, Steve]; Breen, Barry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b44bce1a71e4a95acaf82f2fbc858b0-BBREEN]; Ross, David P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=119cd8b52dd14305a84863124ad6d8a6-Ross, David]; Forsgren, Lee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a055d7329d5b470fbaa9920ce1b68a7d-Forsgren, D]; Best-Wong, Benita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ee79b3d0fc0429b99f2c05481b0b957-bbestwon]; Dunn, Alexandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=426d0177eaab4001a5c85f051565997e-Dunn, Alexa]; Szaro, Deb [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC: Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]; Stanich, Ted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c444a91e01694758bea5b4815566032f-Ted Stanich]; Lawrence, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b116bfc513a412ab22f8c48b4a67819-TLAWRENC]; Etzel, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96a20535abb54ed4abf1e40d2aa916d9-Etzel, Ruth]; Reed, Khesha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c62327cee1fd4da29a1cc485efe546f7-Reed, Khesha]; Torres, Ramon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d04da59501947cbaa7dbcfaa6edf5e1-Torres, Ramon]; Maher, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: SIGNED: Strengthening Transparency in Regulatory Science

Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

Importance: High

FYI… please read below regarding an action taken by the Administrator today.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-XXXX-XX]

RIN 2080-AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

DATES: Comments must be received on or before **[insert date 30 days after date of publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA-2018-0259, at *https:// www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a

written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/ commenting-epa-dockets.*

FOR FURTHER INFORMATION, CONTACT: Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-0221; email address: *staff_osa@epa.gov*.

SUPPLEMENTARY INFORMATION:

Submitting CBI. Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address using U.S Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA–HQ–OA-2018-0259, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For other methods of delivery, see https://www.epa.gov/dockets/where-send-comments-epa-dockets.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information

A. Does this action apply to me?

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

B. What action is the agency taking?

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

C. What is the agency's authority for taking this action?

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048;

Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

II. Background

The best available science must serve as the foundation of EPA's regulatory actions.[1] Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in enhancing the public's ability to understand and meaningfully participate in the regulatory process.[2] In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models

[1] See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

[2] See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.[3] This proposed rule is also consistent with Executive Orders 13777[4] and 13783,[5] and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*[6] (the Guidelines) and OMB *Memorandum 13-13: Open Data Policy – Managing Information as an Asset.*[7] It builds upon prior EPA actions[8] in response to government-wide data access and sharing policies, as well as the experience of other

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[3] EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

[4] Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

[5] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

[6] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

[7] *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

[8] Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency; ;

federal agencies in this space.[9] In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.[10] These policies are informed by the policies recently adopted by some major scientific journals,[11] spurred in some part by the "replication crisis." [12]

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling "pivotal regulatory science." "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory

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[9] For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

[10] These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data*, *Expanding Access to Research Data*, and *Access to Research Data in the 21st Century*; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

[11] For example, see related policies from the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*.

[12] See: https://www.nature.com/articles/s41562-016-0021; http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full

science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying "pivotal regulatory science") is available to the public for validation[13] in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis. Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA's regulatory science should be consistent with the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*.[14] Robust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-

[13] EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.
[14] https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: a broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines[15] (which apply to "third party" information - e.g., non-government scientific research – if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of

[15] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information

the Federal government.[16] Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.[17] The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach."[18] More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy[19] have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,[20] to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.[21] EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective

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[16] See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.
[17] https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.
[18] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.
[19] https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.
[20] For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature.
[21] For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc.

and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.[22]

Implementation of this proposed rule will be consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be "significant regulatory actions" pursuant to E.O. 12866. The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

III. Request for Comment

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other

[22]These recommendations are consistent with those of Lutter and Zorn (2016). https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re

policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above. EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate. Although the proposed regulatory text would impose requirements specifically on final regulations determined to be "significant regulatory actions" under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under EO 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant

final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of "*pivotal regulatory science*," and "*dose response data and models*" and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future

significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

IV. Statutory and Executive Orders Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies[23] This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy,

[23] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to EO 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: "Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. …" They concluded that "an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[24]

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel."

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

[24] https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 30

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

APR 24 2018

Dated: _____.

E. Scott Pruitt,

Administrator

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

PART 30—Transparency in Regulatory Decisionmaking

1. Add part 30 to read as follows:

PART 30—Transparency in Regulatory Decisionmaking

Sec.

Authority: Clean Air Act §§ 103, 301(a), 42 U.S.C. §§ 7403, 7601(a); Clean Water Act §§ 104, 501, 33 U.S.C. §§ 1254, 1361; Safe Drinking Water Act §§ 1442, 1450(a)(1), 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act §§ 2002(a)(1), 7009, 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) §§ 115, 311, 42 U.S.C. §§ 9616, 9660; Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048; Federal Insecticide, Fungicide, and Rodenticide Act §§ 25(a)(1), 136r(a), 7 U.S.C. §§ 136r(a), 136w; and Toxic Substances Control Act, as amended, § 10, 15 U.S.C. § 2609.

§30.1 What is the purpose of this subpart?

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

§30.2 What definitions apply to this subpart?

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

Dose response data and models means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions

typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

Regulatory decisions mean final regulations determined to be "significant regulatory actions" by the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory science means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

Research data means "research data" as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

§30.3 How do the provisions of this subpart apply?

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of

this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

§30.4 What requirements apply to EPA's use of studies in taking final action?

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

§30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered "publicly available in a manner sufficient for independent validation" when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

(a) Data (where necessary, data would be made available subject to access and use restrictions).

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

§30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default

assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

§30.7 What role does independent peer review in this section?

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

§30.8 How is EPA to account for cost under this subpart?

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

§30.9 May the EPA Administrator grant exemptions to this subpart?

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or

(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

§30.10 What other requirements apply under this subpart?

EPA shall implement the provisions of this section consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

Message

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Sent: 5/10/2018 7:50:46 PM
To: Askinazi, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f11a6972234134ae9b2f59a4a26709-Askinazi, V]; Barkas, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=808724835d8a457fb0c5333e62b34291-Barkas, Jessica]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; Brown, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da0a099605514dbeb3ebab7aaf253de6-Brown, Sam]; Buster, Pamela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0d03c8a52440b7a95343287b8928c5-PBuster]; Canavan, Sheila [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5453ba7f3d4582a0eff06ed80a5e79-Canavan, Sheila]; Caraballo, Mario [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e9d657e48042fea4bb7c68f78a023c-Caraballo, Mario]; Carroll, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882c7705ed3f4d50aba9a7870f9eb6cc-MCarr03]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Christian, Myrta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=207ad12497b04bcf8e80a0024b35a18a-MChris02]; Corado, Ana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb9257919594061b763f306c2f8be60-ACorado]; Davies, Clive [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eca39ab66ea413993d7355fd46b1008-Davies, Clive]; DeDora, Caroline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e587cd3b59b46f59a369df26390fd9f-Newton, Caroline]; Devito, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be78622515bd451e96e948786357fb45-SDevito]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Drewes, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1107458a6d814a61ab24b605aff2c7ba-Drewes, Scott]; Dunton, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ffa0e71e87448cc9fd86ba1379ea93a-Dunton, Cheryl]; Ebzery, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5729928cba7e4025bbdcd3504c791095-JEbzery]; Edelstein, Rebecca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9549e6e2f43e4a3c88cc3bea8f7220f5-Rebecca L Edelstein]; Edmonds, Marc [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed31dcc62754411aae5e1be96ed01f1d-MEdmonds]; Eglsaer, Kristie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5365adea6f9a4f3397bdc735dafe4c32-Friesenhahn, Kristie]; Elwood, Holly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc14ca33efe94036a4b406c9951eb70a-HElwood]; Farquharson, Chenise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b240335cb7b41d79edb4ef922386a23-Farquharson, Chenise]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt Resumes Courting Industry as Ethics Controversies Swirl

By Jennifer A. Dlouhy and Ari Natter

Posted May 9, 2018, 6:34 PM

Embattled EPA Administrator Scott Pruitt is seeking to shift the limelight away from questions about his ethics and instead focus attention on his efforts to eliminate regulations on oil drillers, farmers, home builders, and automakers.

Industry Clamors for EPA's Ear on Revising Cost-Benefit Reviews

By Abby Smith

Posted May 9, 2018, 3:08 PM

Industry groups are lining up to share their thoughts on how the EPA should evaluate the costs and benefits of regulations differently, just as the agency is poised to release an overhaul of its approach.

Asbestos Controls, Testing Flame Retardants Among New EPA Rules (1)

By Pat Rizzuto

Posted May 9, 2018, 1:23 PMUpdated May 9, 2018, 6:00 PM

The EPA would restrict some uses of asbestos and require manufacturers to generate new toxicity data for some flame-retardant chemicals under updated regulatory plans the agency released May 9.

EPA Obscures Deadline for Science Transparency Plan

By Sylvia Carignan

Posted May 9, 2018, 1:07 PM

The EPA has yet to release a timeline for its plans to increase the transparency of the scientific studies it uses to set environmental protection standards, according to the Office of Management and Budget's regulatory agenda released May 9.

INSIDEEPA.COM ARTICLES

House Vote Bolsters Critics' Efforts To Kill EPA Policies Under 'Review' Act

Congress has approved a first-time Congressional Review Act (CRA) resolution repealing a years-old agency guidance, a measure that appears likely to bolster efforts by deregulatory opponents, who are currently seeking a precedent-setting court ruling that would allow them to enforce the law's mandate that agencies submit such documents to Congress for approval or disapproval.

GREENWIRE ARTICLES

Half-hour of confusion at Pruitt's condo

Kevin Bogardus and Hannah Northey, E&E News reporters

Published: Thursday, May 10, 2018

EPA Administrator Scott Pruitt rented this Capitol Hill condominium from the wife of a lobbyist whose clients lobbied EPA. Kevin Bogardus/E&E News

One March evening last year, the Washington, D.C., fire department dispatched an emergency team at 5:18 p.m. — someone was reportedly unconscious.

First responders from Engine Co. 3 raced to the other side of Capitol Hill, arriving just five minutes later at a plush condo building down the street from Senate office buildings. The sequence of events as recorded by the dispatch center indicates concern over what prompted the call, according to the incident report obtained by E&E News under a public records request.

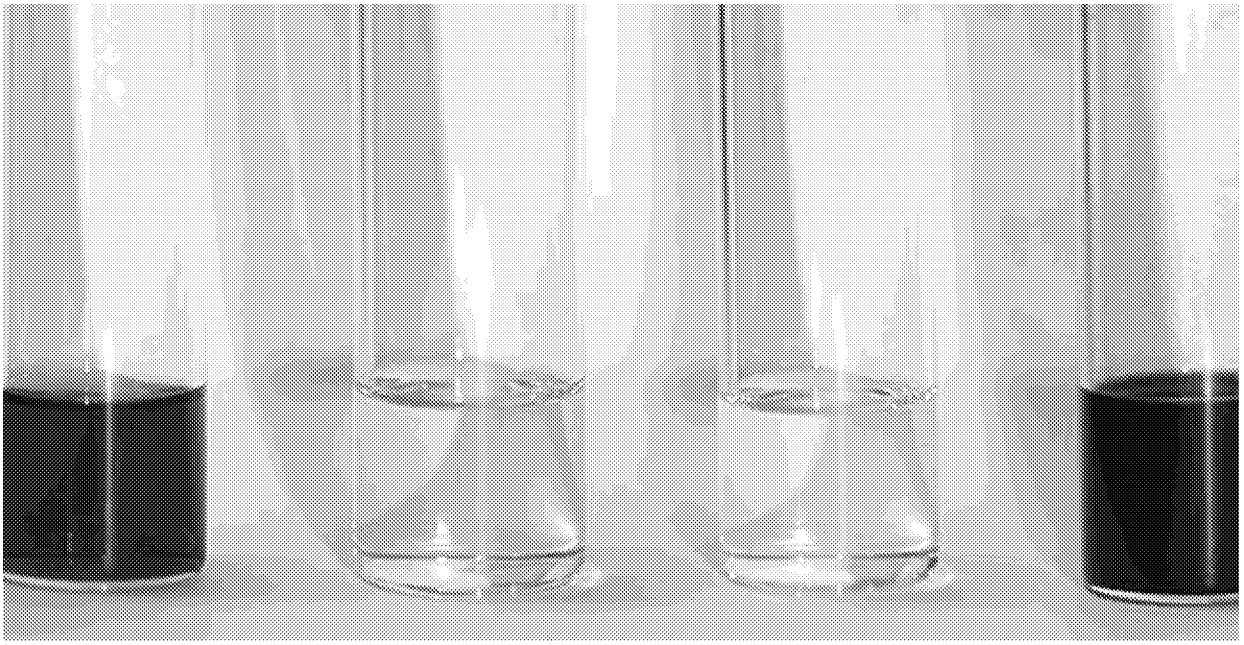
With some redacted words legible under light, the report's narrative reads, "The caller is unable to assess the patient's breathing status" and "He is still unconscious." Other notes hint at the confusion on the scene, such as "Fainting" and "Conscious, Breathing."

https://www.eenews.net/greenwire/2018/05/10/stories/1060081395

Surprise: EPA will finalize Obama curbs on paint stripper

Corbin Hiar, E&E News reporter

Published: Thursday, May 10, 2018



EPA has pledged to take action on methylene chloride. LHcheM/Wikimedia Commons

In an unexpected move, EPA said today it "intends to finalize" an Obama-era proposal that sought to restrict the sale of a deadly paint-stripping chemical.

The agency also announced it wouldn't re-evaluate "the paint stripping uses of methylene chloride and is relying on previous risk assessments," which found the chemical can trigger asphyxiation and heart attacks. The 2011 risk assessment also determined that long-term exposure can cause cancer and damage to the liver and kidneys.

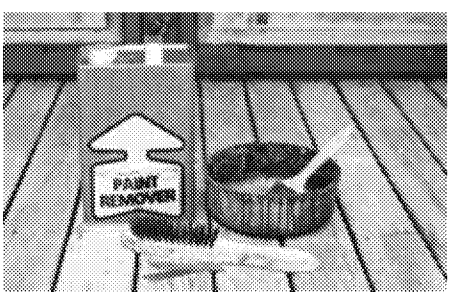
https://www.eenews.net/greenwire/2018/05/10/stories/1060081379

CHEMICAL WATCH ARTICLES

Methylene chloride campaigners meet with EPA Administrator

Pressure mounts on Pruitt

9 May 2018 / Built environment, Solvents, United States



NGO campaigners have met with EPA Administrator Scott Pruitt to request that the agency act on its proposed rule to ban methylene chloride paint strippers.

The meeting is the latest development in a months-long push for action on the paint removal products, which have caused dozens of consumer and worker deaths in recent years.

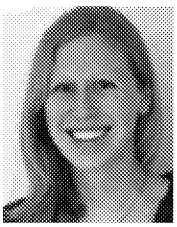
Mr Pruitt has continued to insist that the proposal – which was issued in the final days of the previous administration – has not been dropped, but rather is under review.

But NGOs and families of those who have died using the products are urging the agency act immediately.

Cindy Wynne – the mother of a South Carolina man who was killed while using a paint stripper containing methylene chloride – added that while she appreciated the meeting, Mr Pruitt's "words of consolation and explanation" are insufficient.

Meanwhile, NGO Safer Chemicals, Healthy Families is leading health advocacy groups in a "week of action" in dozens of states demanding that Lowe's home improvement stores pull the products from their shelves.

Under the organisation's Mind the Store campaign, more than 120,000 consumers have petitioned the company to stop selling the paint strippers.



Kelly Franklin

North America editor

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- US EPA proposes prohibitions on methylene chloride, NMP
- Pruitt: EPA may act on methylene chloride ban 'this year'
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA
- NGOs push Lowe's on methylene chloride paint strippers

Further Information:

- Statement on Pruitt meeting
- 'Week of action'

Anses warns against hazardous substances in homemade toy 'slime

9 May 2018 / Children's products, France, Substances of concern

Homemade toy 'slime' can pose health risks to children as they may contain hazardous substances, the French Agency for Food, Environmental and Occupational Health and Safety has warned.

Several cases of skin damage related to the product have been reported to the agency, poison control centres and various allergy control networks, Anses said.

The slime kits have become very popular with younger children and teenagers in France, and tutorials on the internet on home fabrication have increased interest in the product.

In a joint warning with the French Directorate-General for Competition, Consumer Affairs and Fraud Control (DGCCRF), Anses said detergents and adhesives used in homemade slime contain allergenic or irritant preservatives that are not meant to be handled in large quantities, repeatedly and for a prolonged time.

Liquid adhesives – the most common ingredient – contain preservatives such as formaldehyde liberators or isothiazolinones, which are "very allergenic substances", as well as many solvents, which can cause irritation of the airways and damage to the central nervous system, Anses said.

The majority of online do-it-yourself recipes also contain boron compounds. These substances, intended for cleaning contact lenses or as detergents, are reprotoxic, may impact foetal development and "must not be manipulated by children repeatedly", it said.

The DGCCRF also conducted a survey of slime kits sold in shops. Of the 15 samples analysed, two contained a boron content exceeding the permissible limit and were withdrawn from the market. The DGCCRF will continue its market controls in 2018.

Last month, the Norwegian Environmental Directorate removed some ready-made slime products from the market, after it found they contained high levels of lead and arsenic.

Related Articles

- Norway bans 'slime' toy products containing lead, arsenic

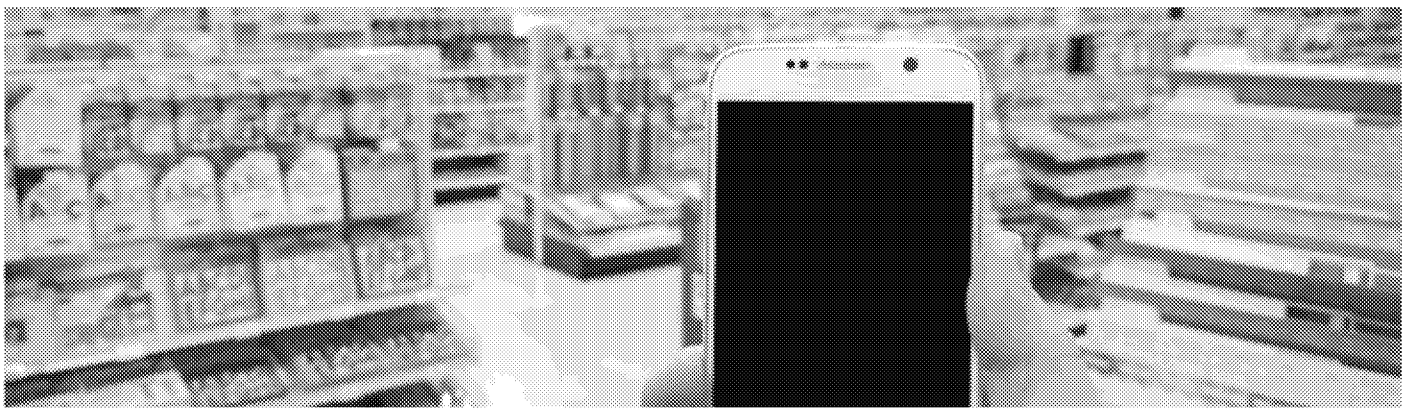
Further Information:

- Anses press release (in French)

There's an app for that

The AskREACH project aims to make Article 33 of REACH work better by enabling consumers to track SVHCs in articles

Global Business Briefing, May 2018



The duty of suppliers of articles containing substances of very high concern (SVHCs) at concentrations above 0.1% w/w in an article, including – as per a European Court of Justice (ECJ) ruling in 2015 – each article "incorporated as a component of a complex product", is enshrined in REACH Article 33. What is happening in practice is quite another matter.

Article 33 stipulates that suppliers "shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance". It also requires suppliers to provide consumers with the same information, free of charge, within 45 days of receiving a request.

Recently, representatives of industries including automotive, electronic, aerospace, apparel, furniture and chemicals began discussions on collecting and sharing material data for articles, including their chemical composition. Although they have their own material declaration systems, there is little information sharing and it is recognised that a common approach could:

- facilitate the collection and sharing of material
- composition information;
- allow companies to better identify SVHCs; and
- ensure compliance as regulations change.

This would be particularly helpful to upstream companies, which currently receive multiple requests for the same or similar information in multiple formats. An accord is some way off as there has to be agreement on such thorny issues as a common data structure, the level of detail to be communicated, data quality and data security.

When implementing legislation, says Martin Führ, professor of public law, comparative theory and legal theory at Hochschule Darmstadt University of Applied Sciences in Germany, it is important to follow the legislators' intentions as well as the letter of the law. In this case, it is clear that REACH aims to substitute SVHCs with other solutions.

Moreover, he says, Article 1, which aims for a high level of protection for health and environment, requires "a dynamic approach, involving the actors in the supply chain directly. No interference by public authorities as such is needed." Obviously the definitions in Article 33 are extremely broad.

A 'supplier' could be a producer, distributor or other actor in the supply chain. An 'article' can be tiny but, as the principle states, "once an article, always an article", as the ECJ also established in 2015. 'Placing on the market' can mean simply selling it, but also holding it as stock in an online shop or offering it free of charge, such as a paper towel in a public restroom. All in all, says Professor Führ, "it's difficult not to be a supplier of an article".

These findings are mirrored when it comes to the question who is entitled to a consumer request: REACH does not define a 'consumer'; but from a legal perspective, a consumer does not necessarily have to be a buyer. Downstream users are excluded, as they are covered by Article 32 (1), but all other natural and legal persons are entitled to ask for information - possibly including the authorities in their role as buyers of articles.

"Behind Article 33 is the duty to cooperate with other actors in the supply chain," Professor Führ says. "This is not written in the legal text but it is the precondition that the whole system works on."

For consumers to be informed, as the legislators clearly intended, there has to be transparency and traceability. This has the extra benefits of complying with product safety and liability requirements.

There are many ways to comply with Article 33. Often, they can be rather unhelpful. For example, some major electronic goods suppliers have put generic information on the internet about how some of their hundreds of products "might contain" unspecified SVHCs, saying that they all do to be on the safe side, or sending test results running to many pages, which may not refer to SVHCs or may be out of date because the candidate list has since been updated.

This will no longer be acceptable, Professor Führ says. The EU's circular economy package is on its way and a provision in that links Article 33 to a central database that Echa will host. This is due to go online in 18 months, with obligations starting after 30 months' time.

The upcoming review of the waste framework Directive is another relevant issue here. In March, a proposed amendment was added to Article 9, requiring suppliers to notify Echa of the presence of SVHCs in articles. This followed on from a European Parliament vote to adopt other proposed changes with the specific aim of ensuring a 'progressive substitution' of SVHCs.

The issue also goes beyond the EU framework. It addresses initiatives like the Strategic Approach to International Chemicals Management (Saicm) and the UN's Sustainable Development Goals (SDGs), particularly SDG 12, 'Ensure sustainable consumption and production patterns', for which targets are due in 2020. "Article 33 could have been really helpful to reaching this SDG," says Professor Führ.

Ten years on from REACH coming into force, however, implementation of Article 33 has barely begun. A report by Echa in 2016 showed very low consumer awareness of the right to request information and various studies of compliance have shown that it is not functioning properly.

For instance, in a study commissioned in Belgium by DG Environment in 2016, only 23% of the companies selling construction materials which were sent a request about the presence of SVHCs in their products replied within 45 days.

Of those which did:

- some provided a formal letter of declaration, of the kind they send to downstream users, stating that no SVHCs were present
- in their products;
- some did not understand the request or declined to provide information; and
- some said that they were not obliged to provide information because the request had not been made by a consumer.

"There are various reasons why the system does not work well," says Arno Biwer, senior R&T associate at the Luxembourg Institute of Science and Technology. "Limited awareness among consumers, retailers and suppliers about their rights and obligation; difficulties for consumers in making requests; suppliers' answers being inadequate or wrong, or just not answering. All of this leads to risks to human health and the environment."

In any case, adds Professor Führ, today's consumers see no point in asking questions in a shop that may or may not be answered 45 days later. They want answers immediately. The only viable way to address that is to use mobile apps to scan information from barcodes on the products themselves.

Denmark has already pioneered this approach and the lessons learned there are informing ongoing initiatives. The Tjek Kemien app was launched in 2014 and trialled with the country's two largest supermarkets. In 2016, there were 88 requests but in the first two months of 2018, 100m consumer visits to the Co-op generated only three requests,

according to Jakob Lamm Zeuthen, head of environment policy at the Danish Chamber of Commerce, which represents retailers.

This failure had multiple causes, he says. Consumers are mostly concerned about food and cosmetics, but these were not in the scope of the project. "The scan went to the wrong person in the company, or was lost, or the information was difficult to understand, or people lost interest after waiting for 45 days. Retailers don't want to upload SVHC details into database: they want to answer consumers directly by email, so as to maintain trust with them."

In late 2016, Mr Zeuthen adds, the Danish Consumer Council tested the information on the barcodes of 58 hardware products for the presence of phthalates from the SVHC list. Of these, 8 (31%) incorrectly stated that there were no SVHCs when there were. Usually, this was because the barcodes did not work. No answer was received in many cases and some replies were very late. Key causes of misinformation included:

- difficulty in obtaining suppliers' declarations;
- lack of understanding of how to check these declarations;
- wrong or inadequate information from producers;
- lack of understanding about what questions to ask producers;
- different results from tests on the same product by different bodies; and
- an unclear definition of articles as opposed to products.

The pressure for information is still growing, thanks in part to a press article in January 2017 about consumers buying products containing hormone-disrupting chemicals, and partly as a result of these tests. Both the press and the authorities in Denmark have been urging retailers to act.

The Danish EPA, the Chamber of Commerce, industry and building centres consequently formed a partnership that ran from September 2017 to January 2018. The aim was to solve the reasons for misinformation and help retailers in all sectors fulfil their Article 33 obligations.

Working with consultants, the partners have now created guidelines to ensure that information about candidate list articles is collected and passed through the supply chain consistently in the same format until it reaches consumers.

They have also created a tool to train purchasers in where to look for SVHCs in articles and identify those with highest risk of containing them.

Based on this experience, Mr Zeuthen concludes that what works best for companies is also likely to work better for consumers. Retailers, he agrees, would like to have an EU-wide app that takes their needs into account. He also recommends:

- creating a helpdesk to make it easier for retailers to upload information that is useful for consumers and give reminders of when to update;
- sufficient ongoing verification of data, so as to build trust and exclude misleading information. This is not a business obligation;
- keeping food and cosmetics completely outside the database and making it clear this is only about articles; and

- giving the app a name that does not overpromise - in hindsight, 'Tjek SVHCs' would have been better than 'Tjek Kemien'.

On a pan-European scale, the AskREACH project started in September 2017 and will run for five years. It is coordinated by the German Environment Agency, with 19 partners from 13 member states, including NGOs, authorities and research institutes. AskREACH will mainly produce:

- an EU-wide app for consumers, which will be adapted to each member state, in terms of language but also specific information about any aspects particularly relevant in any of them; and
- a central European database, where article suppliers and retailers can upload information of their articles via a barcode, including SVHC details and where within the article any SVHC(s) are contained.

Two apps already exist in Germany, ToxFox and Scan4Chem, and companies involved in those are part of the consortium, as well as the creators of Tjek Kemien, Mr Biwer says. Thus, AskREACH will be able to apply lessons from these projects, learning from the deficiencies of a national approach.

"The principle is similar. You scan the barcode and receive information directly from the database if available; if it is not, a request can be sent automatically to the barcode owner and the retailer to get an individual answer, and the barcode owner can update the database," he explains.

AskREACH will make the database as easy as possible to use, including:

- bulk uploading of articles;
- automatic updating of information on SVHCs if any changes are made in article composition;
- a standardised data exchange format so that information in existing internal company tools can easily be transferred; and
- compatibility with the Echa database, so that requests can be made in standardised way.

Supplier and retailer duties to the app users will be fulfilled by uploading information, because everything else will be done automatically. Different language versions will use standard sentences so that most translation is done directly.

Professor Führ, who is also involved in the project, hopes to see an additional option of declaring that there are no SVHCs in a product, in order to increase transparency and traceability. Suppliers who feed the database can benefit from the option to offer additional, more detailed information on the scanned article, such as via a link to a company website.

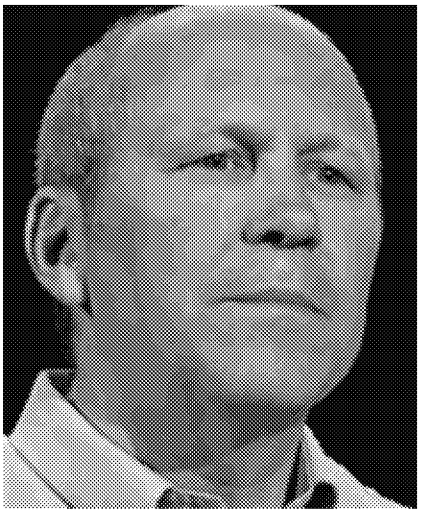
Currently, the project partners are benchmarking the challenges companies are facing, the tools they are using and how to adapt these if needed. Professor Führ says that there are already tools to hand that are "comprehensive, effective, reliable and flexible", as well as and capable of addressing confidential business information (CBI) issues.

The app is due to be launched in April 2019 and AskREACH is inviting companies to participate and to test the tools and give input on possible improvements. "This will give you an opportunity to have an impact early on and show your willingness to take care of consumers' concerns," says Mr Biwer.

Of course, there are technical challenges to overcome, as Professor Führ recognises. "One will be how to identify an article. The supply chain sometimes uses the same barcode for different products and different versions or batches of them. This needs to be addressed when the article identifier system is enhanced," he says.

His concluding advice is: "To all those who are covered by the definition of supplier, be prepared to address a lot of issues." There are a lot of customer demands for information and they might be driven by consumer requests once the European app is available and workable, he says.

"Be prepared for increasing awareness from investors and be aware that existing products as well as new ones are covered. At least consider how to address this, as well as updates of the candidate list and similar lists in other parts of the world."



Dr Andrew Warmington

Commissioning editor, Chemical Watch

Related Articles

- European Court of Justice rules on SVHCs in articles

US body seeks nominees for flame retardant hazard assessment

National Academies plan to inform CPSC OFR rulemaking

10 May 2018 / Built environment, Children's products, Electrical & electronics, Halocarbons, United States

A National Academies committee is recruiting people to help assess organohalogen flame retardants, following a request from the US Consumer Product Safety Commission (CSPC).

The National Academies of Sciences, Engineering, and Medicine's (NASEM) board on environmental studies and toxicology is forming a committee to develop a scoping plan to assess additive, non-polymeric organohalogen flame retardants (OFRs) for their potential chronic health hazards.

Their findings will ultimately be used to inform a CPSC assessment of the risk these substances pose to human health from the following four consumer products categories:

- children's products;
- upholstered residential furniture;
- mattresses; and

- the external casings of electronics devices.

The CPSC's request follows its September decision to grant an NGO petition to begin a rulemaking process under the Federal Hazardous Substances Act (FHSA). It could see OFRs banned from these applications.

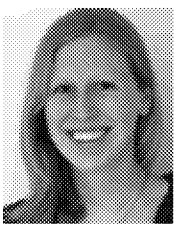
To start this, the CPSC will convene a Chronic Advisory Panel (CHAP) – a group of experts charged with evaluating the scientific evidence on the substances. NASEM will provide the hazard assessment plan which the CHAP will use – together with exposure data – to complete a quantitative risk assessment.

To develop its scoping plan, the NACEM committee will:

- review existing hazard data and identify gaps;
- evaluate the potential for treating OFRs as a single class of substances, for purposes of a hazard assessment; and
- determine recommendations for how to conduct additional research to evaluate OFRs under the FHSA.

NASEM is seeking individuals with expertise in toxicology; epidemiology; pharmacology; statistics and modeling; QSAR/SAR; and risk assessment.

Nominations will be accepted through 20 May.



Kelly Franklin

North America editor

Related Articles

- US CPSC investigates possible action against organohalogen flame retardants

Further Information:

- Call for nominees

Belgian nano registrations 'need improvement'

10 May 2018 / Belgium, Nanomaterials, Substance registration

The quality of registrations for nanomaterials submitted to the Belgian national register needs to be improved, the country's Federal Public Service for Public Health (FPS) said.

In its first report about the nanoregister since its launch in 2015, FPS said an evaluation of submitted registrations showed quality can be improved. It added that not all potential registrants are aware of the obligation to register under a 2014 Royal Decree.

About 77% of the registrations were updated before the April 2017 deadline, the report said.

Importers submitted 56% of the registrations, while distributors and manufacturers accounted for 22% and 11% respectively.

Around a third of the 'active' accounts – those created for one or more registrations – were registered on a voluntary basis, with the remaining two thirds coming from those placing the nano substances on the market themselves, the report said.

Half of the 475 nanomaterials registrations made in 2016 concerned substances in quantities below one tonne, and would therefore be considered out of scope of REACH.

Amendments

EU member states have recently agreed on changes to REACH annexes to address specific requirements for nanomaterials.

The amendments, due to come into effect in 2020, include a provision giving Echa the legal right to request additional information on substances above ten tonnes when safety of those substances is not demonstrated.

NGOs had pressed for the provision to apply to all REACH registered nanomaterials above 1 tonne.

Substances registered to Belgian authority in quantities of more than 1,000 tonnes were:

- amorphous silica;
- calcium carbonate;
- calcium carbonate treated with stearic acid;
- carbon black;
- diiron trioxide;
- iron hydroxide yellow; and
- silicon oxide.

European action

In June last year, Echa launched its EU observatory for nanomaterials (EUON), a public website aimed at increasing transparency of information on nanomaterials on the EU market.

This comes after the Commission opted not to create an EU nano register, given delays in the introduction of new REACH information requirements for nanomaterials.

Elsewhere in Europe, Denmark, France, Norway and Sweden also require companies to report information on nanomaterials to their national inventories.

Related Articles

- Member states agree nanomaterial changes to REACH annexes
- Echa launches EU nanomaterials observatory

- Nano data will be added to Swedish product register next year

Further Information:

- Executive summary

Canada clears EDTA and salts, no further action needed

10 May 2018 / Canada, Environmental Protection Act, Risk assessment

The Canadian government has finalised its assessment that ethylene diaminetetraacetic acid (EDTA) is not harmful and requires no action under the Canadian Environmental Protection Act, 1999 (Cepa). The decision also clears three EDTA salts:

- tetrasodium;
- ferric monosodium; and
- ferric ammonium.

The assessment, published on 5 May, finalises the conclusions of a draft assessment from May 2017.

EDTA and tetrasodium EDTA are used as chelating agents and preservatives in a wide range of products.

The government's assessment concluded – "on the basis of the available empirical data" – that none of the substances were carcinogenic or genotoxic.

Studies showing other adverse effects from oral exposure were "compromised" by "excessively high" doses, and the substances are "of low toxicity" at lower doses, the assessment found.

Related Articles

- Canada provisionally clears EDTA and salts

Further Information:

- Canada Gazette

US NTP requests data on identifying developmental toxicants

Information will inform effort to develop animal testing alternatives

10 May 2018 / Alternative approaches to testing, Test methods, TSCA, United States

The US National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods is requesting data on approaches for identifying potential developmental toxicants.

Niceatm provides scientific and operational support to the Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam), which is charged with implementing a strategy for new, non-animal approaches to evaluating the safety of chemicals and medical products.

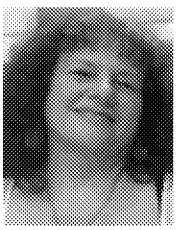
The project is required under the 2016 amendments to TSCA, which set a goal to reduce and eventually replace vertebrate animal testing under the programme.

In March, the EPA published its draft strategy for promoting the development and implementation of alternative test methods. And the agency recently issued guidelines on alternative test methods for determining skin sensitisation.

The new data request, published in the 5 May *Federal Register*, will feed into the ongoing initiative. The information "will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring".

Niceatm specifically requested information "relevant to the development or validation of alternatives to *in vivo* developmental toxicity test methods currently used by federal agencies for regulatory and other decision contexts". It also asked for data from animal or human studies evaluating the same chemicals for comparison.

The deadline for submissions is 15 June.



Julie Miller

Reporter

Related Articles

- Iccvam makes 'significant progress' on implementation plans for NAMs
- US EPA publishes draft strategy to promote alternative tests
- US EPA drafts approach to non-animal testing for skin sensitisation

Further Information:

- Federal Register notice

Australian panel says PFAS ill-health links limited or non-existent

Concerns remain unanswered says MP from affected area

10 May 2018 / Australia, PFCs, Risk assessment

A report from Australia's Expert Health Panel for PFAS has concluded that evidence linking exposure to polyfluorinated substances (PFASs) with human disease is limited or non-existent, and that there is "no current evidence that suggests an increase in overall cancer risk".

The panel, established in October last year to advise the government, reviewed 20 Australian and international reports and reviews examining potential health effects of exposure to PFASs, as well as carrying out a public consultation.

The conclusions concur with advice from the country's health department that "there is no current evidence that supports a substantial impact on an individual's health from PFAS exposure."

PFASs are bioaccumulative substances that were present in fire-repellent foams widely used in Australian military airbases across the country from the early 1970s. The decision to phase them out was made about ten years ago.

They have been linked with long-term health problems.

The expert panel consistently found a number of health effects in reports, reviews and research. But they concluded that, even for those with the highest exposure levels, health effects were still "within normal ranges" for the whole population.

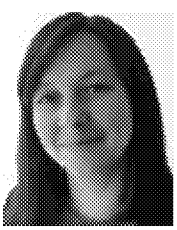
Fears not allayed, says MP

Meryl Swanson, member of parliament for Paterson, New South Wales, an area affected by contamination from PFASs, told Chemical Watch the report "in no way answered questions or allayed fears".

Ms Swanson called the report "contradictory" and cited the summary, which advises both that "important health effects for individuals exposed to PFASs cannot be ruled out based on the current evidence"; and that "evidence does not support any specific biochemical or disease screening or other health interventions for highly exposed groups in Australia, except for research purposes".

She also expressed anger at the timing of the 400-page report's release. It was dated March, but published on 7 May on the eve of the Federal budget, a particularly busy time for parliament, she said.

More available on CW+AsiaHub.



Ellen Tatham

Asia reporter

Related Articles

- PFHxS added to REACH candidate list
- Australia's defence department regrets three-year delay in PFAS warning
- Australian panel: PFASs ill-health links limited or non-existent

Further Information:

- PFAS Expert Health Panel report to Minister
- PFAS Expert Health Panel summary of report
- Department of health – PFAS health effects and exposure pathways

American Chemistry Council defends EPA 'secret science' proposal

Trade body backs non-linear models, increased transparency

10 May 2018 / Data, Exposure modelling, United States

The American Chemistry Council has defended aspects of the US EPA's new science transparency proposal that have come under fire from NGOs.

Formally issued late last month, the agency's proposed rule on "secret science" seeks to allow increased transparency and public validation of studies underpinning agency regulatory decisions.

Among other provisions, it proposes to "increase transparency of the assumptions underlying dose response models". NGOs have raised the alarm that discarding default linear dose models will remove health-protective assumptions and "invite literally an infinite number of model options" on which the agency can base its decision.

But the ACC argues that the EPA has this aspect of the policy right. "For far too long and far too often EPA has relied on default linear dose-response models that have frequently resulted in inflated risk estimates," the trade group said in a blog post.

These, it says, create "misperceptions and confusion about true risks and can lead to unwarranted and costly risk management decisions."

Default linear models concerns

The ACC told Chemical Watch that an example of this occurred with the draft Integrated Risk Information System (IRIS) risk assessment of formaldehyde. It says the programme's use of "overly conservative default assumptions" led it to

proposing a cancer risk value at 0.008 parts per billion – a level significantly lower than the 0.8 to 8.0ppb reported to naturally occur in humans.

The IRIS formaldehyde assessment prompted a scathing review from the National Academy of Sciences (NAS) in 2011. And industry has continued to question the science underlying the programme's conclusion.

The ACC also pointed to the case of 1,4-dioxane, in which the EPA's use of a default linear approach served as the basis for a drinking water guidance as low as 0.35ppb. The trade group said that Health Canada, the EU and other authoritative bodies have concluded the substance acts by a non-linear mechanism, resulting in a drinking water guidance of 350ppb.

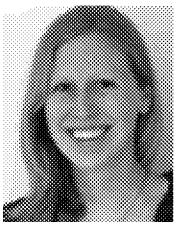
The EPA's plan to consider non-linear models is not satisfying an industry 'ask', added the ACC. Instead, it is "simply a recognition by EPA that old default assumption may not always represent the most up to date science".

Transparency

Separately, the ACC's formaldehyde panel has taken aim at critics who have suggested that industry groups would attempt to use the EPA's new policy to discredit legitimate studies underpinning health protections.

"Industry does not seek access to research to discredit it nor to limit regulation," said the formaldehyde group's blog post.

"In order to help improve public confidence in the decision-making process, it is critical data be made available in a timely and transparent way to ensure decisions are based on scientifically defensible information," the post said.



Kelly Franklin

North America editor

Related Articles

- US EPA proposes controversial science transparency rule
- US EPA science policy to 'change agency culture' on data
- Opening up IRIS
- ACC calls for inclusion of industry analysis in formaldehyde assessment
- TSCA could be undercut by 'secret science' requirements

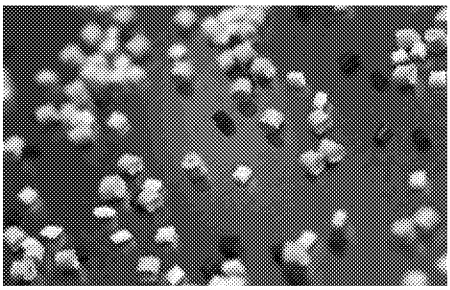
Further Information:

- ACC blog
- Formaldehyde panel blog

EU seeks proposals for 'polymers of concern' project

Contractor will propose criteria for use under REACH

10 May 2018 / Europe, REACH, Risk assessment, Substance registration, Substances of concern



The European Commission is seeking proposals for a project on how "polymers of concern" (PoCs) could be identified and registered under REACH, according to a call for tenders, which has opened.

REACH does not currently require registration or evaluation of polymers, but under Article 138(2) the Commission is required to review the risks they pose and the need for registration of certain types of polymer.

A 2015 study conducted for the Commission proposed two possible registration systems. The first system was based on identification of polymers of low concern (PLCs) and lower or no registration obligations for them; the second on grouping similar polymers.

According to the current call, the successful contractor will:

- propose criteria for the identification of PoCs, including the possibility of grouping based on physico-chemical properties or indication of hazard;
- estimate the potential risks to human health and the environment posed by them, compared with other substances; and
- provide a detailed cost-benefit analysis of the registration requirements for the purposes of impact assessment.

One of the primary tasks will be to "assess which registration requirements would be appropriate for PoCs under REACH". The call for tenders does not discuss registration of polymers that do not meet the PoC requirements.

The maximum budget for the project is €300,000.

Mirror image

Speaking at this week's Chemical Watch Food Contact Regulations Europe 2018 summit, Paul Ashford, managing director of Anthesis-Caleb, said the new project would be a mirror image of the 2015 study that proposed the PLC system. But it was time to ask the authorities to address the polymer identity question, Mr Ashford said.

"If you start to deal with polymers of concern, you have to decide pretty quickly what your polymer substance is," he told the audience in Brussels. "The interesting thing about the Commission's request for a proposal is that is has no mention whatsoever of any further interrogation about what a polymer substance is.

"So this is really speeding up the supply chain bit, saying [stakeholders in the supply chain] really need to engage at least with the [successful contractor], and probably with Echa as well, on this agenda to make sure there is no misunderstanding of at least where the industry has got to on this subject.

"I think the plea the supply chain would make, is it wants to do this with as many downstream user industries as possible, and understand that we are not crossing each other's purposes."

Related Articles

- Study analyses options for REACH polymers registration

Further Information:

- Invitation to tender
- Technical specifications

CIA urges UK government accord on Echa associate membership

High level meetings must transcend a 'temperature check'

10 May 2018 / Europe, United Kingdom

The UK Chemical Industries Association is calling for swift progress towards a "joined-up" approach between itself and the British government on a post-Brexit associate membership of Echa.

Such an approach would pave the way to advancing proposal talks at EU level, CIA head Steve Elliott has told Chemical Watch.

Ahead of a second high level meeting with UK government departments later this month, Mr Elliott said it is essential that the chemicals industry's view of associate membership "chimes" with that of Whitehall.

There is no point, he added, in the UK sector approaching European chemicals trade body, Cefic, and "trying to join the dots when we're not in line with our own government".

At the Chemical Watch Brexit conference on 17 April, Mr Elliott outlined the terms to be considered by both sides of the negotiations as part of an associate membership agreement. They are:

- recognition under EU law and acceptance by both parties of registrations, authorisations, approvals and notifications obtained by UK and EU27 companies;
- existing compliance activities to remain valid and the establishment of a process to avoid reapplications in the EU and UK;

- a mechanism to allow the UK to negotiate access to the Echa database to ensure ongoing and future compliance efforts;
- authorities carrying out assessments on products undergoing testing, registration or authorisation processes at the point of exit, to be allowed to complete them; and
- the UK to continue participating in and maintaining responsibilities under Echa's regulatory processes.

In March, the CIA and Cefic issued a joint statement, in which they called for continued UK participation in Echa. Next, if UK industry – with governmental approval – can get into a position where it is "joined up on some of the detail" with Cefic, Mr Elliott said the proposal has a better chance of support across the Channel.

'Helpful' meetings

In March, the CIA and other industry representatives took part in an inaugural meeting with various government departments to discuss Brexit topics. Subjects included associate membership and rules of origin and the impact they would have on customs arrangements.

Officials from the environment ministry (Defra), the business department (Beis) and the Department for Exiting the European Union (DExEU) attended.

The meetings, which take place every six to eight weeks, are "helpful" Mr Elliott said because it is not just one government department talking to industry. "It's also helpful that an industry like ours, which quite often has been away from the spotlight, now has quite a high profile."

The challenge, he added, is that the UK has to agree a headline deal on Brexit terms with the EU27 by October, "and if that means we've got to work up quite a level of detail then we haven't got long".

What "can't happen", he said, is for the group to do "a temperature check" each time it meets. It needs to have worked out specifics of "what's really important for our industry and our customers, so the officials who are negotiating understand what's valuable and what they could give away more cheaply in negotiations".

And what industry does not want, he said, is time wasted on negotiations from Brexit day of March next year until December 2020 – the date the tentative transition period ends, if formally agreed in the first instance.

That period, he said, "is supposed to be about preparing. The more the UK can do up front the better, to give us that period of grace to get business sorted, rather than ongoing negotiation and a lack of clarity until December 2020 and then suddenly things change overnight."

During a debate on the EU Withdrawal Bill on 8 May, Parliament's House of Lords voted through an amendment that would allow the UK to continue to participate in, or have a formal relationship with, the EU agencies after exit day.

Luke Buxton

Europe desk editor

Related Articles

- Prime minister: UK to seek 'associate membership' of Echa
- UK chemicals industry sees progress, but Brexit 'clock ticking furiously'
- Chemicals industry welcomes Brexit transition period agreement
- UK's ability to keep pace with REACH changes threatened by Bill amendment

Further Information:

- CIA, Cefic joint statement
- Transcript of House of Lords debate
- EU Withdrawal Bill (amended as of 9 May)

UK government denies ban on wet wipes

10 May 2018 / Alternatives assessment & substitution, Microplastics, United Kingdom

The UK says it is not planning a ban on wet wipes, as was recently widely reported in the media, but is working with industry to find "suitable alternatives" that consumers can safely dispose.

Wet wipes, also known as wet towels or baby wipes, are small, moistened pieces of paper or cloth used for cleaning purposes. They contain plastics which, when flushed down the toilet, can block sewers and slowly break down into microplastics that in turn cause harm to marine life.

Reports across the UK media this week suggested that wet wipes would be banned as part of the government's 25-year environment plan, which aims to eliminate all avoidable plastic waste by the end of 2042.

The Department for Environment, Food & Rural Affairs (Defra) subsequently clarified the position, saying that while eliminating single-use plastic waste is one of the government's top priorities, "we have not announced plans to ban wet wipes".

Defra said it is working with manufacturers and water companies to understand which types of wet wipes cause sewer blockages, and make sure labelling on the products "is clear and people know how to dispose of them properly".

Authorities are employing tougher controls on microplastics pollution. The UK ban on the manufacture of cosmetics and personal care products containing plastic microbeads came into effect in January. A ban on sales of such products will follow on 30 June.

Related Articles

- UK promises post-Brexit chemicals strategy that reflects future relations with EU
- UK microbeads ban enters into force

Further Information:

- Defra blog

US EPA round-up

10 May 2018 / United States

IRIS ammonia agenda

The EPA's Integrated Risk Information System (IRIS) programme has released a preliminary agenda for its public science meeting on ammonia.

The 23 May web-based meeting will cover the IRIS Assessment Plan (IAP) non-cancer assessment for oral exposure to ammonia and ammonium salts. The programme is accepting public comments on this through 16 May.

ELAB members sought

The agency is accepting nominations to its Environmental Laboratory Advisory Board (ELAB). This is an advisory committee tasked with providing advice and recommendations to the EPA's leadership about "issues related to enhancing EPA's measurement programmes, and facilitating the operation and expansion of national environmental accreditation".

Related Articles

- US ammonia ingestion study to focus on drinking water concerns

Further Information:

- Public meeting
- ELAB notice

EU consultation on 'what worked well' with 7EAP

10 May 2018 / Europe

The European Commission has launched a public consultation to evaluate its 7th Environmental Action Programme – an overarching set of goals guiding the trade bloc's environment policy until 2020.

Launched in 2014, 7EAP has set out a vision for progress by 2050. This has three key objectives:

- to safeguard EU citizens from environment-related pressures and risks to health and wellbeing;
- to protect, conserve and enhance natural capital in the bloc; and
- a resource-efficient, green and competitive low-carbon economy.

The 7EAP also calls on the Commission develop, this year, a strategy for a non-toxic environment that promotes innovation and the development of sustainable substitutes, including non-chemical solutions. In October, the Commission published seven sub-studies that will form the basis of the strategy.

The consultation period will run between 3 May and 26 July, and assess "what worked well, and how it could have been better", the EU executive said.

It will focus on the "structure and strategic role" played by 7EAP and also assess the programme in terms of its "effectiveness, efficiency, relevance, coherence and added value".

All citizens and organisations are invited to comment. The evaluation will also build on contributions from the European Environment Agency (EEA), the EU Environment Implementation Review (EIR) – a tool to improve implementation of EU environmental law and policy – and consultations with member states and specific interest groups.

Related Articles

- EU publishes sub-studies for non-toxic strategy

Further Information:

- Public consultation
- 7EAP

Post-Brexit IT failure a 'substantial risk' to UK chemicals industry

MPs say poor Defra track record could lead to disruption

10 May 2018 / Substance registration, United Kingdom

MPs have said there are "substantial risks", including disruption to the UK's chemicals industry, if the Department for Food, Environment and Rural Affairs (Defra) is unable to properly update its IT systems before the UK leaves the EU.

In March, junior environment minister Thérèse Coffey said Defra had started work on new IT capability to enable the registration and regulation of chemical substances placed on the national market.

But in a recently published public accounts committee report, MPs express doubt at "how realistic" Defra's – as well as the Department for International Trade's – plans are.

"In light of Defra's poor track record in implementing new IT systems in the past," the report says, "we have concerns over the potential for disruption to the agri-food and chemical industries if these IT systems are not ready in time and contingency plans have to be enacted".

Defra says it has has made "good progress" in developing the system, and, the report adds, is optimistic that it can deliver what's required by March 2019, "whatever the outcome of the negotiations".

Speaking at the Chemical Watch conference on 17 April, Defra's James Dancy said the department aims to make the IT system "very much the same" as Echa's, including Iuclid dossiers. He said that the government will start testing the system with industry, although no date for this has been set.

The report says the department's contingency plan, if the system is not ready in time, includes "manual workarounds". Defra said it will "fall back on to manual systems as it seeks to deliver all that it needs to for Brexit, but this could impede or at least slow down imports and exports causing severe delays at the border".

According to the report, the department has "an impossible challenge" and does not have a "clear plan" of top priorities. It must be clear, it says, about what it will "not be delivering as a result of Brexit".

At the time the report was prepared, 20 of Defra's 43 'workstreams' had an IT component. Four of them have a 'build' element in the event of a 'no deal' scenario, the report says. This includes an import control system to facilitate trade in animals and animal products. The department now has 64 workstreams.

Defra must ensure it has the "necessary resources" in place to complete its IT programmes on time and avoid "costly and embarrassing contingencies involving manual completion and submission of forms". The MP told Defra to provide a progress update by the end of June.

Department difficulties

If the Brexit transition period from exit day of 29 March 2019 to December 2020 is formally agreed, it will give Defra more time to develop these systems. But, the report warns, the department "needs to make sure that it doesn't let progress on their development slip, in case negotiations break down".

Its preparations, however, have been "hampered by the pervasive uncertainty" about the UK's future relationship with the EU. This, the report says, leaves not only departments but also businesses "in the dark" about exactly what they need to do to prepare.

In particular, the report notes, Defra has to work up options for the three different scenarios – deal, no deal or transition. This is "time-consuming and costly", it adds.

Related Articles

- UK starts work on post-Brexit chemicals registration system
- UK chemicals industry sees progress, but Brexit 'clock ticking furiously'

Further Information:

- Report

EU to assess existing policies for circular economy plan

10 May 2018 / Alternatives assessment & substitution, Europe, Substances of concern

The European Commission is planning to evaluate existing EU policies to see how they contribute to the circular economy and to identify ways to better meet the initiative's goals.

It has produced a roadmap document which will look at "the soundness and completeness" of existing EU policy and regulatory instruments. The EU executive will then develop preliminary options for further action based on evidence submitted to a public consultation. This closes on 4 June.

It will also include work undertaken in the follow-up to the refit of the EU Ecolabel, a voluntary ecolabelling scheme.

Some of the existing policy tools target specific product groups through market restrictions for the poorest performing products, the Commission said, while others restrict use of certain substances in product groups or generally – with REACH as an example.

Where multiple policy tools address the same products or product groups, the Commission will explore ways of optimising the interactions between them. It aims to generate a policy drive towards more 'circular' products, "while respecting the specificities of the different policy instruments".

Several product groups, it says, are currently not covered by EU policies even though they have a high circular economy potential, such as food and drinks, textiles, construction products/buildings, furniture and cosmetics.

In January this year, the Commission published a series of planned actions and proposed options to combat the problem of substances of concern in products and waste. The plans are included in a Communication on options to address the links between chemical, product and waste legislation and form part of the circular economy action plan.

Related Articles

- EU sets out actions to tackle hazardous substances in waste, products

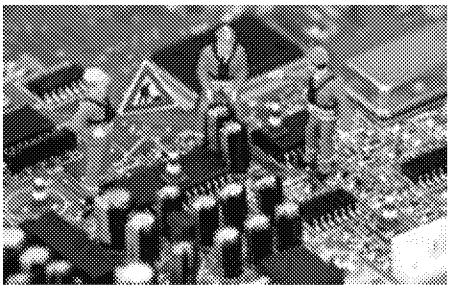
Further Information:

- Roadmap and consultation page

Report finds Samsung workplace link to ill-health unproven

Company not completely exonerated

10 May 2018 / Confidentiality & right-to-know, Electrical & electronics, Legal cases, Occupational hygiene, OSHA, South Korea



There is no clear evidence linking illness with workplace conditions, including exposure to harmful chemicals, at Samsung Electronics, a South Korean independent committee has reported, after completing a two-year investigation.

The committee, established in June 2016 in agreement with workers suffering from a number of illnesses and their families, investigated production lines at the company across South Korea. This included analysing 54 materials used at the company.

Workers and their families have been campaigning for a decade for compensation for diseases – including leukaemia and brain tumours – they say were caused by working at the company.

Stressing that their findings do not necessarily completely exonerate the company, the committee said it could find no link between working at the company and worker illness.

The investigation team, which reported on 24 April, said emissions of potentially dangerous substances were within legal limits; radiation exposure was no different from the general population; and although some toxic substances were found, such as toluene, these were in quantities that posed no effect to health.

Release of company environment reports blocked

The committee's report came just five days after a district court decision to suspend publication of historical workplace environmental reports from Samsung Electronics, ordered by the Ministry of Labour.

The ministry ruled in February that the reports from 2009-2017, not normally made public, should be released to meet concerns about workplace-illnesses raised in the media. However, Samsung immediately filed a motion to overturn the decision.

In South Korea, companies are obliged to conduct "work environment monitoring" by taking and analysing samples from the workplace for harmful substances under the country's Occupational Safety and Health Act (Osha). The reports for Samsung Electronics are said to contain information on workplace exposure to 190 hazardous chemical substances.

The court's decision to suspend publication was prompted by a 17 April report from a panel of semiconductor experts, convened by the Ministry of Trade, Industry and Energy (Motie). The historical reports, said the panel, contained

information on "key national technologies" because they made it possible to guess chip manufacturing technologies and processes.

International campaign

A number of international NGOs and labour groups have criticised Samsung for workplace conditions in South Korea and Vietnam and for blocking disclosure of information on workplace chemical use. Most recently on 1 May, several organisations held a "Global Day of Action Against Samsung" with petitions made to "clean up" the company.

Sunny Lee

Asia editor

Further Information:

- Report of Investigation Committee
- Protests Press Release

TSCA CBI guidance documents a 'missed opportunity'

NGOs seek changes to ease access to protected information

10 May 2018 / Confidentiality & right-to-know, TSCA, United States

A coalition of NGOs says that the US EPA's draft guidance on disclosing confidential information under the new TSCA falls short of what is needed to meet real-world needs.

The comments came in response to the agency's consultation on three guidance documents that outline how certain people can access TSCA confidential business information (CBI) in emergency and specific non-emergency situations.

The EPA issued these consistent with the 2016 amendments to TSCA, which expanded the disclosure of protected information where such data could assist public officials and health professionals helping those at risk from chemical exposures.

But a coalition of 17 NGOs, spearheaded by Safer Chemicals, Healthy Families, says the documents represent a "missed opportunity".

"While dutifully paraphrasing the requirements of the law, they fail to address the larger TSCA goal of enabling front-line professionals and public officials to successfully use the new provisions to meet real-life health and environmental needs," it says.

Changes sought

Among the NGO coalition's concerns is that the intended beneficiaries of the programme, such as first responder and physicians, are unlikely to be familiar with TSCA and legal intricacies around protecting CBI.

As such, the groups recommended the EPA develop outreach and education. And they believe the agency needs to train its staff to ensure "the statutory goal of providing necessary information to officials on the ground will [not] be stymied by poor communication, delays, and bureaucratic snags."

Other NGO commenters and New York's environmental department echoed the coalition in recommending that the EPA include deadlines for how quickly it will process a request, to "avoid unreasonable delays in disclosing information".

And many also asked that the agency develop an electronic system for submitting requests and tracking their status.

More broadly, NGO the Environmental Defense Fund's comments called on the agency to modify the documents to provide an "accurate description" of the confidentiality requirements outlined in section 14 of TSCA.

"EPA needs to accept that Congress consciously chose to impose more stringent substantive and procedural standards on confidentiality claims under TSCA, and that Congress called for wider disclosure of confidential information in this context," it said.

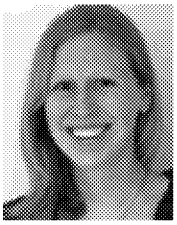
Industry response

Industry groups largely supported the guidance documents, including provisions outlining the obligations on those requesting CBI to maintain the confidentiality of those data.

But the American Chemistry Council expressed concern the agency is not well equipped to respond quickly in emergency situations. It offered the use of its existing Chemtrec emergency response programme to facilitate implementation of this provision.

And the industry group also baulked at a statement in the guidance that suggests the EPA is generally required to release health and safety data. "While ACC agrees that the health and safety effects and results from a health and safety study must be disclosed, the underlying data is not, in fact, 'required' to be disclosed, as the guide suggests," it said.

The EDF, however, squarely disagreed that health and safety data are eligible for protection from disclosure. And it encouraged the agency to clamp down on companies "inaccurately" making overly-broad CBI claims.



Kelly Franklin

North America editor

Related Articles

- US EPA releases guidance for CBI sharing under TSCA

Further Information:

- Docket

Danish investigation finds fluorinated substances in cake packaging

But intentional use has decreased

10 May 2018 / Denmark, Food & drink, Food contact, Halocarbons

Tests carried out in Denmark have found fluorinated substances in paper wrappings used in ready-made cakes.

The discovery comes after a national recommendation to avoid intentionally adding them to food contact materials three years ago.

In three out of 21 baking paper and other cake packaging materials examined, fluorinated substances were detected at such high levels it is "very likely" the substances were intentionally added, the Danish Consumer Council's 'Think Chemicals' initiative said.

There is no specific EU regulation to control harmful chemical substances in paper and board food packaging. But in 2015, the Danish Veterinary and Food Administration introduced a recommendation for manufacturers not to add the substances intentionally to food packaging materials. It is, however, not legally binding.

Think Chemicals said while its tests did not measure the substances inside the cakes, other studies have shown they can migrate to the food and contribute to people's total exposure - the so-called cocktail effect.

A test in 2016 on cake wrappings had revealed intentional use of fluorinated substances. Think Chemicals said this year's retest of the same wrappings indicated their use "has generally decreased".

Investigators found that four samples which contained the substances in 2016 no longer had them.

Last year, Danish tests using a new approach to detect harmful chemicals in FCMs made from paper and board found two phthalates and bisphenol A (BPA) in pizza boxes.

Related Articles

- Danish test finds phthalates and BPA in pizza boxes

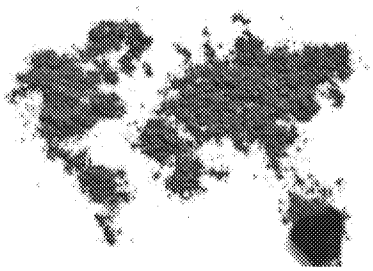
Further Information:

- Press release

CosmeticsEurope: support regulatory compatibility, not harmonisation

Trade group says this will 'maximise compliance' worldwide

10 May 2018 / Cosmetic products Regulation, Europe, Personal care



The global cosmetics industry should not push for global harmonisation of cosmetics regulations, but instead call for compatibility, says Gerald Renner, director of technical regulatory affairs at trade group, CosmeticsEurope.

Speaking at last month's In-Cosmetics regulatory conference in Amsterdam, he said industry interest should not be in "similarly worded laws" across countries and regions.

Instead, it should push for compliance measures, such as product information and notification requirements, that are "portable" between different regulatory approaches.

"All regulations have their historical and cultural backgrounds, and it is hard to overcome that. One size does not fit all," he said.

Harmonised wording, he said, does not mean you will have the same regulatory requirements. For example, he added, many countries have the same definition of cosmetics, but how this is applied is and can be "totally different".

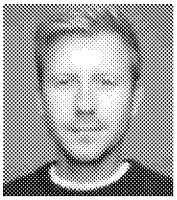
"We want the information and the efforts we take to support regulatory compliance in one country to be used in another," said Dr Renner.

"Whether a law calls it pre-market registration or in-market control, if we can use the same information, and it grants us quick market access, the wording really doesn't matter."

CosmeticsEurope, said Dr Renner, is working on the compatibility of regulatory 'modules' for product information and notification, as well as other requirements.

"However, these laws are implemented around the world, there should be a best practice. Whether we're talking about the Chinese, EU or Israeli approach, we should all have the same understanding of what is needed," he said.

Dr Renner's presentation provided an overview of how different countries regulate cosmetics. He compared rules in China, Taiwan, Australia, the US and India with the EU's cosmetic products Regulation. It showed that some, including China and Australia, are aligning certain measures, such as definitions and animal testing, to the EU's approach.



Leigh Stringer

Global Business Editor

Echa round-up

10 May 2018 / Classification, Europe, Labelling, Microplastics, REACH

Advice on changes to joint submissions

Echa has created a webpage to help registrants identify situations in which they need to contact the agency to request changes to a joint submission once it has been created in REACH-IT. Lead registrants can make some changes themselves but some have to be made by the agency.

The webpage lists six scenarios, including lead role verification, in which such a request would need to be made.

Calls for evidence: restrictions of microplastics and oxo-degradable plastics

It is the last opportunity to provide comments to the agency's call for evidence on the use of intentionally added microplastic particles in products. The deadline is 11 May.

Meanwhile, the deadline for feedback on oxo-degradable plastics has been extended to 31 May.

Webinar: last-minute advice on REACH 2018

A reminder that Echa is running a webinar on 17 May, offering last minute advice on REACH registration with the deadline fast approaching. The event offers the opportunity to pose questions to an expert panel on all aspects of registration.

Workshop on EUSES update needs

The agency is running a workshop looking at what is needed to update Euses, the EU system for the evaluation of substances. This is a decision-support software that enables government authorities, research institutes and chemical companies to carry out a rapid assessment of the risks posed by chemicals.

The main objective is to review the state of the art in environmental exposure assessment, and discussions will be based on recent scientific developments on release estimation and fate assessment within regulatory exposure assessments, the agency says.

The workshop will provide a platform for regulators, industry, academia and other stakeholders of REACH and biocides Regulations to participate in the review.

It is planned from 4-5 June in Brussels.

Update to Echa-term database

The agency has added 45 new terms and their definitions to the Echa-term resource. This is a multilingual terminology database in 23 EU languages, where terms and their definitions can be found and downloaded free of charge.

The new terms come from:

- the *Practical guide for SME managers and REACH coordinators*;
- Iuclid material; and
- the best practices document on how to prepare registration dossiers that cover nanoforms.

Substance evaluation work translations available

- **Guide on substance evaluation**: the practical guide How to act in substance evaluation is now available in 23 languages. This describes how authorities evaluate substances and explains registrants' obligations. The guide also addresses data sharing and communication between registrants of the same substance.
- **Summary of 2017 evaluation report**: The summary and recommendations of the agency's annual progress report on evaluation under REACH are now available in 23 languages. The recommendations help new and existing registrants to comply with REACH requirements and improve the quality of their dossier.

PEG consultation on revised CLP guidance

Echa has sent draft *Guidance on labelling and packaging under CLP* (version 4.0) for Partner Expert Group (PEG) consultation. The guidance has been fully revised. The main changes are:

- alignment with a new annex to the CLP Regulation on harmonised information relating to emergency health response; and
- addition of a new section 6.2, describing the labelling of multi-component products with label examples.

REACH-IT closed 4-5 June

Echa has advised that its REACH-IT tool will be closed from Monday 4 June 00:00 (EEST, GMT+3) until Tuesday 5 June 10:00 (EEST,GMT+3) for maintenance. The tool is not accessible during this period.

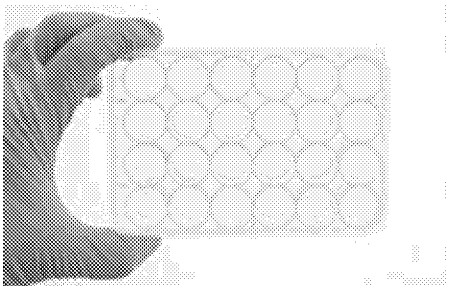
Further Information:

- Joint submissions advice
- Current calls for evidence
- Registration: REACH 2018 webinar
- EUSES workshop
- ECHA-term
- Practical guides
- PEG consultation - draft CLP guidance (version 4.0)

Anses calls for new in vitro genotoxicity tests for titanium dioxide

Inconsistent results have prevented genotoxicity conclusion

10 May 2018 / Classification, France, Nanomaterials, REACH, Test methods



There is an urgent need for new and improved *in vitro* genotoxicity tests for titanium dioxide nanoparticles (NPs), according to the French Agency for Food, Environment and Occupational Health and Safety (Anses).

While collecting carcinogenicity information for hazard assessment of titanium dioxide, Anses found that few *in vivo* studies were good enough to reach a conclusion on genotoxicity. "The low quality of the *in vivo* dataset is likely to lead to possible false interpretation of the genotoxic profile of titanium dioxide NPs," according to a report written by a team from the agency's chemical assessment unit.

"Even if *in vivo* data are considered of higher relevance than *in vitro* data, unfortunately they are too limited to conclude on genotoxicity of titanium dioxide NPs," it writes in *Nanotoxicology*.

Numerous *in vitro* studies are available, but these also give an inconsistent genotoxicity profile, it adds.

Titanium dioxide was added to the Community Rolling Action Plan (Corap) in 2013, but its evaluation has been dogged by issues regarding the identity – the shape, size and coating - of different types of nanomaterials. The difficulties are exacerbated by the myriad uses of the substance.

France updated its Corap justification document in March 2018, stating that "in the absence of reliable *in vivo* assays, there is an essential need for further *in vitro* and *in vivo* investigations of the genotoxicity potential of titanium dioxide NPs".

Room for improvement

Anses found that most *in vitro* studies are on rutile and anatase forms of titanium dioxide. The latter is a photo-catalyst, meaning light could significantly affect test results through formation of reactive oxygen species.

"It is essential to take the effect of light into account when interpreting the *in vitro* genotoxic results obtained from NPs with photocatalytic properties," writes the Anses team.

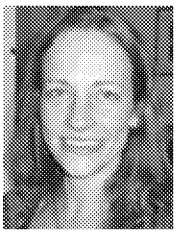
It is also important to choose the cell line carefully and to check that the NPs don't interfere with assay function, it adds. The team calls for *in vitro* tests lasting longer than 24 hours, as well as the standard, shorter assays. This should help to identify a "large range" of DNA damage mechanisms, it suggests.

Negative genotoxic results should be confirmed by checking how the cell line responds to NP exposure and whether the NPs could prevent the test system from working as it should.

Finally, the Anses team calls for studies to be reported in detail, with access to raw data. This is "essential for an adequate explitation by regulatory bodies", it says.

Because TiO_2-NP toxicity is a "topic of interest for society", the agency expects an increase in published data. But it strongly reminds researchers that the "quality needs to be improved over quantity of data".

In 2017, Echa's Risk Assessment Committee decided that TiO_2 should be classified as a category 2 carcinogen by inhalation. Some EU member states suggest that the classification should not be directly translated into CLP but should have a split entry based on particle size or form.



Dr Emma Davies

Reporter

Related Articles

- Poorly soluble, low toxicity particles facing review
- EU member states support change to titanium dioxide classification

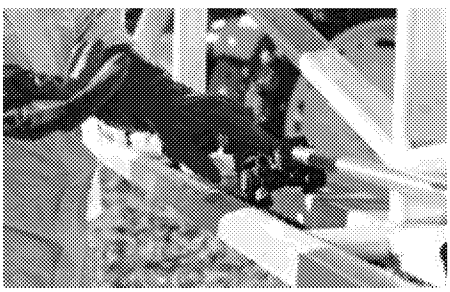
Further Information:

- Nantoxicology article (abstract)
- France's Corap justification

North American organisation examines presence of PFASs in apparel

Study targets 31 substances

10 May 2018 / North America, PFCs, Product testing, Textiles & apparel



A study conducted by the Commission for Environmental Cooperation, a trinational organisation created by Canada, Mexico and the US, has examined 137 articles of clothing and apparel for the presence of PFAS substances.

PFASs (per- and polyfluorinated substances) are used in a wide range of consumer products for their heat, water and oil resistant properties. According to the US EPA, the group of compounds are persistent, resist degradation in the environment and bioaccumulate.

"The degree to which they can migrate out of apparel and contact the skin or saliva of the wearer, or enter the environment, can be a concern," the study says.

It was undertaken because, although environmental monitoring data is available, only limited information exists on the substances' presence and trends in consumer products, including children's items.

The degree to which [PFASs] can migrate out of apparel and contact the skin or saliva of the wearer, or enter the environment, can be a concern, CEC study

Consequently, last summer, the CEC, established under the North American Agreement on Environmental Cooperation (NAAEC), analysed articles of clothing and performance apparel, including children's items, purchased from 27 cities across North America.

Targeting 31 PFAS compounds, it found that 97 articles, or 68.6%, showed positive results for at least one.

Of the articles tested, outdoor jackets presented the highest number of "positive hits". The most frequently detected compounds were perfluorooctanoic acid, or PFOA, (45%) and PFHxA (43%). But low concentrations of PFOS were also found, which the study says may "confirm improvements in the implementation of PFAS regulations in various sectors".

Action on PFAS

In 2009, PFOS was added to Annex B of the UN treaty, the Stockholm Convention on persistent organic pollutants (POPs). This annex requires parties to the convention to take measures to restrict the production and use of the chemicals listed.

Other PFASs have been targets of international and regional regulatory action. PFOA and PFHxS are being considered for listing under the Stockholm Convention.

US state policy experts have predicted addressing PFOA, PFOS and related substances will be the biggest emerging chemical regulation issue at state level this year.

And in December 2017, the US EPA announced a cross-agency effort to address PFASs. However, the agency has not promised regulatory action.

In Europe, the Swedish Chemicals Agency, Kemi, and Germany's federal environment agency (UBA) have submitted a joint proposal to Echa to restrict the manufacturing and placing on the market of six PFASs. And in July last year the Nordic Council, an intergovernmental cooperation body representing five countries, called for prompt regulatory action on the substance group.

In 2006, the US EPA invited eight major fluoropolymer and telomer manufacturers to participate in its PFOA stewardship programme, where they made voluntary corporate commitments to eliminate PFOA and related chemicals from emissions and products by 2015.

Manufacturers in Europe, the US and Japan have largely phased out PFOA. However, its use in other countries, particularly China, has meant that it is still finding its way into the environment.

Meanwhile, a report from Australia's expert health panel for PFAS has concluded that evidence linking exposure to PFASs with human disease is limited or non-existent.

The CEC study is part of its *Greening of Chemicals in North America* project, which aims to develop knowledge useful to chemical risk assessment and/or risk management in the three countries.

The CEC's broader mission is to address "regional environmental concerns, help prevent potential trade and environmental conflicts and promote the effective enforcement of environmental law". It says it "complements the environmental provisions of the North American Free Trade Agreement (Nafta)".

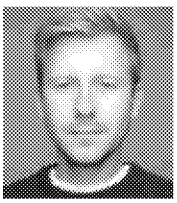
From the PFAS family

perfluorooctanoic acid (PFOA)

perfluorooctanesulfonic acid (PFOS)

Perfluorohexane sulfonic acid (PFHxS)

Perfluorohexanoic acid (PFHxA)



Leigh Stringer

Global Business Editor

Related Articles

- Efforts to ban PFHxS globally move forward
- PFASs seen as biggest emerging chemical issue for US states
- US EPA announces 'cross agency' initiative on PFAS
- Germany and Sweden propose restrictions on six PFASs
- Nordic Council calls for prompt regulatory action on PFASs
- Australian panel says PFAS ill-health links limited or non-existent

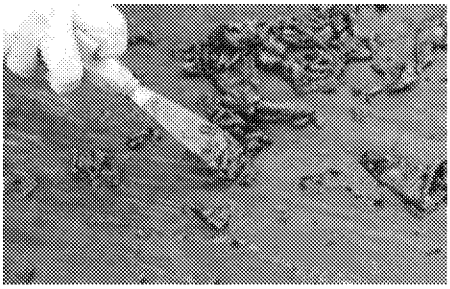
Further Information:

- CEC study

US EPA commits to act on methylene chloride paint strippers

Move follows Pruitt meeting with substance victims' families

10 May 2018 / Built environment, Solvents, United States



The US EPA has announced it will move forward with finalising its proposed rule addressing methylene chloride paint strippers.

Issued in the final days of the Obama administration, the proposal would see a prohibition on consumer and commercial paint stripping uses for methylene chloride. It also proposes to restrict or ban a replacement solvent, N-methylpyrrolidone (NMP).

The agency had suggested in recent months it would be shelving the rule. But in a statement today it said it intends to finalise the proposal. And it is working to send the finalised rulemaking to the White House Office of Management and Budget (OMB) "shortly".

However, while the statement from the EPA refers to "the methylene chloride rulemaking", it is not immediately clear if such a rule would also address NMP.

The agency also confirmed that it does not plan to reevaluate the hazard posed by paint stripping uses of methylene chloride. Instead, it will rely on its previous risk assessment, which identified a range of adverse health effects or death in workers and consumers.

The Halogenated Solvents Industry Alliance (HSIA), representing methylene chloride producers and users, had asked the agency not to adopt the rule. Instead it requested a review of paint stripping under its upcoming TSCA risk evaluation of the substance. Such an approach, it said in 2017 comments to the agency, would allow the EPA to address what the HSIA calls "serious data quality concerns" with the existing risk assessments upon which the proposal is based.

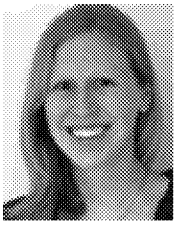
Pressure to act

The EPA's announcement comes just two days after NGO campaigners and families of those who have died using the products met with EPA Administrator Scott Pruitt to urge action on the proposal. It also comes amid an aggressive push on home improvement retailers to pull the products.

Liz Hitchcock, acting director of Safer Chemicals, Healthy Families, praised the work of the families who "have turned their grief into action".

And Sarah Vogel, vice president of health at NGO the Environmental Defense Fund, said she is "encouraged that today EPA has decided to reverse course and move forward to finalise its proposed rule". She also applauded that the agency would not be reevaluating the paint strippers.

But Dr Vogel cautioned that the statement falls short of committing to a ban. "We will delay any celebration until paint strippers containing this deadly chemical are actually off the market," she said.



Kelly Franklin

North America editor

Related Articles

- US EPA proposes prohibitions on methylene chloride, NMP
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA
- US EPA identifies cancer risks with DCM paint strippers
- NGOs blast request to delay TSCA section 6 rules
- EPA names first ten chemicals for new TSCA evaluations
- Methylene chloride campaigners meet with EPA Administrator
- NGOs push Lowe's on methylene chloride paint strippers

Further Information:

- Press release

OTHER ARTICLES

L'Oreal: This Mother's Day, make it toxic-free because moms are worth it!

State PIRGs (blog)

Many of us will be giving our moms perfumes, bath bombs and beauty ... But sadly, potentially harmful chemicals are something we do have to worry ...

Vermont Legislature Approves Controversial Toxic Chemical Bill

Seven Days

The Vermont Senate gave final approval Wednesday to watered-down legislation that would make it easier for residents to sue companies that ...

Cancer warnings for coffee may be overkill, but Proposition 65 is not

Los Angeles Times

California voters approved the Safe Drinking Water and Toxic Enforcement Act, commonly known as Prop. 65, in 1986, by a margin of 2-1. Since then ...

Mainers join effort to pressure Lowe's to drop paint strippers with deadly chemical

Kennebec Journal & Morning Sentinel

Scientific evidence from multiple studies shows that both men's **and** women's exposures to **toxic** solvents are linked to lasting problems with brain ...

Message

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60D0C681A16441A0B4FA16AA2DD4B9C5-BLOCK, MOLL]
Sent: 1/29/2018 5:19:18 PM
To: Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: FYI - Chlorpyrifos coverage

Daily Caller
http://dailycaller.com/2018/01/26/epa-chlorpyrifos-pesticide-environmental-health/
Trump's EPA Targets Academics For Hiding Data Used To Ban Popular Pesticide
By Chris White, 1/26/18, 4:32 PM

The Environmental Protection Agency called out academics for using hidden data to pressure the agency into banning a widely used pesticide.

The EPA has sought data sets from a study Columbia Center for Children's Environmental Health (CCCEH) conducted that the former President Barack Obama-era agency used to justify a proposed rule in November 2015 to revoke the tolerances for chlorpyrifos, essentially banning the pesticide from use.

"Despite multiple requests, an EPA visit to Columbia, and a public commitment to 'share all data gathered,' CCCEH has not provided EPA with the data used," the agency wrote on a webpage connected to its website, which includes a list of the times the EPA has requested the data set.

The agency's Scientific Advisory Panel criticized the environmental health center's handing of the matter as well. "Some Panel members thought the quality of the CCCEH data is hard to assess when raw analytical data have not been made available, and the study has not been reproduced," the panel noted in 2016.

A panel of Ninth Circuit Court of Appeals judges ruled EPA had complied with a previous judicial order to respond to a petition filed by the Natural Resources Defense Council (NRDC) and the Pesticide Action Network North America in 2007.

The ruling was a major blow to environmentalists who have been trying for years to ban the pesticide chlorpyrifos, that farms across the country widely use to keep bugs from ruining food.

EPA denied the environmentalist petition in March to "revoke all food tolerances and cancel all registration" for chlorpyrifos. Dow Chemical, which manufacturers the chemical, applauded EPA's ruling, as did the Department of Agriculture. EPA already restricts products containing chlorpyrifos for home and agricultural use.

U.S. farms use about 6 million pounds of chlorpyrifos each year. If nothing had changed legally, the EPA would no longer have allowed trace amounts of chlorpyrifos in food, effectively banning the pesticide in the country.

Chlorpyrifos is not the only chemical to come under scrutiny recently.

Republican Reps. Lamar Smith of Texas and Andy Biggs of Arizona sent letters to the International Agency for Research on Cancer in 2017 asking the U.N.-affiliated agency to answer questions about reports they edited data showing glyphosate causes health risks.

Separate letters to the agency's Director Chris Wild from both congressmen said they are "concerned about the scientific integrity" of cancer research agency's "monograph" program that assesses whether various substances can cause cancer.

The agency's 2015 study contains crucial edits made to bolster evidence that glyphosate could cause cancer in humans, reports show.

Smith and Biggs also express concerns that research methods are not transparent. They argued in a second letter that the agency's assessment meetings, deliberations and drafts are not made public.

Message

From: Daguillard, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BBE9682B940C4F2C90732E4D37355DD4-DAGUILLARD,]
Sent: 4/27/2018 8:03:14 PM
To: Schultz, David [dSchultz@bloombergenvironment.com]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: RE: EPA secret science rule

Thanks, Nancy. David, feel free to follow up with press@epa.gov, please.

Cheers, R.

Robert Daguillard
Office of Media Relations
U.S. Environmental Protection Agency
Washington, DC
+1 (202) 564-6618 (O)
+1 (202) 360-0476 (M)

From: Schultz, David [mailto:dSchultz@bloombergenvironment.com]
Sent: Friday, April 27, 2018 3:56 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Daguillard, Robert <Daguillard.Robert@epa.gov>
Subject: Re: EPA secret science rule

Thanks!

David Schultz
Reporter
Bloomberg Environment

703.341.3696
dschultz@bloombergenvironment.com

From: Beck, Nancy <Beck.Nancy@epa.gov>
Sent: Friday, April 27, 2018 3:55:04 PM
To: Schultz, David
Cc: Daguillard, Robert
Subject: RE: EPA secret science rule

David,
I'm looping in our Office of Public Affairs to help facilitate getting an answer to your question.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Schultz, David [mailto:dSchultz@bloombergenvironment.com]
Sent: Friday, April 27, 2018 3:06 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: EPA secret science rule

Hi Nancy,

My name is David Schultz and I'm a reporter at Bloomberg Environment. My colleague Patrick Ambrosio recommended I reach out to you for a story I'm working on about the EPA's recent announcement that it would bar the use of unpublished scientific data in rulemaking.

One aspect of this announcement that we're zeroing in on is that this rule would allow the administrator to waive this requirement in the case where scientific data can't be made public for some reason. I wanted to get your opinion about whether this would give the agency too much discretion and whether it could open the EPA up to an "arbitrary and capricious" legal challenge if the agency only grants this waiver to industry-generated data.

If you have a chance, please give me a call so we can discuss this further. I'll be at 202-510-4655 for the remainder of the day.

Looking forward to speaking with you,

David

David Schultz
Reporter
Bloomberg Environment

703.341.3696
dschultz@bloombergenvironment.com

Message

From: EPA Press Office [press=epa.gov@cmail19.com]
on behalf of EPA Press Office [press@epa.gov]
Sent: 4/24/2018 6:30:03 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations

U.S. ENVIRONMENTAL PROTECTION AGENCY

NEWS RELEASE

WWW.EPA.GOV/NEWSROOM

EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations

WASHINGTON (April 24, 2018) - Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and that underlying scientific information is publicly available in a manner sufficient for independent validation.

"The era of secret science at EPA is coming to an end," **said EPA Administrator Scott Pruitt.** "The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives."

This proposed rule is in line with the scientific community's moves toward increased data sharing to address the "replication crisis"—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center's Science for Policy Project and the Administrative Conference of the United States' Science in the Administrative Process Project.

The proposed rule builds upon President Trump's executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility."
- **Executive Order 13783**, also issued in March 2017, provides that "It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

Chairman Lamar Smith (R-TX): "Administrator Pruitt's announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It's likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas."

Senator Mike Rounds (R-SD): "Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA's decisions. Today's directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected."

Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts: "The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process."

Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the Journal *Risk Analysis*: "I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy."

Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law: "EPA's proposed rule, Strengthening Transparency in Regulatory

Science, is badly needed "Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based."

Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM): "IDEM supports transparency in rulemaking. Good, sound science leads to better regulations."

Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA's Clean Air Scientific Advisory Committee (1992 - 1996): "In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations."

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Visit The EPA's Newsroom

Message

No Images? Click here

From: EPA Press Office [press=epa.gov@cmail19.com]
on behalf of EPA Press Office [press@epa.gov]
Sent: 3/23/2018 3:30:02 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: EPA's Weekly Report for 3/23/18

U.S. ENVIRONMENTAL PROTECTION AGENCY

NEWS RELEASE

WWW.EPA.GOV/NEWSROOM

EPA'S WEEKLY REPORT

This week Environmental Protection Agency (EPA) Administrator Scott Pruitt sat down with more than a dozen reporters across all mediums to discuss the important work the Agency is doing to ensure regulatory certainty for America's farmers, ranchers, and businesses during National Agriculture Week. Pruitt also advanced the Trump Administration's infrastructure agenda with a push to eradicate lead from drinking water and convene a national leadership summit on PFAS to update America's crumbling water infrastructure.

NATIONAL NEWS ...

In an exclusive interview with the Daily Caller, EPA Administrator Scott Pruitt laid out his plans to end the use of "secret science" to craft Agency regulations. "Pruitt will reverse long-standing EPA policy allowing regulators to rely on non-public scientific data in crafting rules. Such studies have been used to justify tens of billions of dollars worth of regulations. EPA regulators would only be allowed to consider scientific studies that make their data available for public scrutiny under Pruitt's new policy. Also, EPA-funded studies would need to make all their data public."

EPA Administrator Pruitt sat down with AgDay to talk about issues impacting farmers and ranchers including EPA's efforts to provide certainty by redefining "Waters of the U.S." According to Pruitt, a substitute or replacement definition will be issued sometime this year, a definition that will recognize private property ownership and the roles of states, and will answer the question of what exactly is a water of the United

States. 'We're going to get that right going forward, and the definition is going to provide clarity, objective measurements by which we know where federal jurisdiction begins and ends,' he said."

OP-ED ...

In the Washington Times, EPA Administrator Pruitt outlined the Agency's efforts to overhaul the permitting process to "rebuild and revitalize our nation's crumbling infrastructure." "The president's ambitious proposal calls for the U.S. Environmental Protection Agency to play a leading role in the administration's efforts ... America's infrastructure was once the envy of the world. The president's proposal will restore our roads, bridges and waterways to greatness and create a safer, stronger America. Through regulatory reforms and targeted investments, EPA will spearhead the much-needed repairs to infrastructure in a way that provides tangible environmental benefits to all Americans."

REGIONAL NEWS ...

The Detroit News reported that eradicating lead from drinking water is one of EPA Administrator Pruitt's top priorities. "'I do think that what happened in Flint is something that could happen elsewhere. We just simply need to take steps to do all that we can to address it prospectively and proactively,' Pruitt said. Pruitt said President Donald Trump's $1.5 trillion plan to bolster the nation's infrastructure over the next decade would include investments in aging water infrastructure."

While speaking with the New York Post, Pruitt called for a local, state, and federal response to the lead crisis in New York City and across the country. "EPA Administrator Scott Pruitt called for a 'coordinated' response between New York State and City officials to address the ongoing lead crisis."

In an interview with Newark Star-Ledger, Pruitt discussed efforts to make cleaning up Superfund sites a priority to advance the Agency's core mission. "The Environmental Protection Agency plans to step up efforts to get companies who dumped toxic waste at New Jersey's Superfund sites to pay to clean them up, Administrator Scott Pruitt said. Pruitt on Monday blamed a lack of urgency... New Jersey has 114 designated Superfund sites, the most in the nation, included three of Pruitt's 21 highest-priority locations."

Pruitt reiterated his commitment to prioritizing the Superfund program to clean up America's most contaminated sites, including Tar Creek, in an interview with the Tulsa World. "Administrator Scott Pruitt of the U.S. Environmental Protection Agency said his new push on the nation's Superfund program finally can provide clarity and accountability to the Tar Creek area, for decades one of the oldest, largest and most complex toxic sites in the nation. 'It is really unacceptable,' Pruitt said as he

recalled the history of the Tar Creek area in far northeastern Oklahoma, whose Superfund legacy dates back to 1983, as well as the amount of money and time deployed there."

At this week's regional roundtable, the Albuquerque Journal **reported on progress the Trump Administration is making on claim stemming from the 2015 Gold King Mine spill.** "Environmental Protection Agency Administrator Scott Pruitt said Monday that the federal government is close to finishing its assessment of roughly 400 claims for financial damages stemming from the 2015 Gold King Mine spill, which dumped toxic chemicals into waters in New Mexico, Colorado and Utah, and final recommendations could be ready by the end of the month."

RADIO ...

This week, Administrator Pruitt joined WZFG 1100 AM The Flag - North Dakota **to talk about his first year accomplishments, including repeal and replacement of both "Waters of the U.S." rule and Clean Power Plan.**

Administrator Pruitt also joined the Lars Larson Show**, based in Portland, Ore., and discussed how he's working to get the EPA back to basics and provide regulatory certainty for all Americans.**

On the St. Louis, Missouri's own Mark Reardon Show**, Administrator Pruitt talked a little about baseball and a lot about the good work the Agency is doing to improve environmental outcomes across the country.**

Scott Voorhees on 1110 KFAF-Omaha had Administrator Pruitt on his show Wednesday to talk about what's to come at the EPA this year, including a continued focused on Superfund clean-up and regulatory transparency.

EPA Administrator Scott Pruitt

March 21, 2018 • 9 min

Interesting insight from the former OK AG on his work this past year, the road ahead, how he sees his responsibilities compared with the past administration, and working with President Trump.

TWEETS ...

Administrator Pruitt @EPAScottPruitt · Mar 21

What a beautiful surprise, snow on the second day of spring!

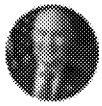
Administrator Pruitt @EPAScottPruitt · Mar 21

Spent the morning with friendly folks from @GaFarmBureau. We had a great discussion about ongoing work at the Agency to rewrite the #WOTUS rule and provide regulatory certainty for our farmers and ranchers across #Amenca. #NationalAgWeek

Administrator Pruitt @EPAScottPruitt · Mar 19

Wrapped up our regional roundtable discussing important environmental issues like air, lead, Superfunds & infrastructure.

Albuquerque Journal, Pittsburgh Post-Gazette, New York Post and 2 others



Administrator Pruitt @EPAScottPruitt · Mar 20

Had a great visit with hardworking farmers and ranchers from Wisconsin and Kentucky on #NationalAgDay! @EPA will continue to work with our agriculture partners across the country. #AgDay

#EPAInAction

WI Farm Bureau

Administrator Pruitt @EPAScottPruitt · 15h

#ICYMI ,@EPA announced $463K in funding for 31 Phase 1 student teams through the People, Prosperity, and the Planet grants program. Find out more

epa.gov/newsreleases/g...

CONTACT: press@epa.gov

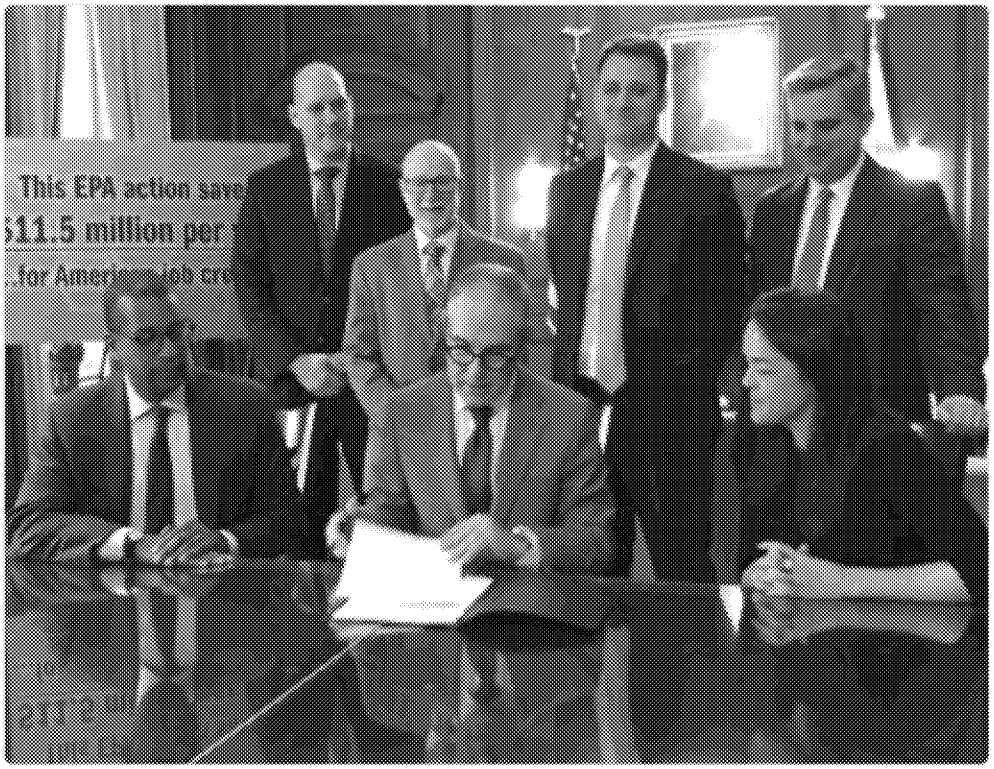
EPA Awards Grants to 31 College Teams for Innovative Technology Projects

WASHINGTON (March 22, 2018) – Today, the U.S. Environmental Protection Agency (EPA) announced over $463,000 in funding for 31 Phase I student teams through the People, Prosperity, and the Planet (P3) grants program. These teams, made up of college students from across the country, are developing sustainable technologies to solve current environmental and public health challenges.

"This year's P3 teams are applying their classroom learning to create innovative and practical technologies," **said EPA Administrator Scott Pruitt.** "This next generation of scientists has

Administrator Pruitt @EPAScottPruitt · Mar 20

Every bit of certainty matters. I just signed proposed amendments that will simplify compliance with national standards, generate significant cost-savings while protecting human health and the environment. #EPAInAction



FRONT PAGES ...

South Jersey TIMES
GLOUCESTER COUNTY TIMES Edition

$1 WEDNESDAY, MARCH 21, 2018 N

AFFILIATED WITH nj.com

GLOUCESTER TWP.

Cut down on the way home

Megan Pierl holds a wedding photo of her and her husband, Joseph Pierl, on Monday. Joe Pierl, 42, died approximately a week after suffering injuries in a road rage assault in Deptford Township on March 9. Lou M. Nichols, for South Jersey Times

Victim of deadly road rage, a devoted father 'came face-to-face with evil' during storm

Matt Gray For South Jersey Times

Sitting on a couch in the living room of her Blackwood home, Megan Pierl carefully recalled the last conversation she had with her husband.

Joe Pierl was preparing to head home from work and wanted his wife to know he might be a little later than usual. It was March 7 and a nor'easter was dumping snow across the region, making for a slow commute.

"Just take your time and be careful," she told him. They ended their conversation with their traditional "I love you."

Joe Pierl never made it home that night.

Pierl, 42, was shoved to the face during a road rage assault in Deptford Township that afternoon. He died of his injuries a week later.

"He just wanted to come home and he didn't make it home," his wife said, her voice cracking with grief.

Pierl was able to speak to emergency responders and gave them his wife's phone number. By the time his family arrived at the hospital, they couldn't speak with him, explained Megan Pierl's mother, Betsy Jean Hampton.

"He was gasping," she said. "He never came to."

His family was covered by the time they saw him. "Pieces from one side of his nose to the other side of his face," Hampton said. "We don't know what happened. We just know a very good man was taken from all of us."

He remained on life support until Thursday.

Pierl was an organ donor and "he saved seven lives," she said, praising the doctors and nurses who cared for him at [SEE PIERL, A8]

PERSONAL

4 who trafficked dogs for pit fights are sent to prison

Thomas Moriarty For South Jersey Times

Three South Jersey men were among four sentenced this month to years in federal prison for their roles in a criminal network prosecutors said trafficked dogs across state lines for bloody pit fights.

In the course of a sprawling multistate investigation, the U.S. attorney's office said in a statement, federal agents discovered the basement of a defendant's home called to mind, evidence it had been used as a fighting pit. One man admitted his dog died on the way home after losing a fight.

Of the four defendants, Maryland resident Anthony "Money" Gaines and Federal Harris received sentences of 42 months and 37 months, respectively, for charges that included conspiracy and possessing a dog with the intent to use it in a dog fight.

Frank Nichols, of Millville, was sentenced to 37 months on charges that included being a felon in possession of a firearm. The fourth defendant, Peden Chandler of Willow Springs, Illinois, received a year in prison after pleading guilty to a misdemeanor charge.

All four of the men previously had pleaded guilty before U.S. District Judge Mary L. Cooper in Trenton.

Prosecutors said their arrests stemmed from Operation Grand Champion, a coordinated effort targeting dog fighting across multiple federal districts.

Court records show agents seized six pit bulls when they served a search warrant at Gaines' home in November 2015, and federal authorities have said a total of 44 dogs were recovered in New Jersey as part of the investigation. Investigators said they also seized treadmills, heavy chains and breeding stands — meant to restrain female dogs — as they built their case against the men.

Prosecutors said a fifth defendant, 42-year-old Asbury Park resident Kevin Atkinson, has also pleaded guilty and is scheduled to be sentenced on April 18. Other defendants remain awaiting trial.

Thomas Moriarty, NJ Advance Media, tmoriarty@njadvancemedia.com

STATEHOUSE

AG orders random drug tests for police

N.F. Sullivan For South Jersey Times

All police officers in New Jersey are now subject to random drug testing under a directive from the state's new attorney general.

Police departments are also required to implement "early warning systems" triggered by problem behavior such as excessive force accusations, lawsuits, domestic abuse and drunken driving, under a separate directive announced by Attorney General Gurbir Grewal's office.

Grewal, who was appointed by Gov. Phil Murphy in January, said Tuesday that most police departments and county prosecutors already have such policies in place. The two new directives would mandate them statewide.

"We support our officers in their difficult jobs, and at times that means intervening with a troubled officer to protect the public, the individual officer, and his or her fellow officers," he said in a statement announcing the move.

How it works

Under the new rules, every state, county and local law enforcement agency is required to conduct one random drug screening in 2018 and perform such tests twice a year going forward.

Departments are required to report any failed tests — or officers who refuse a test — as well as any resulting discipline to the county prosecutor or other supervising agency.

The early warning system requirement spells out 10 "performance indicators" that are triggers. A5

WASHINGTON

EPA to make polluters clean Superfund sites in N.J.

Jonathan D. Salant For South Jersey Times

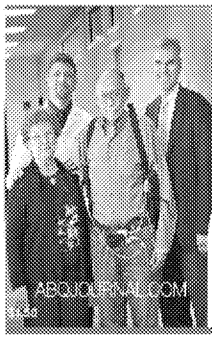
The Environmental Protection Agency plans to step up efforts to get the companies that dumped toxic waste at New Jersey's Superfund sites to pay to clean them up, administrator Scott Pruitt said.

Pruitt on Monday blamed a lack of urgency, not a lack of funding, for the slow progress in cleaning up the sites. New Jersey has 114 unregulated Superfund sites, the most in the nation, including three of Pruitt's 13 highest priority locations.

"I'm going to get accountability with whomever it is on these Superfund sites and we will use every means of enforcement to do so," Pruitt said. "I don't think we've done it as well as we should have historically and we're going to do better going forward."

While President Donald Trump has proposed cutting the EPA's budget, Pruitt said the agency will have the money it needs by ensuring that the companies responsible for the contamination clean it up.

"Most of our sites across the country have a responsible party," Pruitt said. "We have very few orphan sites." [SEE EPA, A8]



BRIGHT SPOT

Heart help

First recipient has device implanted after new procedure is approved for use in New Mexico

HEALTH >> B5

Back to the Pit

UNM women's basketball team faces Rice tonight in a WNIT second-round game

SPORTS >> B1

NEW MEXICO'S LEADING NEWS SOURCE

ALBUQUERQUE JOURNAL

TUESDAY
MARCH 20, 2018

FINAL ****

A few gun owners brought their AR-15 rifles to the Las Cruces City Council meeting and spoke out against a resolution to ask the governor and state legislators to restrict semiautomatic weapon sales and ownership in New Mexico.

Cruces council tables gun restriction measure

Resolution intended to urge action against semiautomatic weapons

BY ANGELA KOCHERGA

LAS CRUCES — A standing-room-only crowd packed the Las Cruces City Council meeting Monday, where councilors voted to table a resolution asking the governor and state lawmakers to restrict semiautomatic weapons.

Some members of the audience openly carried firearms.

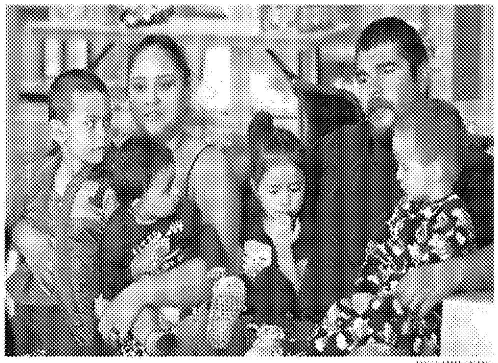
"[illegible]," said Councilor Greg Smith, who introduced the resolution.

Smith said the "Resolution to [illegible] the Safety of Students in Las Cruces Schools" was in response to "parents and grandparents" who were concerned after lockdowns at some schools following threats made on social media.

"[illegible]," [illegible], a student at Las Cruces High School, told the council.

She said students [illegible]

See COUNCIL >> A4



Jacqueline Arellano and her fiancé, Daniel Crespin, talk in the Manzano Mesa Multigenerational Center on Monday about their escape from a fire at their apartment building on Sunday. With them are their children, from left, Francisco Arellano Crespin, 5; Daniel Crespin Jr., 3 months; Alaniey Crespin, 4; and Vincente Crespin, 2.

Residents smelled gas before fire

30 stay in shelter after blaze destroys, damages SE Albuquerque apartments

BY RICK NATHANSON

Residents say a fire that destroyed or damaged a number of units at a Southeast Heights apartment complex Sunday was caused by the same leaky gas meter [illegible] claim to have repeatedly reported to the apartment manager for more than a year.

The property manager Tuesday denied receiving the reports.

About 30 people who lived in the apartment building in the 400 block of Georgia SE were temporarily relocated to the Manzano Mesa Multigenerational Center, where they were housed overnight, and given provisions by the city of Albuquerque and the Red Cross, said Anna Sanchez, director of the city's Office of Senior Affairs.

The center was closed to the public Monday. Sanchez thanked the public for being understanding, and said the building would reopen for normal activities and services today.

St. Martin's HopeWorks homeless provided vouchers so the displaced families, which include 16 people under age 18, could stay at a local motel, Sanchez said.

See RESIDENTS >> A2

Union urges teachers to skip survey

ATF leader calls APS budget questionnaire problematic, divisive and inappropriate

BY SHELBY PEREA

Former Albuquerque Public Schools teacher Julia Barraza says she left APS after two years because she felt like she had no voice in the district.

She often tried to share her input on classroom and curriculum procedures with administration, saying she was shot down time and time again.

But Barraza, now a second- and third-grade math teacher at the state-chartered Mission Achievement and Success Charter School, was encouraged when she saw APS' new 2018-2019 budget survey on the district's website that invites members of the public, including parents, teachers and students, to weigh in on budget priorities for next year.

"I was excited to hear they were progressing," she said.

That excitement was tempered when she learned of an email blast by the Albuquerque Teachers Federation, the local union, urging APS employees to skip the survey about APS' $1.3 billion budget.

APS' online survey [illegible] included ranking school subjects and programs in order of importance and suggestions for reducing expenses, among other questions.

The district has conducted several online budget surveys [illegible]

Albuquerque Teachers Federation President Ellen Bernstein

See UNION >> A4

ABQ TIES IN FACEBOOK DATA MINING SCANDAL

A powerful private data mining firm bankrolled by Albuquerque native Robert Mercer harvested Facebook user information to help propel Donald Trump into the White House in 2016.

METRO & NM >> A6

EPA close to settling claims on mine spill

$1.2 billion in damages sought after toxic waste polluted rivers

Scott Pruitt

BY MICHAEL COLEMAN

WASHINGTON — Environmental Protection Agency Administrator Scott Pruitt said Monday that the federal government is close to finalizing the assessment of roughly 380 claims for financial damages stemming from the 2015 Gold King Mine spill, which dumped toxic chemicals into waters in New Mexico, Colorado and Utah, and final recommendations could be ready by the end of the month.

Former EPA Administrator Gina McCarthy, an Obama-era appointee, announced toward the end of her tenure in 2016 that the government would not pay any damages to farmers and others harmed by the toxic spill, arguing it was not allowed under the Federal Tort Claims Act. But after President Donald Trump

See EPA >> A4

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U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
Sent: 4/12/2018 3:31:20 PM
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Subject: EPA News Highlights 4.12.18

Attachments: EPA News Highlights 4.12.18.docx

EPA News Highlights 4.12.18

The Oklahoman: EPA Gains Clouded By Controversies Involving Pruitt

It looked for a time last week as though Scott Pruitt, embroiled in another controversy, might be shown the door as administrator of the Environmental Protection Agency. But Pruitt remains on the job and we hope that continues, because he's made a difference at the EPA. At the same time, however, it's hard to ignore the constant drumbeat of criticism, even if it largely stems from those on the left who were mortified when President Trump tapped Pruitt for the job and have worked unceasingly to derail his work since arriving in Washington. Yet pointing at the other guy and saying "He (or she) did plenty of things wrong, too," isn't a great defense. Pruitt has led major reform at EPA by, among other things, undoing the Waters of the U.S. rule, working to repeal the Clean Power Plan and revising burdensome fuel-economy standards, all products of the Obama administration. These moves and others have enraged the left and he'll continue to be their chief target, but he nonetheless should take pains not to give them more fodder for their assaults.

The Daily Caller: SCOOP: The White House Just Got Pruitt's Plan To Repeal WOTUS. Here Are The Details

White House officials are reviewing an updated Environmental Protection Agency (EPA) proposal to repeal the Obama administration's "waters of the United States" that expanded federal control over waters on private property. EPA officials submitted a supplemental proposal to the Office of Management and Budget (OMB) on Thursday. The proposal clarifies the agency is in fact repealing the Obama-era regulation and addressing some concerns brought up by stakeholders. The proposal also states EPA will be re-codifying the pre-Obama definition of WOTUS, The Daily Caller News Foundation has learned. The Obama administration finalized the Clean Water Rule in 2015 that expanded the definition of "waters of the United States" (WOTUS), arguing the rule was needed to clear up uncertainties in the wake of two U.S. Supreme Court decisions. More than half of U.S. states sued EPA to have the rule overturned. The courts quickly issued regulatory stays on the Clean Water Rule, meaning it never really went into effect. Manufacturers, energy companies, farmers, ranchers and land developers said the Obama-era rule would only make it harder to do business and manage land.

CBS News: Here Are Some Of The Threats Made Against EPA Administrator Scott Pruitt

CBS News has obtained an August 2017 report prepared by the Environmental Protection Agency's office of inspector general that contains a list of 13 threats made against EPA Administrator Scott Pruitt and his family. The threats range in severity, credibility and specificity. One tweet flagged by investigators said, "Pruitt, I'm gonna find you and put a bullet between your eyes. Don't think I'm joking. I'm planning this." Investigators believe the threat was made by someone living in India. Another person wished the administrator "a very painful and horrible death through poisoning. Please explain the scientific method to this freaking neanderthal." The inspector general also looked into a complaint that "unknown protesters attempted to disrupt the EPA Administrator's speech during a closed event." Another person emailed the EPA threatening to dump old paint outside Pruitt's door. The threats took various forms -- some arriving via social media and email, others by postcard. Pruitt's daughter received a menacing message on Facebook, the document reveals.

CNN: Vote Slated For Thursday For Former Inhofe Aide Wheeler To Be EPA's No. 2

The Senate is set to vote on Andrew Wheeler to be the number two official at the Environmental Protection Agency amid ethics concerns plaguing EPA chief Scott Pruitt and calls from Democrats for him to resign. If Pruitt left, it could fall

to Wheeler to run the agency until a new administrator is confirmed. Two GOP leadership aides told CNN they expected Wheeler to be approved, which would make him the latest appointee at the agency with close ties to the energy industry. While there is widespread opposition to Wheeler in the Democratic caucus, two Democrats running for reelection from energy producing states that strongly backed President Donald Trump in 2016 have said they will vote for him: Joe Manchin of West Virginia and Heidi Heitkamp of North Dakota.

Bloomberg: Here's Why Friends And Foes Of EPA Chief Pruitt Are So Adamant

Supporters and detractors of Environmental Protection Agency head Scott Pruitt agree on this much: He matters. Narrow that list to the new rules that have actually been issued, and Pruitt's impact is even harder to spot. Of the 24 economically significant regulations that have been approved by the White House under President Donald Trump, just one was issued by the EPA, according to data posted by the Office of Information and Regulatory Affairs. And that rule set the amount of renewable fuels that must be used in 2018 -- a regulation the EPA must issue every year, regardless of who's in charge. "Without a doubt, Scott Pruitt has been the single most effective appointment of the president of the United States," said Tim Huelskamp, president of the Heartland Institute, an industry-funded nonprofit that advocates for less regulation.

The Washington Times: Here Are The Legitimate Death Threats Against Scott Pruitt That Dems Claim Don't Exist

One of the more sickening episodes of the full-court press by members of The Swamp against EPA Administrator Scott Pruitt is the claim that he has spent too much money on extravagant security details. Democrats in the Senate have questioned the legitimacy of death threats against Pruitt and his family and have demanded hearings to investigate the matter: Two top Democrats on the committee, ranking member Thomas R. Carper of Delaware and Sheldon Whitehouse of Rhode Island, on Tuesday demanded such hearings, saying they have confidential documents that contradict public statements made by Pruitt, EPA spokespersons and President Donald Trump regarding the administrator's security spending. The lawmakers in their letter asserted that the documents in their hands fall far short of supporting claims by Pruitt's office that he needed elaborate security measure to protect him from death threats.

The Washington Free Beacon: Breaking: Liberals Suddenly Care About Wasting Taxpayer Money

I suddenly have a lot of competition covering my beat. Who knew the mainstream media cared how our taxpayer dollars are wasted? Security costs for cabinet secretaries are "steep." Spending is "lavish" again. When, God forbid, a secretary takes his wife with him on a business trip, CNN is there with the documents in hand, showing her "involvement." The New York Times is now giving tips on how to save taxpayers money, while lambasting Treasury Secretary Steven Mnuchin's use of military charter flights. (Mnuchin's travel ended up costing half of what Obama administration secretaries spent on average. Oddly, the Times never followed up.) The latest target is Scott Pruitt, arguably President Trump's most effective cabinet secretary. While there is questionable conduct for sure, like using an obscure law to give aides huge taxpayer-funded raises, it's curious the media suddenly care how much international junkets cost. The first scandal that caught the press's attention was Pruitt's trip to Italy last summer to attend the G-7 summit, which cost $84,000 in airfare and security, roughly the same that Lisa Jackson, Obama's first EPA administrator, spent on average on flights and security for four international trips. The headlines for Jackson's trip to the same summit in Syracuse, Italy, in early 2009 were slightly different. The Times has hit Pruitt for his "extravagant spending" on private flights and 24-hour security. But not too long ago it was the Times defending lavish trips on the taxpayer's dime. "There is nothing like a little Mediterranean beach vacation to unwind," the Times wrote back in August 2010. Do tell.

Reuters: Trump Administration Weighs High-Ethanol Fuel Waiver To Placate Farmers

The Trump administration is considering allowing the sale of a higher ethanol fuel blend in the summer, a source familiar with the issue said, a move that would placate corn growers worried about the future of U.S. biofuels policy. President Donald Trump recently met with the heads of the Environmental Protection Agency and the U.S. Department of Agriculture to discuss ways to make the Renewable Fuel Standard less expensive to the oil industry without undercutting demand for ethanol. The RFS requires refiners to add increasing volumes of biofuels like corn-based ethanol into the nation's fuel supply each year which is a boon to farmers but a headache for refining companies that must either blend the fuels themselves or purchase credits from those who do.

City Journal: Scott Pruitt, Warrior for Science

Imagine if the head of a federal agency announced a new policy for its scientific research: from now on, the agency would no longer allow its studies to be reviewed and challenged by independent scientists, and its researchers would not share the data on which their conclusions were based. The response from scientists and journalists would be outrage. By refusing peer review from outsiders, the agency would be rejecting a fundamental scientific tradition. By not sharing data with other researchers, it would be violating a standard transparency requirement at leading scientific journals. If a Republican official did such a thing, you'd expect to hear denunciations of this latest offensive in the "Republican war on science." That's the accusation being hurled at Scott Pruitt, the Republican who heads the Environmental Protection Agency. But Pruitt hasn't done anything to discourage peer review. In fact, he's done the opposite: he has called for the use of more independent experts to review the EPA's research and has just announced that the agency would rely only on studies for which data are available to be shared. Yet Democratic officials and liberal journalists have denounced these moves as an "attack on science," and Democrats have cited them (along with accusations of ethical violations) in their campaign to force Pruitt out of his job.

National News Highlights 4.12.18

The Wall Street Journal: U.S. Weekly Jobless Claims Hold Below 300,000 for Longest Streak on Record
The number of Americans claiming new unemployment benefits has never been so low for so long. Initial jobless claims, a proxy for layoffs across the U.S., decreased by 9,000 to a seasonally adjusted 233,000 in the week ended April 7, the Labor Department said Thursday. This means claims have now held below 300,000 for 162 consecutive weeks, cementing the longest streak for weekly records dating back to 1967. The current streak eclipsed the previous longest stretch that ended in April 1970. The consistently low claims levels point to labor market health because they mean relatively few Americans are losing their jobs and applying for benefits to tide them over until they can find new employment. After several years of consistent job growth, firms are reluctant to let employees go in a tightening labor market in which many available workers are quickly snapped up.

The Washington Post: As Fears Mount Over Open U.S.-Russia Conflict, Moscow Seeks To Lower The Temperature
Russian officials on Thursday sought to tamp down public fears of a looming conflict with the United States, even as Syrian government forces took control of the town where they are suspected of carrying out a chemical attack last weekend. Russian military police also entered Douma on Thursday to act as "guarantors of law and order in the town," the Russian Defense Ministry said, according to Russian news agencies. Russian troops had arrived earlier Monday under the terms of a surrender deal reached with the rebels after the suspected chemical attack — which Russia and Syria say did not happen. The recapture of Douma, in the region of Eastern Ghouta on the outskirts of Damascus, effectively represents the end of the war between Syrian President Bashar al-Assad and the rebel groups opposing his rule. Although chunks of the country remain under opposition control, none are as symbolic as Eastern Ghouta.

TRUMP TWEETS

The Oklahoman
http://newsok.com/epa-gains-clouded-by-controversies-involving-pruitt/article/5590556
EPA Gains Clouded By Controversies Involving Pruitt
By The Oklahoman Editorial Board, 4/12/18

It looked for a time last week as though Scott Pruitt, embroiled in another controversy, might be shown the door as administrator of the Environmental Protection Agency. But Pruitt remains on the job and we hope that continues, because he's made a difference at the EPA.

At the same time, however, it's hard to ignore the constant drumbeat of criticism, even if it largely stems from those on the left who were mortified when President Trump tapped Pruitt for the job and have worked unceasingly to derail his work since arriving in Washington.

Late last week, the federal government's top ethics official wrote a letter to the person in charge of ethics at the EPA warning of possible ethics violations by Pruitt, who served six years as Oklahoma's attorney general before going to Washington.

"Reports of the administrator making frequent official trips to his home state at government expense to offset the expense of returning home for personal or political reasons do raise concerns about whether the administrator is using his public office for personal gain in violation of ethics rules," the letter said.

In recent weeks, some Republican members of Congress have called for Pruitt to resign or be fired. One member, Rep. Carlos Curbelo of Florida, said Pruitt's "corruption scandals are an embarrassment to the administration."

Among other things, Pruitt has been criticized for occasional first-class travel — the bill during his first year on the job totaled about $105,000, according to Politico — and for expensive security expenditures. Most recently, Pruitt has come under fire for spending several months last year in a lobbyist's D.C. condominium at $50 per night, and for giving two top aides large pay raises after the White House denied the request.

Pruitt has said the raises were enacted not by him but by someone else, and that they had been reversed. As for the condo deal, it was approved by an EPA ethics official who has been at the agency 18 years. Mollie Ziegler Hemmingway, writing at the conservative website The Federalist, noted: "The general rental space also was used by three members of Congress for fundraising on days Pruitt wasn't in town. He wasn't invited to the events, didn't attend them, and even if he had no ethics laws would have been violated …"

Conservative defenders of Pruitt note that the Obama EPA had numerous controversies when led by administrators Lisa Jackson and Gina McCarthy. It is indeed a hoot that Jackson, who used a fake name and private email address while conducting official EPA business, has criticized Pruitt for a lack of transparency.

Yet pointing at the other guy and saying "He (or she) did plenty of things wrong, too," isn't a great defense. Pruitt has led major reform at EPA by, among other things, undoing the Waters of the U.S. rule, working to repeal the Clean Power Plan and revising burdensome fuel-economy standards, all products of the Obama administration. These moves and others have enraged the left and he'll continue to be their chief target, but he nonetheless should take pains not to give them more fodder for their assaults.

The Daily Caller

http://dailycaller.com/2018/04/12/scoop-white-house-gets-pruitts-plan-to-repeal-wotus/

SCOOP: The White House Just Got Pruitt's Plan To Repeal WOTUS. Here Are The Details

By Michael Bastasch, 4/12/18

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The Obama administration finalized the Clean Water Rule in 2015 that expanded the definition of "waters of the United States" (WOTUS), arguing the rule was needed to clear up uncertainties in the wake of two U.S. Supreme Court decisions.

More than half of U.S. states sued EPA to have the rule overturned. The courts quickly issued regulatory stays on the Clean Water Rule, meaning it never really went into effect. Manufacturers, energy companies, farmers, ranchers and land developers said the Obama-era rule would only make it harder to do business and manage land.

President Donald Trump signed an executive order last year, asking EPA and the U.S. Army Corps of Engineers to replace the Obama-era WOTUS rule with one consistent with former U.S. Supreme Court Justice Antonin Scalia's plurality opinion in the 2006 Rapanos v. United States case.

EPA began the WOTUS repeal process in June and published a plan for WOTUS repeal in the Federal Register the following month. EPA's new submission clarifies some concerns stakeholders expressed last summer, but the details aren't clear because it's still under review.

"From day one, EPA and the Department of the Army have been committed to providing certainty and clarity to our state and tribal co-regulators and farmers, ranchers and other stakeholders across the country," an EPA spokeswoman told TheDCNF.

"After reviewing this input, EPA and the Army have decided to issue a supplemental proposal to provide the public with additional clarity on the scope of the agencies' efforts," the spokeswoman said.

The move comes after environmentalists published a memo related to Clean Water Act enforcement. The memo, obtained by Public Employees for Environmental Responsibility (PEER), detailed how Pruitt would reserve the final say on jurisdiction under the Clean Water Act that was formerly delegated to regional officers.

PEER lambasted Pruitt's "restore regulatory certainty" as a "crude Clean Water Act coup d'état."

"This action subjects safeguards for clean water across the U.S. to filtration through one politician's hands," PEER's New England Director Kyla Bennett said in a statement. "Every corporation that wants a pass on Clean Water Act compliance is invited to privately meet with the most user friendly EPA Administrator in history."

However, Pacific Legal Foundation attorney Jonathan Wood said the memo could "promote both consistency in application and more accountability." PLF has challenged WOTUS in federal court.

"As it stands now, it makes a huge difference which regional office reviews your case — and often which bureaucrat within the office you happen to draw," Wood told TheDCNF. "Centralizing final decision making should lead to more consistent decision-making."

"There's also an important accountability issue here," Wood said. "Clean Water Act decisions require a mix of science and policy judgment."

"As the person appointed by the President and confirmed by the Senate to make those judgments, Pruitt can be forced to answer for the exercise of that policy-making power," Wood said. "When these decisions are made by anonymous regional bureaucrats, it is exponentially harder to hold anyone accountable."

CBS News

https://www.cbsnews.com/news/here-are-some-of-the-threats-made-against-epa-administrator-scott-pruitt/

Here Are Some Of The Threats Made Against EPA Administrator Scott Pruitt

By Jacqueline Alemany, Arden Farhi, 4/11/18

CBS News has obtained an August 2017 report prepared by the Environmental Protection Agency's office of inspector general that contains a list of 13 threats made against EPA Administrator Scott Pruitt and his family.

The threats range in severity, credibility and specificity.

One tweet flagged by investigators said, "Pruitt, I'm gonna find you and put a bullet between your eyes. Don't think I'm joking. I'm planning this." Investigators believe the threat was made by someone living in India.

Another person wished the administrator "a very painful and horrible death through poisoning. Please explain the scientific method to this freaking neanderthal."

The inspector general also looked into a complaint that "unknown protesters attempted to disrupt the EPA Administrator's speech during a closed event." Another person emailed the EPA threatening to dump old paint outside Pruitt's door.

The threats took various forms -- some arriving via social media and email, others by postcard.

Pruitt's daughter received a menacing message on Facebook, the document reveals.

In certain cases, cases were referred to the Justice Department, but just one was deemed serious enough to prosecute. The report covers the period from Oct. 2016 to Aug. 2017.

EPA Spokesman Jahan Wilcox responded that Pruitt had faced "unprecedented" threats.

In an email to the EPA's "Threat Coordination Group," Patrick Sullivan, the assistant inspector general for investigations at the EPA outlined an incident that occurred on March 6, 2018, in which a trespasser gained entry to the EPA headquarters and identified himself as a student attending a "Microsoft event."

"The personal asked about Scott Pruitt and wanted to know where Pruitt's office was and if Pruitt ever walked in the hallway outside the room," wrote Sullivan.

The intruder was soon escorted out of the EPA but called the desk phone of an employee and left voicemails following the intrusion claiming "he can gain entry into EPA space anytime he wants."

The security vulnerability was soon thereafter investigated.

Wilcox told CBS News, "We do not comment on matters pertaining to EPA's IG." A spokesperson for the EPA inspector general had no comment.

In early March, Pruitt told CBS News, "The quantity and the type of threats I've faced are unprecedented."

The inspector general report also details threats made against EPA employees and facilities and two threats against Gina McCarthy, the EPA administrator under President Obama.

McCarthy's office received a series of hostile phone calls from a person who is currently being prosecuted for making "Felony Threats." The caller said, "I will kill ya'll (sic) and f*** up Gina McCarthy," according to the report.

Democratic Sens. Tom Carper, of Delaware, and Sheldon Whitehouse, of Rhode Island, released a letter on Tuesday to Wyoming Sen. John Barrasso, chairman of the Senate committee that oversees the EPA, that said the assertions of "ongoing threats associated with the administrator's air travel" were inconsistent with an internal memo they obtained from a whistleblower at the EPA.

The memo, dated Feb. 14, 2018, according to the letter sent by Carper and Whitehouse, claimed that "EPA Intelligence has not identified any specific direct threat to the EPA administrator."

In a statement provided to the New York Times, Barrasso said that he Democrats had selectively released parts of the internal memo.

On Wednesday, Democratic senators held a press conference demanding answers from Pruitt about why he had ordered costly security measures and full time protection -- even on personal trips.

Sen. Tom Udall, D-New Mexico, said Pruitt had committed some of the worst "ethical transgressions of the entire Trump administration."

"The list of abuses just keeps getting longer," Udall told reporters at the press conference. "Lavish first class flights around the world, swanky hotel stays, taxpayers footing the bill for personal trips to Oklahoma, a $43,000 soundproof phone booth in his office, taking 30 EPA enforcement officers away from investigating polluters to serve as his round the clock personal security detail, speeding down the streets of Washington with sirens and lights blaring to get to fancy restaurants, huge unauthorized salary raises for his friends, allowing a close aide not to come to work for three months while still getting paid, and finally detailing EPA staff to find him a place to live. These are just a few of the things he is doing."

As Udall sees it, "Scott Pruitt has misused taxpayer dollars while enhancing his own personal perks."

The AP first reported that Pruitt's 20-member full time security detail "approached $3 million when pay is added in travel expenses." But EPA spokesman Jahan Wilcox defended the EPA administrator and said he has faced "unprecedented" threats.

The EPA administrator has been embroiled in scandal during his term, facing persistent rumors about the future of his job in the Trump administration. But he has also been called the president's most effective Cabinet secretary by Republican allies around Washington – including the president himself.

Last Thursday, the president praised Pruitt aboard Air Force One en route to Washington, calling him "a good man."

"I think he's done a fantastic job at EPA," Trump told reporters. "I think he's done an incredible job. He's been very courageous. Hasn't been easy, but I think he's done an absolutely fantastic job. I think he'll be fine."

The president added that the White House was looking into reports about Pruitt's ethical entanglements: he has not only come under fire for habitually traveling first class or by military jet at considerable taxpayer expense but he is now also is under investigation by House Oversight Committee Chairman Trey Gowdy for a housing arrangement in Washington, D.C., in 2017. ABC News first reported that Pruitt had lived in a Capitol Hill apartment owned by the wife of a fossil fuels lobbyist and rented the space for $50 a night – only paying for nights that he slept there.

Here are some of the documents obtained by CBS News:

CNN

https://www.cnn.com/2018/04/12/politics/andrew-wheeler-environmental-protection-agency-scott-pruitt-congress/index.html

Vote Slated For Thursday For Former Inhofe Aide Wheeler To Be EPA's No. 2

By Daniella Diaz and Ted Barrett, 4/12/18

The Senate is set to vote on Andrew Wheeler to be the number two official at the Environmental Protection Agency amid ethics concerns plaguing EPA chief Scott Pruitt and calls from Democrats for him to resign.

If Pruitt left, it could fall to Wheeler to run the agency until a new administrator is confirmed.

Two GOP leadership aides told CNN they expected Wheeler to be approved, which would make him the latest appointee at the agency with close ties to the energy industry.

His firm's clients include Murray Energy, which bills itself as "the largest coal mining company in America."

Senate Minority Leader Chuck Schumer, D-New York, blasted Wheeler as "a former industry lobbyist who has worked on behalf of big polluters and climate change deniers. He has spent years working to undermine or lobby against the environmental protections he may soon oversee."

Prior to his lobbying work, Wheeler served on Capitol Hill as a Republican staff member for the Senate Environment and Public Works Committee and as a top aide to Sen. Jim Inhofe, an Oklahoma Republican and an outspoken climate change skeptic who told CNN last month the EPA is "brainwashing our kids."

New Mexico Democratic Sen. Tom Udall said Wednesday that Wheeler should be carefully vetted, as if he were taking over for Pruitt now. Udall told reporters that he believes Wheeler wouldn't be a much better option to run the agency.

"The problem with the Wheeler nomination is if Trump (fires Pruitt) tomorrow, Wheeler is in fact the administrator, and that is a very, very serious problem," Udall said. "I know that there are many Republicans who haven't spoken out yet, but privately they are very disturbed by what Scott Pruitt is doing at the EPA."

While there is widespread opposition to Wheeler in the Democratic caucus, two Democrats running for reelection from energy producing states that strongly backed President Donald Trump in 2016 have said they will vote for him: Joe Manchin of West Virginia and Heidi Heitkamp of North Dakota.

"After meeting with Mr. Wheeler and reviewing his record, I've decided to support his nomination," Heitkamp said in a statement provided to CNN. "I believe he'll be open to working on issues important to North Dakota in a pragmatic and fair way, and I'll hold him accountable to make sure he implements the mission of the EPA in a way that works for my state."

One key centrist Republican has also signaled support for Wheeler.

"Mr. Wheeler has demonstrated that he understands the mission of the EPA and the role of Congress when it comes to oversight and accountability," said Maine Sen. Susan Collins in a statement.

Wheeler's nomination comes amid a steady stream of negative headlines involving Pruitt in recent weeks and months that has official Washington wondering whether the embattled agency chief can hold onto his job.

Most recently, Pruitt has been fighting stories revealing he paid about $6,100 over the course of a six-month lease last year to rent a room in a condo owned by Vicki Hart, a health care lobbyist whose husband, Steven Hart, has lobbied the EPA. His daughter also reportedly lived there while she was interning in Washington.

He paid $50 per night, according to the reports, and paid only for the nights he used the condo.

The federal government's top voice on ethics David Apol sent a letter to the agency outlining areas of concern regarding Pruitt. Apol, the acting director and general counsel of the Office of Government Ethics, summarized reports of Pruitt's conduct, including the rental agreement, as well as EPA spending on Pruitt's travel and security.

The letter also expresses concern with reports of Pruitt bypassing the White House to give raises to favored aides and other employees who faced job changes after raising concerns over his conduct.

Bloomberg

https://www.bloomberg.com/news/articles/2018-04-12/here-s-why-friends-and-foes-of-epa-chief-pruitt-are-so-adamant

Here's Why Friends And Foes Of EPA Chief Pruitt Are So Adamant

By Christopher Flavelle, Ari Natter, and Jennifer Dlouhy, 4/12/18

Supporters and detractors of Environmental Protection Agency head Scott Pruitt agree on this much: He matters.

Pruitt, whose continued tenure has been put in doubt by a series of ethics controversies, has attracted an extraordinary outpouring of support among conservative boosters who say he's the most effective member of President Donald

Trump's cabinet. Likewise, the organizers of a "Boot Pruitt" movement see him as a serious risk to the environment he's supposed to be protecting.

Yet it is hard to assess Pruitt's tenure by traditional standards. Many of his high-profile initiatives, such as overturning the Obama administration's plan to curb carbon emissions from power plants, face years of legal challenges.

Nor can Pruitt's significance be tied to a roster of regulatory actions -- including those designed to jettison old rules. Federal data show that since Trump's inauguration, the agency has submitted nine "economically significant" rules, defined as those with likely economic impact of at least $100 million, to the White House for review. By comparison, the Department of Health and Human Services has produced 31 such rules, the Department of Labor six and the Department of the Interior five.

Narrow that list to the new rules that have actually been issued, and Pruitt's impact is even harder to spot. Of the 24 economically significant regulations that have been approved by the White House under President Donald Trump, just one was issued by the EPA, according to data posted by the Office of Information and Regulatory Affairs. And that rule set the amount of renewable fuels that must be used in 2018 -- a regulation the EPA must issue every year, regardless of who's in charge.

Those figures don't include regulations that were in the works when Pruitt arrived in Washington and that he has blocked.

EPA spokesman Jahan Wilcox cited the agency's work to repeal Obama-era rules governing carbon dioxide emissions and water pollution as evidence Pruitt is advancing Trump's agenda.

"From advocating to leave the Paris Accord, working to repeal Obama's Clean Power Plan and Waters of the United States, declaring a war on lead and cleaning up toxic Superfund sites, Administrator Pruitt is focused on advancing President Trump's agenda of regulatory certainty and environmental stewardship," Wilcox said in an emailed statement.

A fuller assessment of Pruitt's 14 months in office shows that he's laid the groundwork for a wholesale revision of environmental policy, one that delights anti-regulatory groups and frightens environmentalists.

"Without a doubt, Scott Pruitt has been the single most effective appointment of the president of the United States," said Tim Huelskamp, president of the Heartland Institute, an industry-funded nonprofit that advocates for less regulation.

Vera Pardee, senior counsel for the Center for Biological Diversity, shared that view, albeit from the opposite direction. "The deregulatory agenda of Trump finds its most destructive expression in Mr. Pruitt," she said.

That shared view of Pruitt's importance helps explain the effort that advocates have poured into keeping him in his job -- or getting him removed. The outpouring is far greater than was expended on behalf of other embattled cabinet members, such as Secretary of State Rex Tillerson or Veterans Affairs Secretary David Shulkin who both ended up losing their jobs.

Pruitt has been dogged by a series of controversies, including expensive first-class tickets and 24-hour security details, hefty raises for aides and renting a Capitol Hill bedroom from a lobbyist for $50 a night. In response, environmentalists have mounted a campaign to seek Pruitt's ouster; advocates of smaller government, meanwhile, have set up a coordinated effort of their own to retain him at the EPA.

Both sides put Pruitt's effort to reduce the influence of academic scientists within the EPA near the top of their list of reasons why he matters. Pruitt has removed many of those scientists from advisory boards, replacing them with people who reflect the concerns of industries the EPA regulates.

Those boards are important. The Clean Air Scientific Advisory Committee, for example, helps establish ozone standards that the agency is required to implement.

JunkScience.com
Steven Milloy, publisher of the website JunkScience.com and a senior fellow at the Energy and Legal Institute, praised Pruitt for installing as chairmen of the Science Advisory Board and the Clean Air Scientific Advisory Committee "people I consider to be very strongly grounded in science."

Michael Halpern, deputy director of the Center for Science and Democracy at the Union of Concerned Scientists, echoed Milloy's point about the importance of those boards -- although he characterized Pruitt's appointments as "stacking" them.

Another point of agreement is Pruitt's changing the rules on so-called "secret science." He has directed the EPA to use only research whose underlying data is publicly available. Environmental advocates say that prevents the EPA from issuing air and water regulations supported by health research, since the identities of patients studied in those papers is kept private.

Huelskamp, of the Heartland Institute, praised that change. Halpern criticized it.

Pruitt also has made major policy pivots outside the formal rulemaking process. That includes the EPA's decision not to ban the commercial use of the pesticide chlorpyrifos and methylene chloride used in paint strippers. The EPA also has relaxed air pollution requirements via memos and internal opinions -- navigating around the federal rulemaking process in a way that has already drawn at least one legal challenge.

Environmental advocates also argue that Pruitt has restrained the EPA's willingness to fine polluters for violating the law.

"If you look at his enforcement record, it is disastrous and terrifying," said Lukas Ross, climate and energy advocate for Friends of the Earth. "It's not just the number of cases lodged, but it's also the amount of money that's been captured through lodging those cases."

Equally consequential, Ross added, are Pruitt's efforts to change the mission of the agency, in a way that will drive away staff who care about protecting the environment.

"There is a very real threat of brain drain because of the morale crisis being created by Scott Pruitt," Ross said. "If I worked at the EPA, I would be thinking about quitting too."

On that point as well, Milloy, the Junk Science publisher, agreed.

"Are these people sad?" Milloy asked. "The rest of America is happy."

The Washington Times
https://www.washingtontimes.com/news/2018/apr/12/here-are-legitimate-death-threats-against-scott-pr/
Here Are The Legitimate Death Threats Against Scott Pruitt That Dems Claim Don't Exist
By Larry O'Connor, 4/12/18

One of the more sickening episodes of the full-court press by members of The Swamp against EPA Administrator Scott Pruitt is the claim that he has spent too much money on extravagant security details.

Democrats in the Senate have questioned the legitimacy of death threats against Pruitt and his family and have demanded hearings to investigate the matter:

Two top Democrats on the committee, ranking member Thomas R. Carper of Delaware and Sheldon Whitehouse of Rhode Island, on Tuesday demanded such hearings, saying they have confidential documents that contradict public statements made by Pruitt, EPA spokespersons and President Donald Trump regarding the administrator's security spending.

The lawmakers in their letter asserted that the documents in their hands fall far short of supporting claims by Pruitt's office that he needed elaborate security measure to protect him from death threats.

"Documents provided to us by EPA official(s) suggest the agency has relied on questionable threats to the Administrator, including reports of non-violent protests, negative feedback about the administrators actions or other First Amendment protected activity to justify millions of dollars in additional security spending, inducing first-class air travel, as compared to his predecessors at the agency," Carper and Whitehouse wrote.

This is how vicious the opposition to Pruitt has become. As if a person would go out of their way to have an obtrusive and heavy-handed security detail for no good reason.

CBS News has obtained (probably from staffers at the EPA hoping to push back on the despicable narrative from Senate Democrats) documentation on just some of the death threats against Pruitt that had been detailed in August 2017 and, no, the threats are not isolated to anonymous tweets:

In an email to the EPA's "Threat Coordination Group," Patrick Sullivan, the assistant inspector general for investigations at the EPA outlined an incident that occurred on March 6, 2018, in which a trespasser gained entry to the EPA headquarters and identified himself as a student attending a "Microsoft event."

"The person asked about Scott Pruitt and wanted to know where Pruitt's office was and if Pruitt ever walked in the hallway outside the room," wrote Sullivan.
The intruder was soon escorted out of the EPA but called the desk phone of an employee and left voicemails following the intrusion claiming "he can gain entry into EPA space anytime he wants."

The security vulnerability was soon thereafter investigated.

McCarthy's office received a series of hostile phone calls from a person who is currently being prosecuted for making "Felony Threats." The caller said, "I will kill ya'll (sic) and f*** up Gina McCarthy," according to the report.

The Daily Caller also has a summary of some of the threats Pruitt has had to deal with presumably from global warming enthusiasts who care more about carbon emission hysteria than they do human life:

Investigators flagged one tweet that stated: "Pruitt, I'm gonna find you and put a bullet between your eyes. Don't think I'm joking. I'm planning this." Investigators determined the threat came from someone living in India. The investigation is ongoing.

These types of threats were a common occurrence, the report notes.

For instance, another person mailed a postcard to Pruitt telling him to "get out while you still can, Scott, you are evil incarnate you ignorant fuck." An investigation was unable to determine who sent the message. The case was not presented to the United States Attorney's Office for prosecution.

Pruitt's opponents hate how effective he has been (as we detailed last week) and they hate that President Trump has stood by him in the face of unfair and duplicitous attacks against his ethics and credibility. But to question the cost of his security detail for partisan purposes is beyond the pale.

It's time for Senate Republicans to unequivocally stand behind Pruitt and publicly shame these Democrats for their unprecedented attacks. They are even going out of their way to minimize real and credible threats against a man's wife and against innocent government workers.

It's time for a Joseph Welch moment. "Have you no decency? At long last, have you no shame?"

The Washington Free Beacon

http://freebeacon.com/blog/breaking-liberals-suddenly-care-wasting-taxpayer-money/

Breaking: Liberals Suddenly Care About Wasting Taxpayer Money

By Elizabeth Harrington, 4/11/18

I suddenly have a lot of competition covering my beat. Who knew the mainstream media cared how our taxpayer dollars are wasted?

Security costs for cabinet secretaries are "steep." Spending is "lavish" again. When, God forbid, a secretary takes his wife with him on a business trip, CNN is there with the documents in hand, showing her "involvement."

The New York Times is now giving tips on how to save taxpayers money, while lambasting Treasury Secretary Steven Mnuchin's use of military charter flights. (Mnuchin's travel ended up costing half of what Obama administration secretaries spent on average. Oddly, the Times never followed up.)

The latest target is Scott Pruitt, arguably President Trump's most effective cabinet secretary. While there is questionable conduct for sure, like using an obscure law to give aides huge taxpayer-funded raises, it's curious the media suddenly care how much international junkets cost.

The first scandal that caught the press's attention was Pruitt's trip to Italy last summer to attend the G-7 summit, which cost $84,000 in airfare and security, roughly the same that Lisa Jackson, Obama's first EPA administrator, spent on average on flights and security for four international trips.

The headlines for Jackson's trip to the same summit in Syracuse, Italy, in early 2009 were slightly different.

The Times has hit Pruitt for his "extravagant spending" on private flights and 24-hour security. But not too long ago it was the Times defending lavish trips on the taxpayer's dime.

"There is nothing like a little Mediterranean beach vacation to unwind," the Times wrote back in August 2010. Do tell.

"Unless you happen to travel with dozens of Secret Service agents, trailed by photographers and dogged by controversy."

Ah, poor Michelle Obama. She just wanted to get away, but those mean Republicans had to spoil her vacation.

"Michelle Obama hoped to enjoy a quiet summer break in southern Spain with her younger daughter and a few friends," the Times wrote. "But the Andalusian getaway has gotten away from her as the European media document her every flamenco dance step and critics back home question the wisdom of such a lavish vacation, which involves at least some taxpayer money, in a time of austerity."

"At least some" turned into a measly $467,585, including $26,670.61 for a "chauffeur tour of Costa del Sol."

The Times wrote approvingly of Mrs. Obama and "her entourage" touring the "picturesque southern city of Ronda," and hobnobbing with Eva Longoria Parker and Antonio Banderas.

Besides, reports on the trips "had been exaggerated," the Times said.

"Mrs. Obama is not traveling with 40 friends," the Times assured us. It was only "two friends and four of their daughters, as well as a couple of aides and a couple of advance staff members."

It was no big deal for Mrs. Obama and friends to stay at the five-star Hotel Villa Padierna, where "at least 30 rooms were reserved for the entourage."

"The hotel is one of Spain's more luxurious establishments, with rooms ranging from $500-a-night to a $6,600 suite with 24-hour butler service," the Times wrote.

"While some Americans frown," the Times concluded, "the Spanish eagerly welcomed the Obama group, seeing it as a boost for a tourism sector severely hit by the country's economic downturn."

It might not have been great for the taxpayers, but it was good for Spain!

It wasn't just the first lady's taxpayer-funded trips the media were either uninterested in covering or eager to defend. It was the entire Obama cabinet.

In fact, then-congressman Barney Frank had to apologize for scrutinizing Timothy Geitner's use of military charter flights, which cost at least $150,000 for international trips and totaled "several million dollars a year."

The only Obama official who came close to scrutiny from the mainstream media was Attorney General Eric Holder, who along with his predecessor Michael Mukasey and former FBI director Robert Mueller, now the special counsel, spent over $11 million on taxpayer-funded private jets for personal travel.

Holder used the FBI's private Gulfstream V to go to the Super Bowl in New Orleans in 2013, costing $15,000 each way.

Holder alone spent $4.3 million on travel in three years, including 31 personal trips and "two jaunts to Martha's Vineyard that totaled $95,184 in flight expenses."

Tom Price was ousted from the Department of Health and Human Services for far less.

The media didn't report on Energy Secretary Ernest Moniz's travel costs either, which lasted up until 11 days before Trump's inauguration. Who knows how much it cost us for Moniz to travel to Mexico City on January 9, 2017, to sign a "non-binding" document on electricity grids.

Republicans shouldn't be hypocrites, careless, or both, when it comes to how they spend our money. But let's not kid ourselves by pretending the media actually cares.

Reuters

https://www.reuters.com/article/us-usa-biofuels/trump-administration-weighs-high-ethanol-fuel-waiver-to-placate-farmers-idUSKBN1HI3EU

Trump administration weighs high-ethanol fuel waiver to placate farmers

By Jarrett Renshaw and Chris Prentice, 4/11/18, 7:20 PM

NEW YORK (Reuters) - The Trump administration is considering allowing the sale of a higher ethanol fuel blend in the summer, a source familiar with the issue said, a move that would placate corn growers worried about the future of U.S. biofuels policy.

President Donald Trump recently met with the heads of the Environmental Protection Agency and the U.S. Department of Agriculture to discuss ways to make the Renewable Fuel Standard less expensive to the oil industry without undercutting demand for ethanol.

The RFS requires refiners to add increasing volumes of biofuels like corn-based ethanol into the nation's fuel supply each year which is a boon to farmers but a headache for refining companies that must either blend the fuels themselves or purchase credits from those who do.

Trump has tried in vain over the past several months to broker a deal between "Big Oil" and "Big Corn" over the issue, and has faced mounting pressure from lawmakers in the Midwest who are concerned that he will weaken domestic demand for ethanol at a time farmers are already facing a potential trade war with China that could hurt export demand for corn and soybeans.

Sources had told Reuters this week that Trump was temporarily suspending his consideration of a refining industry-backed proposal to cap prices for blending credits, an idea that the biofuels industry has opposed as damaging to farmers.

But in the meantime, the administration is considering moving forward with plans to allow for the ethanol industry's long sought waiver to sell gasoline containing 15 percent ethanol in the summer, instead of the usual 10 percent blend, the source familiar with the issue told Reuters on Wednesday.

The higher ethanol blend, called E15, is currently banned by the Environmental Protection Agency due to concerns it contributes to smog on hot days, a worry that biofuels advocates say is baseless. If done soon, the waiver could be in effect in time for the 2018 summer driving season.

EPA spokeswoman Liz Bowman did not immediately respond to a request for comment. White House spokeswoman Kelly Love did not comment on the E15 waiver but said that during Trump's meeting Monday he "instructed his Cabinet to continue to explore options that protect American farmers and America's refinery workers."

Biofuels proponents have heaped pressure on the White House after reports that the EPA was granting dozens of small refineries exemptions from the RFS to help them avoid the costs of compliance, something the ethanol industry says will weaken demand for their product.

On Monday, Trump acknowledged farmers may bear the brunt of the economic harm if China retaliates against Washington's threat of tariffs, noting that "we'll make it up to them". Many U.S. farmers are battling debt after years of excess global supplies and depressed prices.

"We need some good news out here," said Monte Shaw, the Executive Director of the Iowa Renewable Fuels Association.

"The best news (Trump) could give us right now is year-round sales of E15," he said.

City Journal

https://www.city-journal.org/html/scott-pruitt-warrior-science-15821.html

Scott Pruitt, Warrior for Science

By John Tierney, 4/11/18

Imagine if the head of a federal agency announced a new policy for its scientific research: from now on, the agency would no longer allow its studies to be reviewed and challenged by independent scientists, and its researchers would not share the data on which their conclusions were based. The response from scientists and journalists would be outrage. By refusing peer review from outsiders, the agency would be rejecting a fundamental scientific tradition. By not sharing data with other researchers, it would be violating a standard transparency requirement at leading scientific journals. If a Republican official did such a thing, you'd expect to hear denunciations of this latest offensive in the "Republican war on science."

That's the accusation being hurled at Scott Pruitt, the Republican who heads the Environmental Protection Agency. But Pruitt hasn't done anything to discourage peer review. In fact, he's done the opposite: he has called for the use of more

independent experts to review the EPA's research and has just announced that the agency would rely only on studies for which data are available to be shared. Yet Democratic officials and liberal journalists have denounced these moves as an "attack on science," and Democrats have cited them (along with accusations of ethical violations) in their campaign to force Pruitt out of his job.

How could "the party of science," as Democrats like to call themselves, be opposed to transparency and peer review? Because better scientific oversight would make it tougher for the EPA to justify its costly regulations. To environmentalists, rigorous scientific protocols are fine in theory, but not in practice if they interfere with the green political agenda. As usual, the real war on science is the one waged from the left.

The EPA has been plagued by politicized science since its inception in 1970. One of its first tasks was to evaluate the claim, popularized in Rachel Carson's Silent Spring, that the use of DDT pesticide was causing an epidemic of cancer. The agency held extensive hearings that led to the conclusion that DDT was not a carcinogen, a finding that subsequent research would confirm. Yet the EPA administrator, William Ruckelshaus, reportedly never even bothered to read the scientific testimony. Ignoring the thousands of pages of evidence, he declared DDT a potential carcinogen and banned most uses of it.

Since then, the agency has repeatedly been criticized for relying on weak or cherry-picked evidence to promote needless alarms justifying the expansion of its authority (and budget). Its warnings about BPA, a chemical used in plastics, were called unscientific by leading researchers in the field. Its conclusion that secondhand smoke was killing thousands of people annually was ruled by a judge to be in violation of "scientific procedure and norms"—and was firmly debunked by later research.

To justify the costs of the Obama administration's Clean Power Plan restricting coal-burning power plants, the EPA relied on a controversial claim that a particular form of air pollution (from small particulates) was responsible for large numbers of premature deaths. To reach that conclusion, the agency ignored contradictory evidence and chose to rely on 1990s research whose methodology and conclusions were open to question. The EPA's advisory committee on air pollution, a group of outside scientists, was sufficiently concerned at the time to ask to see the supporting data. But the researchers and the EPA refused to share the data, citing the confidentiality of the medical records involved, and they have continued refusing demands from Congress and other researchers to share it, as Steve Milloy recounts in his book, Scare Pollution: Why and How to Fix the EPA.

Pruitt's new policy will force the EPA to rely on studies for which data is available to other researchers, ensuring the transparency that enables findings to be tested and confirmed. So why is he being attacked? His critics argue that some worthwhile research will be ignored because it is based on confidential records that are impractical to share. They say that it would cost the EPA several hundred million dollars to redact personal medical information in the air-pollution studies used to justify the Obama administration's Clean Power Plan. But even if that estimate is correct—it seems awfully high—it's a pittance compared with the costs of the EPA's regulations. The Obama EPA estimated the annual cost of its Clean Power Plan at $8 billion; others estimated it at more than $30 billion. Before saddling utility customers with those higher bills year after year, the EPA could at least pay for reliable research.

Pruitt's critics have also excoriated him for insisting that the EPA's advisory boards consist of independent scientists, ending the practice of including researchers who receive grants from the agency—exactly the sort of conflict of interest that progressives object to when researchers receive money from private industry. He has also proposed an analysis of climate change using a "red-team/blue-team" exercise, an innovative technique that has been used to draw up plans at the Defense Department and the CIA and by private industry for industrial operations and projects such as designing spacecraft. A group of outside experts, the red team, is brought in to critique the work of the in-house blue team, which then responds, and the teams keep going back and forth, under the supervision of a moderator. It's an enhanced form of peer review, forcing researchers and bureaucrats to defend or reconsider their ideas, and ideally leading to sounder conclusions and better plans. A version of this exercise has already been used to bolster the case for man-made global warming, as noted by Joseph Majkut of the Niskanen Institute.

Given the high stakes and the many uncertainties related to climate change—the dozens of computer climate models, the widely varying estimates of costs and benefits of mitigation strategies—who could object to studying the problem carefully? Yet Pruitt's proposal has been denounced by Democrats as well as liberal Republicans like Christine Whitman, the former New Jersey governor, who argued that the facts are so well-established that further examination is unnecessary. As a former head of the EPA, Whitman no doubt appreciates how much easier it is to make regulations without the nuisance of debate. But what's good for bureaucrats is not good for science.

The Wall Street Journal

https://www.wsj.com/articles/u-s-weekly-jobless-claims-hold-below-300-000-for-longest-streak-on-record-1523536549

U.S. Weekly Jobless Claims Hold Below 300,000 For Longest Streak On Record

By Sarah Chaney, 4/12/18

WASHINGTON—The number of Americans claiming new unemployment benefits has never been so low for so long.

Initial jobless claims, a proxy for layoffs across the U.S., decreased by 9,000 to a seasonally adjusted 233,000 in the week ended April 7, the Labor Department said Thursday. This means claims have now held below 300,000 for 162 consecutive weeks, cementing the longest streak for weekly records dating back to 1967.

The current streak eclipsed the previous longest stretch that ended in April 1970.

The consistently low claims levels point to labor market health because they mean relatively few Americans are losing their jobs and applying for benefits to tide them over until they can find new employment.

After several years of consistent job growth, firms are reluctant to let employees go in a tightening labor market in which many available workers are quickly snapped up.

"Even if you aren't aggressively hiring, if you know the labor market is tight and it's going to be difficult to hire someone…you're only going to lay someone off if you had to," said Stephen Stanley, chief economist at Amherst Pierpont Securities.

Data on jobless claims can be volatile from week to week, especially around holidays when seasonal adjustments can be tricky.

"The changing date of the Easter holiday from year to year makes the seasonal adjustment process tricky from late March through late April, so further volatility in headline claims over the next few weeks can't be ruled out," wrote Ian Shepherdson, chief economist at Pantheon Macroeconomics, in a note to clients.

The four-week moving average of initial claims, a more-stable measure, increased last week to 230,000.

The low level of claims is among multiple signs of health in the U.S. labor market. The unemployment rate has held at 4.1% since October, its lowest level since late 2000. Employers have added to nonfarm payrolls for 90 straight months in the longest continuous jobs expansion on record.

Thursday's report showed the number of claims workers made for longer than a week increased by 53,000 to 1,871,000 in the week ended March 31. That figure, known as continuing claims, is reported with a one-week lag.

The Washington Post

https://www.washingtonpost.com/world/middle_east/russia-seeks-to-allay-fears-of-open-conflict-with-the-us-over-syria/2018/04/12/2d2407c4-3e38-11e8-8d53-eba0ed2371cc_story.html?utm_term=.587c5a0bc9a8

As Fears Mount Over Open U.S.-Russia Conflict, Moscow Seeks To Lower The Temperature

By Anton Troianovski, Louisa Loveluck, 4/12/18

MOSCOW — Russian officials on Thursday sought to tamp down public fears of a looming conflict with the United States, even as Syrian government forces took control of the town where they are suspected of carrying out a chemical attack last weekend.

Russian military police also entered Douma on Thursday to act as "guarantors of law and order in the town," the Russian Defense Ministry said, according to Russian news agencies. Russian troops had arrived earlier Monday under the terms of a surrender deal reached with the rebels after the suspected chemical attack — which Russia and Syria say did not happen.

The recapture of Douma, in the region of Eastern Ghouta on the outskirts of Damascus, effectively represents the end of the war between Syrian President Bashar al-Assad and the rebel groups opposing his rule. Although chunks of the country remain under opposition control, none are as symbolic as Eastern Ghouta.

But the situation in Syria remained in flux ahead of an anticipated airstrike by the United States, which President Trump has signaled he plans to carry out in response to the suspected use of chemical weapons by Assad's forces.

Trump appeared to moderate his tone with a tweet early Thursday, saying he did not mean to suggest that missile strikes are imminent.

"Never said when an attack on Syria would take place," he tweeted. "Could be very soon or not so soon at all!"

A spokesman for the Kremlin told reporters Thursday that Russia is watching the American declarations closely.

"We continue to believe that it is extremely important to avoid any steps that may lead to an increase of tensions in Syria," Dmitry Peskov said.

Russian officials in recent days had warned of the possibility of a direct military confrontation with the United States as a result of a U.S. strike. Any missile attack that puts Russian lives at risk, Moscow has said, would result in Russia striking back at the missiles and at the planes or ships that launched them.

Russia has deployed air defense systems in Syria, including its sophisticated S-400 long-range surface-to-air missile system. The fact that thousands of Russian troops and military advisers are stationed across the country means there's a chance that a large-scale U.S. strike on Syrian government forces would — deliberately or not — also kill Russians, military analysts in Moscow say.

In the wake of Trump's Wednesday tweet warning Russia of a planned U.S. missile strike, however, Moscow appears to be trying to make clear that it does not want a war and that a limited attack that doesn't risk Russian lives would not precipitate a military response.

Moscow bureau chief Anton Troianovski describes Russia's tensions with the U.S. and how state media are covering the alleged chemical weapons attack in Syria. (Sarah Parnass, Anton Troianovski/The Washington Post)

"I rule out a scenario in which the United States will intentionally strike a facility in Syria where Russian servicemen are located," Military Sciences Academy Vice President Sergei Modestov said in Thursday's edition of the government newspaper Rossiyskaya Gazeta.

The Kommersant newspaper quoted anonymous Defense Ministry sources as saying that Russia's General Staff was in touch with the U.S. Joint Chiefs of Staff and expected to receive coordinates on airstrike targets from the Pentagon to avoid Russian casualties.

"Right now, the talk is about the necessity of de-escalation," said Alexander Golts, an independent military analyst in Moscow. "We've practically come to the brink of war."

On the ground, fighters from the hard-line Jaish al-Islam group have trickled out of Douma in recent days under the terms of a deal that followed Saturday's suspected chemical attack. Local residents said Wednesday that the militants had insisted on emptying their magazines into the air instead of handing them to the Syrian military, and that they wounded civilians in the process.

But by Thursday morning, a monitoring group reported that they had surrendered their weapons altogether. Russia says that more than 13,000 militants and their families have left Douma since April 1.

Negotiations for the group's withdrawal had taken months, stalling and resuming as the fighting ebbed and flowed. But Jaish al-Islam's political chief said Thursday that the suspected chemical attacks had been the final straw.

"Of course, the chemical attack is what pushed us to agree," Yasser Dalwan told the Agence France-Presse news agency.

The World Health Organization has said that during the shelling of Douma on Saturday, about 500 patients exhibited "signs and symptoms consistent with exposure to toxic chemicals."

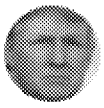
A network of local flight monitors said they had tracked several helicopters heading southwest from a government air base on Saturday evening. The same models of aircraft were then seen circling over Douma at 7:26 p.m. and 7:38 p.m.

Reports of a suspected gas attack began circulating minutes later. In one apartment block, rescuers would later find rooms filled with tangled bodies and the stench of chlorine. Some people had died foaming at the mouth, according to video footage.

Russia, however, says that its specialists who have visited Douma have found no evidence of a chemical attack. Instead, Saturday's incident represented the latest example of rebel trying to stage such an attack to undermine the Assad regime, Lt. Gen. Viktor Poznikhir, deputy chief of operations of the Russian General Staff, said Wednesday.

Rebel supporters on Saturday "once again tried to imitate in front of video cameras a staged chemical attack on civilians in the town of Douma," he said.

TRUMP TWEETS

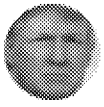


Donald J. Trump @realDonaldTrump · 4h

Good luck to Mike Pompeo during his Confirmation Hearing today. He will be a great Secretary of State!

5.9K 6.0K 29K

Show this thread



Donald J. Trump @realDonaldTrump · 4h

Never said when an attack on Syria would take place. Could be very soon or not so soon at all! In any event, the United States, under my Administration, has done a great job of ridding the region of ISIS. Where is our "Thank you America?"

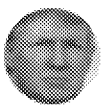
29K 14K 55K

Show this thread

Donald J. Trump @realDonaldTrump · 4h

California Governor Jerry Brown is doing the right thing and sending the National Guard to the Border. Thank you Jerry, good move for the safety of our Country!

4.3K 8.1K 45K



Donald J. Trump @realDonaldTrump · 4h

If I wanted to fire Robert Mueller in December, as reported by the Failing New York Times, I would have fired him. Just more Fake News from a biased newspaper!

10K 10K 45K

EPA News Highlights 4.12.18

The Oklahoman: EPA Gains Clouded By Controversies Involving Pruitt

It looked for a time last week as though Scott Pruitt, embroiled in another controversy, might be shown the door as administrator of the Environmental Protection Agency. But Pruitt remains on the job and we hope that continues, because he's made a difference at the EPA. At the same time, however, it's hard to ignore the constant drumbeat of criticism, even if it largely stems from those on the left who were mortified when President Trump tapped Pruitt for the job and have worked unceasingly to derail his work since arriving in Washington. Yet pointing at the other guy and saying "He (or she) did plenty of things wrong, too," isn't a great defense. Pruitt has led major reform at EPA by, among other things, undoing the Waters of the U.S. rule, working to repeal the Clean Power Plan and revising burdensome fuel-economy standards, all products of the Obama administration. These moves and others have enraged the left and he'll continue to be their chief target, but he nonetheless should take pains not to give them more fodder for their assaults.

The Daily Caller: SCOOP: The White House Just Got Pruitt's Plan To Repeal WOTUS. Here Are The Details

White House officials are reviewing an updated Environmental Protection Agency (EPA) proposal to repeal the Obama administration's "waters of the United States" that expanded federal control over waters on private property. EPA officials submitted a supplemental proposal to the Office of Management and Budget (OMB) on Thursday. The proposal clarifies the agency is in fact repealing the Obama-era regulation and addressing some concerns brought up by stakeholders. The proposal also states EPA will be re-codifying the pre-Obama definition of WOTUS, The Daily Caller News Foundation has learned. The Obama administration finalized the Clean Water Rule in 2015 that expanded the definition of "waters of the United States" (WOTUS), arguing the rule was needed to clear up uncertainties in the wake of two U.S. Supreme Court decisions. More than half of U.S. states sued EPA to have the rule overturned. The courts quickly issued regulatory stays on the Clean Water Rule, meaning it never really went into effect. Manufacturers, energy companies, farmers, ranchers and land developers said the Obama-era rule would only make it harder to do business and manage land.

CBS News: Here Are Some Of The Threats Made Against EPA Administrator Scott Pruitt

CBS News has obtained an August 2017 report prepared by the Environmental Protection Agency's office of inspector general that contains a list of 13 threats made against EPA Administrator Scott Pruitt and his family. The threats range in severity, credibility and specificity. One tweet flagged by investigators said, "Pruitt, I'm gonna find you and put a bullet between your eyes. Don't think I'm joking. I'm planning this." Investigators believe the threat was made by someone living in India. Another person wished the administrator "a very painful and horrible death through poisoning. Please explain the scientific method to this freaking neanderthal." The inspector general also looked into a complaint that "unknown protesters attempted to disrupt the EPA Administrator's speech during a closed event." Another person emailed the EPA threatening to dump old paint outside Pruitt's door. The threats took various forms -- some arriving via social media and email, others by postcard. Pruitt's daughter received a menacing message on Facebook, the document reveals.

CNN: Vote Slated For Thursday For Former Inhofe Aide Wheeler To Be EPA's No. 2

The Senate is set to vote on Andrew Wheeler to be the number two official at the Environmental Protection Agency amid ethics concerns plaguing EPA chief Scott Pruitt and calls from Democrats for him to resign. If Pruitt left, it could fall to Wheeler to run the agency until a new administrator is confirmed. Two GOP leadership aides told CNN they expected Wheeler to be approved, which would make him the latest appointee at the agency with close ties to the energy industry. While there is widespread opposition to Wheeler in the Democratic caucus, two Democrats running for reelection from energy producing states that strongly backed President Donald Trump in 2016 have said they will vote for him: Joe Manchin of West Virginia and Heidi Heitkamp of North Dakota.

Bloomberg: Here's Why Friends And Foes Of EPA Chief Pruitt Are So Adamant

Supporters and detractors of Environmental Protection Agency head Scott Pruitt agree on this much: He matters. Narrow that list to the new rules that have actually been issued, and Pruitt's impact is even harder to spot. Of the 24 economically significant regulations that have been approved by the White House under President Donald Trump, just

one was issued by the EPA, according to data posted by the Office of Information and Regulatory Affairs. And that rule set the amount of renewable fuels that must be used in 2018 -- a regulation the EPA must issue every year, regardless of who's in charge. "Without a doubt, Scott Pruitt has been the single most effective appointment of the president of the United States," said Tim Huelskamp, president of the Heartland Institute, an industry-funded nonprofit that advocates for less regulation.

The Washington Times: Here Are The Legitimate Death Threats Against Scott Pruitt That Dems Claim Don't Exist

One of the more sickening episodes of the full-court press by members of The Swamp against EPA Administrator Scott Pruitt is the claim that he has spent too much money on extravagant security details. Democrats in the Senate have questioned the legitimacy of death threats against Pruitt and his family and have demanded hearings to investigate the matter: Two top Democrats on the committee, ranking member Thomas R. Carper of Delaware and Sheldon Whitehouse of Rhode Island, on Tuesday demanded such hearings, saying they have confidential documents that contradict public statements made by Pruitt, EPA spokespersons and President Donald Trump regarding the administrator's security spending. The lawmakers in their letter asserted that the documents in their hands fall far short of supporting claims by Pruitt's office that he needed elaborate security measure to protect him from death threats.

The Washington Free Beacon: Breaking: Liberals Suddenly Care About Wasting Taxpayer Money

I suddenly have a lot of competition covering my beat. Who knew the mainstream media cared how our taxpayer dollars are wasted? Security costs for cabinet secretaries are "steep." Spending is "lavish" again. When, God forbid, a secretary takes his wife with him on a business trip, CNN is there with the documents in hand, showing her "involvement." The New York Times is now giving tips on how to save taxpayers money, while lambasting Treasury Secretary Steven Mnuchin's use of military charter flights. (Mnuchin's travel ended up costing half of what Obama administration secretaries spent on average. Oddly, the Times never followed up.) The latest target is Scott Pruitt, arguably President Trump's most effective cabinet secretary. While there is questionable conduct for sure, like using an obscure law to give aides huge taxpayer-funded raises, it's curious the media suddenly care how much international junkets cost. The first scandal that caught the press's attention was Pruitt's trip to Italy last summer to attend the G-7 summit, which cost $84,000 in airfare and security, roughly the same that Lisa Jackson, Obama's first EPA administrator, spent on average on flights and security for four international trips. The headlines for Jackson's trip to the same summit in Syracuse, Italy, in early 2009 were slightly different. The Times has hit Pruitt for his "extravagant spending" on private flights and 24-hour security. But not too long ago it was the Times defending lavish trips on the taxpayer's dime. "There is nothing like a little Mediterranean beach vacation to unwind," the Times wrote back in August 2010. Do tell.

Reuters: Trump Administration Weighs High-Ethanol Fuel Waiver To Placate Farmers

The Trump administration is considering allowing the sale of a higher ethanol fuel blend in the summer, a source familiar with the issue said, a move that would placate corn growers worried about the future of U.S. biofuels policy. President Donald Trump recently met with the heads of the Environmental Protection Agency and the U.S. Department of Agriculture to discuss ways to make the Renewable Fuel Standard less expensive to the oil industry without undercutting demand for ethanol. The RFS requires refiners to add increasing volumes of biofuels like corn-based ethanol into the nation's fuel supply each year which is a boon to farmers but a headache for refining companies that must either blend the fuels themselves or purchase credits from those who do.

City Journal: Scott Pruitt, Warrior for Science

Imagine if the head of a federal agency announced a new policy for its scientific research: from now on, the agency would no longer allow its studies to be reviewed and challenged by independent scientists, and its researchers would not share the data on which their conclusions were based. The response from scientists and journalists would be outrage. By refusing peer review from outsiders, the agency would be rejecting a fundamental scientific tradition. By not sharing data with other researchers, it would be violating a standard transparency requirement at leading scientific journals. If a Republican official did such a thing, you'd expect to hear denunciations of this latest offensive in the "Republican war on science." That's the accusation being hurled at Scott Pruitt, the Republican who heads the Environmental Protection Agency. But Pruitt hasn't done anything to discourage peer review. In fact, he's done the opposite: he has called for the use of more independent experts to review the EPA's research and has just announced

that the agency would rely only on studies for which data are available to be shared. Yet Democratic officials and liberal journalists have denounced these moves as an "attack on science," and Democrats have cited them (along with accusations of ethical violations) in their campaign to force Pruitt out of his job.

National News Highlights 4.12.18

The Wall Street Journal: U.S. Weekly Jobless Claims Hold Below 300,000 for Longest Streak on Record
The number of Americans claiming new unemployment benefits has never been so low for so long. Initial jobless claims, a proxy for layoffs across the U.S., decreased by 9,000 to a seasonally adjusted 233,000 in the week ended April 7, the Labor Department said Thursday. This means claims have now held below 300,000 for 162 consecutive weeks, cementing the longest streak for weekly records dating back to 1967. The current streak eclipsed the previous longest stretch that ended in April 1970. The consistently low claims levels point to labor market health because they mean relatively few Americans are losing their jobs and applying for benefits to tide them over until they can find new employment. After several years of consistent job growth, firms are reluctant to let employees go in a tightening labor market in which many available workers are quickly snapped up.

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TRUMP TWEETS

The Oklahoman
http://newsok.com/epa-gains-clouded-by-controversies-involving-pruitt/article/5590556
EPA Gains Clouded By Controversies Involving Pruitt
By The Oklahoman Editorial Board, 4/12/18

It looked for a time last week as though Scott Pruitt, embroiled in another controversy, might be shown the door as administrator of the Environmental Protection Agency. But Pruitt remains on the job and we hope that continues, because he's made a difference at the EPA.

At the same time, however, it's hard to ignore the constant drumbeat of criticism, even if it largely stems from those on the left who were mortified when President Trump tapped Pruitt for the job and have worked unceasingly to derail his work since arriving in Washington.

Late last week, the federal government's top ethics official wrote a letter to the person in charge of ethics at the EPA warning of possible ethics violations by Pruitt, who served six years as Oklahoma's attorney general before going to Washington.

"Reports of the administrator making frequent official trips to his home state at government expense to offset the expense of returning home for personal or political reasons do raise concerns about whether the administrator is using his public office for personal gain in violation of ethics rules," the letter said.

In recent weeks, some Republican members of Congress have called for Pruitt to resign or be fired. One member, Rep. Carlos Curbelo of Florida, said Pruitt's "corruption scandals are an embarrassment to the administration."

Among other things, Pruitt has been criticized for occasional first-class travel — the bill during his first year on the job totaled about $105,000, according to Politico — and for expensive security expenditures. Most recently, Pruitt has come under fire for spending several months last year in a lobbyist's D.C. condominium at $50 per night, and for giving two top aides large pay raises after the White House denied the request.

Pruitt has said the raises were enacted not by him but by someone else, and that they had been reversed. As for the condo deal, it was approved by an EPA ethics official who has been at the agency 18 years. Mollie Ziegler Hemmingway, writing at the conservative website The Federalist, noted: "The general rental space also was used by three members of Congress for fundraising on days Pruitt wasn't in town. He wasn't invited to the events, didn't attend them, and even if he had no ethics laws would have been violated …"

Conservative defenders of Pruitt note that the Obama EPA had numerous controversies when led by administrators Lisa Jackson and Gina McCarthy. It is indeed a hoot that Jackson, who used a fake name and private email address while conducting official EPA business, has criticized Pruitt for a lack of transparency.

Yet pointing at the other guy and saying "He (or she) did plenty of things wrong, too," isn't a great defense. Pruitt has led major reform at EPA by, among other things, undoing the Waters of the U.S. rule, working to repeal the Clean Power Plan and revising burdensome fuel-economy standards, all products of the Obama administration. These moves and others have enraged the left and he'll continue to be their chief target, but he nonetheless should take pains not to give them more fodder for their assaults.

The Daily Caller

http://dailycaller.com/2018/04/12/scoop-white-house-gets-pruitts-plan-to-repeal-wotus/

SCOOP: The White House Just Got Pruitt's Plan To Repeal WOTUS. Here Are The Details

By Michael Bastasch, 4/12/18

White House officials are reviewing an updated Environmental Protection Agency (EPA) proposal to repeal the Obama administration's "waters of the United States" that expanded federal control over waters on private property.

EPA officials submitted a supplemental proposal to the Office of Management and Budget (OMB) on Thursday. The proposal clarifies the agency is in fact repealing the Obama-era regulation and addressing some concerns brought up by stakeholders. The proposal also states EPA will be re-codifying the pre-Obama definition of WOTUS, The Daily Caller News Foundation has learned.

The Obama administration finalized the Clean Water Rule in 2015 that expanded the definition of "waters of the United States" (WOTUS), arguing the rule was needed to clear up uncertainties in the wake of two U.S. Supreme Court decisions.

More than half of U.S. states sued EPA to have the rule overturned. The courts quickly issued regulatory stays on the Clean Water Rule, meaning it never really went into effect. Manufacturers, energy companies, farmers, ranchers and land developers said the Obama-era rule would only make it harder to do business and manage land.

President Donald Trump signed an executive order last year, asking EPA and the U.S. Army Corps of Engineers to replace the Obama-era WOTUS rule with one consistent with former U.S. Supreme Court Justice Antonin Scalia's plurality opinion in the 2006 Rapanos v. United States case.

EPA began the WOTUS repeal process in June and published a plan for WOTUS repeal in the Federal Register the following month. EPA's new submission clarifies some concerns stakeholders expressed last summer, but the details aren't clear because it's still under review.

"From day one, EPA and the Department of the Army have been committed to providing certainty and clarity to our state and tribal co-regulators and farmers, ranchers and other stakeholders across the country," an EPA spokeswoman told TheDCNF.

"After reviewing this input, EPA and the Army have decided to issue a supplemental proposal to provide the public with additional clarity on the scope of the agencies' efforts," the spokeswoman said.

The move comes after environmentalists published a memo related to Clean Water Act enforcement. The memo, obtained by Public Employees for Environmental Responsibility (PEER), detailed how Pruitt would reserve the final say on jurisdiction under the Clean Water Act that was formerly delegated to regional officers.

PEER lambasted Pruitt's "restore regulatory certainty" as a "crude Clean Water Act coup d'état."

"This action subjects safeguards for clean water across the U.S. to filtration through one politician's hands," PEER's New England Director Kyla Bennett said in a statement. "Every corporation that wants a pass on Clean Water Act compliance is invited to privately meet with the most user friendly EPA Administrator in history."

However, Pacific Legal Foundation attorney Jonathan Wood said the memo could "promote both consistency in application and more accountability." PLF has challenged WOTUS in federal court.

"As it stands now, it makes a huge difference which regional office reviews your case — and often which bureaucrat within the office you happen to draw," Wood told TheDCNF. "Centralizing final decision making should lead to more consistent decision-making."

"There's also an important accountability issue here," Wood said. "Clean Water Act decisions require a mix of science and policy judgment."

"As the person appointed by the President and confirmed by the Senate to make those judgments, Pruitt can be forced to answer for the exercise of that policy-making power," Wood said. "When these decisions are made by anonymous regional bureaucrats, it is exponentially harder to hold anyone accountable."

CBS News

https://www.cbsnews.com/news/here-are-some-of-the-threats-made-against-epa-administrator-scott-pruitt/

Here Are Some Of The Threats Made Against EPA Administrator Scott Pruitt

By Jacqueline Alemany, Arden Farhi, 4/11/18

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The threats took various forms -- some arriving via social media and email, others by postcard.

Pruitt's daughter received a menacing message on Facebook, the document reveals.

In certain cases, cases were referred to the Justice Department, but just one was deemed serious enough to prosecute. The report covers the period from Oct. 2016 to Aug. 2017.

EPA Spokesman Jahan Wilcox responded that Pruitt had faced "unprecedented" threats.

In an email to the EPA's "Threat Coordination Group," Patrick Sullivan, the assistant inspector general for investigations at the EPA outlined an incident that occurred on March 6, 2018, in which a trespasser gained entry to the EPA headquarters and identified himself as a student attending a "Microsoft event."

"The personal asked about Scott Pruitt and wanted to know where Pruitt's office was and if Pruitt ever walked in the hallway outside the room," wrote Sullivan.

The intruder was soon escorted out of the EPA but called the desk phone of an employee and left voicemails following the intrusion claiming "he can gain entry into EPA space anytime he wants."

The security vulnerability was soon thereafter investigated.

Wilcox told CBS News, "We do not comment on matters pertaining to EPA's IG." A spokesperson for the EPA inspector general had no comment.

In early March, Pruitt told CBS News, "The quantity and the type of threats I've faced are unprecedented."

The inspector general report also details threats made against EPA employees and facilities and two threats against Gina McCarthy, the EPA administrator under President Obama.

McCarthy's office received a series of hostile phone calls from a person who is currently being prosecuted for making "Felony Threats." The caller said, "I will kill ya'll (sic) and f*** up Gina McCarthy," according to the report.

Democratic Sens. Tom Carper, of Delaware, and Sheldon Whitehouse, of Rhode Island, released a letter on Tuesday to Wyoming Sen. John Barrasso, chairman of the Senate committee that oversees the EPA, that said the assertions of "ongoing threats associated with the administrator's air travel" were inconsistent with an internal memo they obtained from a whistleblower at the EPA.

The memo, dated Feb. 14, 2018, according to the letter sent by Carper and Whitehouse, claimed that "EPA Intelligence has not identified any specific direct threat to the EPA administrator."

In a statement provided to the New York Times, Barrasso said that he Democrats had selectively released parts of the internal memo.

On Wednesday, Democratic senators held a press conference demanding answers from Pruitt about why he had ordered costly security measures and full time protection -- even on personal trips.

Sen. Tom Udall, D-New Mexico, said Pruitt had committed some of the worst "ethical transgressions of the entire Trump administration."

"The list of abuses just keeps getting longer," Udall told reporters at the press conference. "Lavish first class flights around the world, swanky hotel stays, taxpayers footing the bill for personal trips to Oklahoma, a $43,000 soundproof phone booth in his office, taking 30 EPA enforcement officers away from investigating polluters to serve as his round the clock personal security detail, speeding down the streets of Washington with sirens and lights blaring to get to fancy restaurants, huge unauthorized salary raises for his friends, allowing a close aide not to come to work for three months while still getting paid, and finally detailing EPA staff to find him a place to live. These are just a few of the things he is doing."

As Udall sees it, "Scott Pruitt has misused taxpayer dollars while enhancing his own personal perks."

The AP first reported that Pruitt's 20-member full time security detail "approached $3 million when pay is added in travel expenses." But EPA spokesman Jahan Wilcox defended the EPA administrator and said he has faced "unprecedented" threats.

The EPA administrator has been embroiled in scandal during his term, facing persistent rumors about the future of his job in the Trump administration. But he has also been called the president's most effective Cabinet secretary by Republican allies around Washington – including the president himself.

Last Thursday, the president praised Pruitt aboard Air Force One en route to Washington, calling him "a good man."

"I think he's done a fantastic job at EPA," Trump told reporters. "I think he's done an incredible job. He's been very courageous. Hasn't been easy, but I think he's done an absolutely fantastic job. I think he'll be fine."

The president added that the White House was looking into reports about Pruitt's ethical entanglements: he has not only come under fire for habitually traveling first class or by military jet at considerable taxpayer expense but he is now also is under investigation by House Oversight Committee Chairman Trey Gowdy for a housing arrangement in Washington, D.C., in 2017. ABC News first reported that Pruitt had lived in a Capitol Hill apartment owned by the wife of a fossil fuels lobbyist and rented the space for $50 a night – only paying for nights that he slept there.

Here are some of the documents obtained by CBS News:

CNN

https://www.cnn.com/2018/04/12/politics/andrew-wheeler-environmental-protection-agency-scott-pruitt-congress/index.html

Vote Slated For Thursday For Former Inhofe Aide Wheeler To Be EPA's No. 2

By Daniella Diaz and Ted Barrett, 4/12/18

The Senate is set to vote on Andrew Wheeler to be the number two official at the Environmental Protection Agency amid ethics concerns plaguing EPA chief Scott Pruitt and calls from Democrats for him to resign.

If Pruitt left, it could fall to Wheeler to run the agency until a new administrator is confirmed.

Two GOP leadership aides told CNN they expected Wheeler to be approved, which would make him the latest appointee at the agency with close ties to the energy industry.

His firm's clients include Murray Energy, which bills itself as "the largest coal mining company in America."

Senate Minority Leader Chuck Schumer, D-New York, blasted Wheeler as "a former industry lobbyist who has worked on behalf of big polluters and climate change deniers. He has spent years working to undermine or lobby against the environmental protections he may soon oversee."

Prior to his lobbying work, Wheeler served on Capitol Hill as a Republican staff member for the Senate Environment and Public Works Committee and as a top aide to Sen. Jim Inhofe, an Oklahoma Republican and an outspoken climate change skeptic who told CNN last month the EPA is "brainwashing our kids."

New Mexico Democratic Sen. Tom Udall said Wednesday that Wheeler should be carefully vetted, as if he were taking over for Pruitt now. Udall told reporters that he believes Wheeler wouldn't be a much better option to run the agency.

"The problem with the Wheeler nomination is if Trump (fires Pruitt) tomorrow, Wheeler is in fact the administrator, and that is a very, very serious problem," Udall said. "I know that there are many Republicans who haven't spoken out yet, but privately they are very disturbed by what Scott Pruitt is doing at the EPA."

While there is widespread opposition to Wheeler in the Democratic caucus, two Democrats running for reelection from energy producing states that strongly backed President Donald Trump in 2016 have said they will vote for him: Joe Manchin of West Virginia and Heidi Heitkamp of North Dakota.

"After meeting with Mr. Wheeler and reviewing his record, I've decided to support his nomination," Heitkamp said in a statement provided to CNN. "I believe he'll be open to working on issues important to North Dakota in a pragmatic and fair way, and I'll hold him accountable to make sure he implements the mission of the EPA in a way that works for my state."

One key centrist Republican has also signaled support for Wheeler.

"Mr. Wheeler has demonstrated that he understands the mission of the EPA and the role of Congress when it comes to oversight and accountability," said Maine Sen. Susan Collins in a statement.

Wheeler's nomination comes amid a steady stream of negative headlines involving Pruitt in recent weeks and months that has official Washington wondering whether the embattled agency chief can hold onto his job.

Most recently, Pruitt has been fighting stories revealing he paid about $6,100 over the course of a six-month lease last year to rent a room in a condo owned by Vicki Hart, a health care lobbyist whose husband, Steven Hart, has lobbied the EPA. His daughter also reportedly lived there while she was interning in Washington.

He paid $50 per night, according to the reports, and paid only for the nights he used the condo.

The federal government's top voice on ethics David Apol sent a letter to the agency outlining areas of concern regarding Pruitt. Apol, the acting director and general counsel of the Office of Government Ethics, summarized reports of Pruitt's conduct, including the rental agreement, as well as EPA spending on Pruitt's travel and security.

The letter also expresses concern with reports of Pruitt bypassing the White House to give raises to favored aides and other employees who faced job changes after raising concerns over his conduct.

Bloomberg

https://www.bloomberg.com/news/articles/2018-04-12/here-s-why-friends-and-foes-of-epa-chief-pruitt-are-so-adamant

Here's Why Friends And Foes Of EPA Chief Pruitt Are So Adamant

By Christopher Flavelle, Ari Natter, and Jennifer Dlouhy, 4/12/18

Supporters and detractors of Environmental Protection Agency head Scott Pruitt agree on this much: He matters.

Pruitt, whose continued tenure has been put in doubt by a series of ethics controversies, has attracted an extraordinary outpouring of support among conservative boosters who say he's the most effective member of President Donald Trump's cabinet. Likewise, the organizers of a "Boot Pruitt" movement see him as a serious risk to the environment he's supposed to be protecting.

Yet it is hard to assess Pruitt's tenure by traditional standards. Many of his high-profile initiatives, such as overturning the Obama administration's plan to curb carbon emissions from power plants, face years of legal challenges.

Nor can Pruitt's significance be tied to a roster of regulatory actions -- including those designed to jettison old rules. Federal data show that since Trump's inauguration, the agency has submitted nine "economically significant" rules, defined as those with likely economic impact of at least $100 million, to the White House for review. By comparison, the Department of Health and Human Services has produced 31 such rules, the Department of Labor six and the Department of the Interior five.

Narrow that list to the new rules that have actually been issued, and Pruitt's impact is even harder to spot. Of the 24 economically significant regulations that have been approved by the White House under President Donald Trump, just one was issued by the EPA, according to data posted by the Office of Information and Regulatory Affairs. And that rule set the amount of renewable fuels that must be used in 2018 -- a regulation the EPA must issue every year, regardless of who's in charge.

Those figures don't include regulations that were in the works when Pruitt arrived in Washington and that he has blocked.

EPA spokesman Jahan Wilcox cited the agency's work to repeal Obama-era rules governing carbon dioxide emissions and water pollution as evidence Pruitt is advancing Trump's agenda.

"From advocating to leave the Paris Accord, working to repeal Obama's Clean Power Plan and Waters of the United States, declaring a war on lead and cleaning up toxic Superfund sites, Administrator Pruitt is focused on advancing President Trump's agenda of regulatory certainty and environmental stewardship," Wilcox said in an emailed statement.

A fuller assessment of Pruitt's 14 months in office shows that he's laid the groundwork for a wholesale revision of environmental policy, one that delights anti-regulatory groups and frightens environmentalists.

"Without a doubt, Scott Pruitt has been the single most effective appointment of the president of the United States," said Tim Huelskamp, president of the Heartland Institute, an industry-funded nonprofit that advocates for less regulation.

Vera Pardee, senior counsel for the Center for Biological Diversity, shared that view, albeit from the opposite direction. "The deregulatory agenda of Trump finds its most destructive expression in Mr. Pruitt," she said.

That shared view of Pruitt's importance helps explain the effort that advocates have poured into keeping him in his job -- or getting him removed. The outpouring is far greater than was expended on behalf of other embattled cabinet members, such as Secretary of State Rex Tillerson or Veterans Affairs Secretary David Shulkin who both ended up losing their jobs.

Pruitt has been dogged by a series of controversies, including expensive first-class tickets and 24-hour security details, hefty raises for aides and renting a Capitol Hill bedroom from a lobbyist for $50 a night. In response, environmentalists have mounted a campaign to seek Pruitt's ouster; advocates of smaller government, meanwhile, have set up a coordinated effort of their own to retain him at the EPA.

Both sides put Pruitt's effort to reduce the influence of academic scientists within the EPA near the top of their list of reasons why he matters. Pruitt has removed many of those scientists from advisory boards, replacing them with people who reflect the concerns of industries the EPA regulates.

Those boards are important. The Clean Air Scientific Advisory Committee, for example, helps establish ozone standards that the agency is required to implement.

JunkScience.com
Steven Milloy, publisher of the website JunkScience.com and a senior fellow at the Energy and Legal Institute, praised Pruitt for installing as chairmen of the Science Advisory Board and the Clean Air Scientific Advisory Committee "people I consider to be very strongly grounded in science."

Michael Halpern, deputy director of the Center for Science and Democracy at the Union of Concerned Scientists, echoed Milloy's point about the importance of those boards -- although he characterized Pruitt's appointments as "stacking" them.

Another point of agreement is Pruitt's changing the rules on so-called "secret science." He has directed the EPA to use only research whose underlying data is publicly available. Environmental advocates say that prevents the EPA from issuing air and water regulations supported by health research, since the identities of patients studied in those papers is kept private.

Huelskamp, of the Heartland Institute, praised that change. Halpern criticized it.

Pruitt also has made major policy pivots outside the formal rulemaking process. That includes the EPA's decision not to ban the commercial use of the pesticide chlorpyrifos and methylene chloride used in paint strippers. The EPA also has relaxed air pollution requirements via memos and internal opinions -- navigating around the federal rulemaking process in a way that has already drawn at least one legal challenge.

Environmental advocates also argue that Pruitt has restrained the EPA's willingness to fine polluters for violating the law.

"If you look at his enforcement record, it is disastrous and terrifying," said Lukas Ross, climate and energy advocate for Friends of the Earth. "It's not just the number of cases lodged, but it's also the amount of money that's been captured through lodging those cases."

Equally consequential, Ross added, are Pruitt's efforts to change the mission of the agency, in a way that will drive away staff who care about protecting the environment.

"There is a very real threat of brain drain because of the morale crisis being created by Scott Pruitt," Ross said. "If I worked at the EPA, I would be thinking about quitting too."

On that point as well, Milloy, the Junk Science publisher, agreed.

"Are these people sad?" Milloy asked. "The rest of America is happy."

The Washington Times
https://www.washingtontimes.com/news/2018/apr/12/here-are-legitimate-death-threats-against-scott-pr/
Here Are The Legitimate Death Threats Against Scott Pruitt That Dems Claim Don't Exist
By Larry O'Connor, 4/12/18

One of the more sickening episodes of the full-court press by members of The Swamp against EPA Administrator Scott Pruitt is the claim that he has spent too much money on extravagant security details.

Democrats in the Senate have questioned the legitimacy of death threats against Pruitt and his family and have demanded hearings to investigate the matter:

Two top Democrats on the committee, ranking member Thomas R. Carper of Delaware and Sheldon Whitehouse of Rhode Island, on Tuesday demanded such hearings, saying they have confidential documents that contradict public statements made by Pruitt, EPA spokespersons and President Donald Trump regarding the administrator's security spending.

The lawmakers in their letter asserted that the documents in their hands fall far short of supporting claims by Pruitt's office that he needed elaborate security measure to protect him from death threats.

"Documents provided to us by EPA official(s) suggest the agency has relied on questionable threats to the Administrator, including reports of non-violent protests, negative feedback about the administrators actions or other First Amendment protected activity to justify millions of dollars in additional security spending, inducing first-class air travel, as compared to his predecessors at the agency," Carper and Whitehouse wrote.

This is how vicious the opposition to Pruitt has become. As if a person would go out of their way to have an obtrusive and heavy-handed security detail for no good reason.

CBS News has obtained (probably from staffers at the EPA hoping to push back on the despicable narrative from Senate Democrats) documentation on just some of the death threats against Pruitt that had been detailed in August 2017 and, no, the threats are not isolated to anonymous tweets:

In an email to the EPA's "Threat Coordination Group," Patrick Sullivan, the assistant inspector general for investigations at the EPA outlined an incident that occurred on March 6, 2018, in which a trespasser gained entry to the EPA headquarters and identified himself as a student attending a "Microsoft event."

"The person asked about Scott Pruitt and wanted to know where Pruitt's office was and if Pruitt ever walked in the hallway outside the room," wrote Sullivan.
The intruder was soon escorted out of the EPA but called the desk phone of an employee and left voicemails following the intrusion claiming "he can gain entry into EPA space anytime he wants."

The security vulnerability was soon thereafter investigated.

McCarthy's office received a series of hostile phone calls from a person who is currently being prosecuted for making "Felony Threats." The caller said, "I will kill ya'll (sic) and f*** up Gina McCarthy," according to the report.

The Daily Caller also has a summary of some of the threats Pruitt has had to deal with presumably from global warming enthusiasts who care more about carbon emission hysteria than they do human life:

Investigators flagged one tweet that stated: "Pruitt, I'm gonna find you and put a bullet between your eyes. Don't think I'm joking. I'm planning this." Investigators determined the threat came from someone living in India. The investigation is ongoing.

These types of threats were a common occurrence, the report notes.

For instance, another person mailed a postcard to Pruitt telling him to "get out while you still can, Scott, you are evil incarnate you ignorant fuck." An investigation was unable to determine who sent the message. The case was not presented to the United States Attorney's Office for prosecution.

Pruitt's opponents hate how effective he has been (as we detailed last week) and they hate that President Trump has stood by him in the face of unfair and duplicitous attacks against his ethics and credibility. But to question the cost of his security detail for partisan purposes is beyond the pale.

It's time for Senate Republicans to unequivocally stand behind Pruitt and publicly shame these Democrats for their unprecedented attacks. They are even going out of their way to minimize real and credible threats against a man's wife and against innocent government workers.

It's time for a Joseph Welch moment. "Have you no decency? At long last, have you no shame?"

The Washington Free Beacon

http://freebeacon.com/blog/breaking-liberals-suddenly-care-wasting-taxpayer-money/

Breaking: Liberals Suddenly Care About Wasting Taxpayer Money

By Elizabeth Harrington, 4/11/18

I suddenly have a lot of competition covering my beat. Who knew the mainstream media cared how our taxpayer dollars are wasted?

Security costs for cabinet secretaries are "steep." Spending is "lavish" again. When, God forbid, a secretary takes his wife with him on a business trip, CNN is there with the documents in hand, showing her "involvement."

The New York Times is now giving tips on how to save taxpayers money, while lambasting Treasury Secretary Steven Mnuchin's use of military charter flights. (Mnuchin's travel ended up costing half of what Obama administration secretaries spent on average. Oddly, the Times never followed up.)

The latest target is Scott Pruitt, arguably President Trump's most effective cabinet secretary. While there is questionable conduct for sure, like using an obscure law to give aides huge taxpayer-funded raises, it's curious the media suddenly care how much international junkets cost.

The first scandal that caught the press's attention was Pruitt's trip to Italy last summer to attend the G-7 summit, which cost $84,000 in airfare and security, roughly the same that Lisa Jackson, Obama's first EPA administrator, spent on average on flights and security for four international trips.

The headlines for Jackson's trip to the same summit in Syracuse, Italy, in early 2009 were slightly different.

The Times has hit Pruitt for his "extravagant spending" on private flights and 24-hour security. But not too long ago it was the Times defending lavish trips on the taxpayer's dime.

"There is nothing like a little Mediterranean beach vacation to unwind," the Times wrote back in August 2010. Do tell.

"Unless you happen to travel with dozens of Secret Service agents, trailed by photographers and dogged by controversy."

Ah, poor Michelle Obama. She just wanted to get away, but those mean Republicans had to spoil her vacation.

"Michelle Obama hoped to enjoy a quiet summer break in southern Spain with her younger daughter and a few friends," the Times wrote. "But the Andalusian getaway has gotten away from her as the European media document her every flamenco dance step and critics back home question the wisdom of such a lavish vacation, which involves at least some taxpayer money, in a time of austerity."

"At least some" turned into a measly $467,585, including $26,670.61 for a "chauffeur tour of Costa del Sol."

The Times wrote approvingly of Mrs. Obama and "her entourage" touring the "picturesque southern city of Ronda," and hobnobbing with Eva Longoria Parker and Antonio Banderas.

Besides, reports on the trips "had been exaggerated," the Times said.

"Mrs. Obama is not traveling with 40 friends," the Times assured us. It was only "two friends and four of their daughters, as well as a couple of aides and a couple of advance staff members."

It was no big deal for Mrs. Obama and friends to stay at the five-star Hotel Villa Padierna, where "at least 30 rooms were reserved for the entourage."

"The hotel is one of Spain's more luxurious establishments, with rooms ranging from $500-a-night to a $6,600 suite with 24-hour butler service," the Times wrote.

"While some Americans frown," the Times concluded, "the Spanish eagerly welcomed the Obama group, seeing it as a boost for a tourism sector severely hit by the country's economic downturn."

It might not have been great for the taxpayers, but it was good for Spain!

It wasn't just the first lady's taxpayer-funded trips the media were either uninterested in covering or eager to defend. It was the entire Obama cabinet.

In fact, then-congressman Barney Frank had to apologize for scrutinizing Timothy Geitner's use of military charter flights, which cost at least $150,000 for international trips and totaled "several million dollars a year."

The only Obama official who came close to scrutiny from the mainstream media was Attorney General Eric Holder, who along with his predecessor Michael Mukasey and former FBI director Robert Mueller, now the special counsel, spent over $11 million on taxpayer-funded private jets for personal travel.

Holder used the FBI's private Gulfstream V to go to the Super Bowl in New Orleans in 2013, costing $15,000 each way.

Holder alone spent $4.3 million on travel in three years, including 31 personal trips and "two jaunts to Martha's Vineyard that totaled $95,184 in flight expenses."

Tom Price was ousted from the Department of Health and Human Services for far less.

The media didn't report on Energy Secretary Ernest Moniz's travel costs either, which lasted up until 11 days before Trump's inauguration. Who knows how much it cost us for Moniz to travel to Mexico City on January 9, 2017, to sign a "non-binding" document on electricity grids.

Republicans shouldn't be hypocrites, careless, or both, when it comes to how they spend our money. But let's not kid ourselves by pretending the media actually cares.

Reuters
https://www.reuters.com/article/us-usa-biofuels/trump-administration-weighs-high-ethanol-fuel-waiver-to-placate-farmers-idUSKBN1HI3EU

Trump administration weighs high-ethanol fuel waiver to placate farmers

By Jarrett Renshaw and Chris Prentice, 4/11/18, 7:20 PM

NEW YORK (Reuters) - The Trump administration is considering allowing the sale of a higher ethanol fuel blend in the summer, a source familiar with the issue said, a move that would placate corn growers worried about the future of U.S. biofuels policy.

President Donald Trump recently met with the heads of the Environmental Protection Agency and the U.S. Department of Agriculture to discuss ways to make the Renewable Fuel Standard less expensive to the oil industry without undercutting demand for ethanol.

The RFS requires refiners to add increasing volumes of biofuels like corn-based ethanol into the nation's fuel supply each year which is a boon to farmers but a headache for refining companies that must either blend the fuels themselves or purchase credits from those who do.

Trump has tried in vain over the past several months to broker a deal between "Big Oil" and "Big Corn" over the issue, and has faced mounting pressure from lawmakers in the Midwest who are concerned that he will weaken domestic demand for ethanol at a time farmers are already facing a potential trade war with China that could hurt export demand for corn and soybeans.

Sources had told Reuters this week that Trump was temporarily suspending his consideration of a refining industry-backed proposal to cap prices for blending credits, an idea that the biofuels industry has opposed as damaging to farmers.

But in the meantime, the administration is considering moving forward with plans to allow for the ethanol industry's long sought waiver to sell gasoline containing 15 percent ethanol in the summer, instead of the usual 10 percent blend, the source familiar with the issue told Reuters on Wednesday.

The higher ethanol blend, called E15, is currently banned by the Environmental Protection Agency due to concerns it contributes to smog on hot days, a worry that biofuels advocates say is baseless. If done soon, the waiver could be in effect in time for the 2018 summer driving season.

EPA spokeswoman Liz Bowman did not immediately respond to a request for comment. White House spokeswoman Kelly Love did not comment on the E15 waiver but said that during Trump's meeting Monday he "instructed his Cabinet to continue to explore options that protect American farmers and America's refinery workers."

Biofuels proponents have heaped pressure on the White House after reports that the EPA was granting dozens of small refineries exemptions from the RFS to help them avoid the costs of compliance, something the ethanol industry says will weaken demand for their product.

On Monday, Trump acknowledged farmers may bear the brunt of the economic harm if China retaliates against Washington's threat of tariffs, noting that "we'll make it up to them". Many U.S. farmers are battling debt after years of excess global supplies and depressed prices.

"We need some good news out here," said Monte Shaw, the Executive Director of the Iowa Renewable Fuels Association.

"The best news (Trump) could give us right now is year-round sales of E15," he said.

City Journal

https://www.city-journal.org/html/scott-pruitt-warrior-science-15821.html

Scott Pruitt, Warrior for Science

By John Tierney, 4/11/18

Imagine if the head of a federal agency announced a new policy for its scientific research: from now on, the agency would no longer allow its studies to be reviewed and challenged by independent scientists, and its researchers would not share the data on which their conclusions were based. The response from scientists and journalists would be outrage. By refusing peer review from outsiders, the agency would be rejecting a fundamental scientific tradition. By not sharing data with other researchers, it would be violating a standard transparency requirement at leading scientific journals. If a Republican official did such a thing, you'd expect to hear denunciations of this latest offensive in the "Republican war on science."

That's the accusation being hurled at Scott Pruitt, the Republican who heads the Environmental Protection Agency. But Pruitt hasn't done anything to discourage peer review. In fact, he's done the opposite: he has called for the use of more independent experts to review the EPA's research and has just announced that the agency would rely only on studies for which data are available to be shared. Yet Democratic officials and liberal journalists have denounced these moves as an "attack on science," and Democrats have cited them (along with accusations of ethical violations) in their campaign to force Pruitt out of his job.

How could "the party of science," as Democrats like to call themselves, be opposed to transparency and peer review? Because better scientific oversight would make it tougher for the EPA to justify its costly regulations. To environmentalists, rigorous scientific protocols are fine in theory, but not in practice if they interfere with the green political agenda. As usual, the real war on science is the one waged from the left.

The EPA has been plagued by politicized science since its inception in 1970. One of its first tasks was to evaluate the claim, popularized in Rachel Carson's Silent Spring, that the use of DDT pesticide was causing an epidemic of cancer. The agency held extensive hearings that led to the conclusion that DDT was not a carcinogen, a finding that subsequent research would confirm. Yet the EPA administrator, William Ruckelshaus, reportedly never even bothered to read the scientific testimony. Ignoring the thousands of pages of evidence, he declared DDT a potential carcinogen and banned most uses of it.

Since then, the agency has repeatedly been criticized for relying on weak or cherry-picked evidence to promote needless alarms justifying the expansion of its authority (and budget). Its warnings about BPA, a chemical used in plastics, were called unscientific by leading researchers in the field. Its conclusion that secondhand smoke was killing thousands of people annually was ruled by a judge to be in violation of "scientific procedure and norms"—and was firmly debunked by later research.

To justify the costs of the Obama administration's Clean Power Plan restricting coal-burning power plants, the EPA relied on a controversial claim that a particular form of air pollution (from small particulates) was responsible for large numbers of premature deaths. To reach that conclusion, the agency ignored contradictory evidence and chose to rely on 1990s research whose methodology and conclusions were open to question. The EPA's advisory committee on air pollution, a group of outside scientists, was sufficiently concerned at the time to ask to see the supporting data. But the researchers and the EPA refused to share the data, citing the confidentiality of the medical records involved, and they have continued refusing demands from Congress and other researchers to share it, as Steve Milloy recounts in his book, Scare Pollution: Why and How to Fix the EPA.

Pruitt's new policy will force the EPA to rely on studies for which data is available to other researchers, ensuring the transparency that enables findings to be tested and confirmed. So why is he being attacked? His critics argue that some worthwhile research will be ignored because it is based on confidential records that are impractical to share. They say that it would cost the EPA several hundred million dollars to redact personal medical information in the air-pollution studies used to justify the Obama administration's Clean Power Plan. But even if that estimate is correct—it seems awfully high—it's a pittance compared with the costs of the EPA's regulations. The Obama EPA estimated the annual cost of its Clean Power Plan at $8 billion; others estimated it at more than $30 billion. Before saddling utility customers with those higher bills year after year, the EPA could at least pay for reliable research.

Pruitt's critics have also excoriated him for insisting that the EPA's advisory boards consist of independent scientists, ending the practice of including researchers who receive grants from the agency—exactly the sort of conflict of interest that progressives object to when researchers receive money from private industry. He has also proposed an analysis of climate change using a "red-team/blue-team" exercise, an innovative technique that has been used to draw up plans at the Defense Department and the CIA and by private industry for industrial operations and projects such as designing spacecraft. A group of outside experts, the red team, is brought in to critique the work of the in-house blue team, which then responds, and the teams keep going back and forth, under the supervision of a moderator. It's an enhanced form of peer review, forcing researchers and bureaucrats to defend or reconsider their ideas, and ideally leading to sounder conclusions and better plans. A version of this exercise has already been used to bolster the case for man-made global warming, as noted by Joseph Majkut of the Niskanen Institute.

Given the high stakes and the many uncertainties related to climate change—the dozens of computer climate models, the widely varying estimates of costs and benefits of mitigation strategies—who could object to studying the problem carefully? Yet Pruitt's proposal has been denounced by Democrats as well as liberal Republicans like Christine Whitman, the former New Jersey governor, who argued that the facts are so well-established that further examination is unnecessary. As a former head of the EPA, Whitman no doubt appreciates how much easier it is to make regulations without the nuisance of debate. But what's good for bureaucrats is not good for science.

The Wall Street Journal

https://www.wsj.com/articles/u-s-weekly-jobless-claims-hold-below-300-000-for-longest-streak-on-record-1523536549

U.S. Weekly Jobless Claims Hold Below 300,000 For Longest Streak On Record

By Sarah Chaney, 4/12/18

WASHINGTON—The number of Americans claiming new unemployment benefits has never been so low for so long.

Initial jobless claims, a proxy for layoffs across the U.S., decreased by 9,000 to a seasonally adjusted 233,000 in the week ended April 7, the Labor Department said Thursday. This means claims have now held below 300,000 for 162 consecutive weeks, cementing the longest streak for weekly records dating back to 1967.

The current streak eclipsed the previous longest stretch that ended in April 1970.

The consistently low claims levels point to labor market health because they mean relatively few Americans are losing their jobs and applying for benefits to tide them over until they can find new employment.

After several years of consistent job growth, firms are reluctant to let employees go in a tightening labor market in which many available workers are quickly snapped up.

"Even if you aren't aggressively hiring, if you know the labor market is tight and it's going to be difficult to hire someone…you're only going to lay someone off if you had to," said Stephen Stanley, chief economist at Amherst Pierpont Securities.

Data on jobless claims can be volatile from week to week, especially around holidays when seasonal adjustments can be tricky.

"The changing date of the Easter holiday from year to year makes the seasonal adjustment process tricky from late March through late April, so further volatility in headline claims over the next few weeks can't be ruled out," wrote Ian Shepherdson, chief economist at Pantheon Macroeconomics, in a note to clients.

The four-week moving average of initial claims, a more-stable measure, increased last week to 230,000.

The low level of claims is among multiple signs of health in the U.S. labor market. The unemployment rate has held at 4.1% since October, its lowest level since late 2000. Employers have added to nonfarm payrolls for 90 straight months in the longest continuous jobs expansion on record.

Thursday's report showed the number of claims workers made for longer than a week increased by 53,000 to 1,871,000 in the week ended March 31. That figure, known as continuing claims, is reported with a one-week lag.

The Washington Post

https://www.washingtonpost.com/world/middle_east/russia-seeks-to-allay-fears-of-open-conflict-with-the-us-over-syria/2018/04/12/2d2407c4-3e38-11e8-8d53-eba0ed2371cc_story.html?utm_term=.587c5a0bc9a8

As Fears Mount Over Open U.S.-Russia Conflict, Moscow Seeks To Lower The Temperature

By Anton Troianovski, Louisa Loveluck, 4/12/18

MOSCOW — Russian officials on Thursday sought to tamp down public fears of a looming conflict with the United States, even as Syrian government forces took control of the town where they are suspected of carrying out a chemical attack last weekend.

Russian military police also entered Douma on Thursday to act as "guarantors of law and order in the town," the Russian Defense Ministry said, according to Russian news agencies. Russian troops had arrived earlier Monday under the terms of a surrender deal reached with the rebels after the suspected chemical attack — which Russia and Syria say did not happen.

The recapture of Douma, in the region of Eastern Ghouta on the outskirts of Damascus, effectively represents the end of the war between Syrian President Bashar al-Assad and the rebel groups opposing his rule. Although chunks of the country remain under opposition control, none are as symbolic as Eastern Ghouta.

But the situation in Syria remained in flux ahead of an anticipated airstrike by the United States, which President Trump has signaled he plans to carry out in response to the suspected use of chemical weapons by Assad's forces.

Trump appeared to moderate his tone with a tweet early Thursday, saying he did not mean to suggest that missile strikes are imminent.

"Never said when an attack on Syria would take place," he tweeted. "Could be very soon or not so soon at all!"

A spokesman for the Kremlin told reporters Thursday that Russia is watching the American declarations closely.

"We continue to believe that it is extremely important to avoid any steps that may lead to an increase of tensions in Syria," Dmitry Peskov said.

Russian officials in recent days had warned of the possibility of a direct military confrontation with the United States as a result of a U.S. strike. Any missile attack that puts Russian lives at risk, Moscow has said, would result in Russia striking back at the missiles and at the planes or ships that launched them.

Russia has deployed air defense systems in Syria, including its sophisticated S-400 long-range surface-to-air missile system. The fact that thousands of Russian troops and military advisers are stationed across the country means there's a chance that a large-scale U.S. strike on Syrian government forces would — deliberately or not — also kill Russians, military analysts in Moscow say.

In the wake of Trump's Wednesday tweet warning Russia of a planned U.S. missile strike, however, Moscow appears to be trying to make clear that it does not want a war and that a limited attack that doesn't risk Russian lives would not precipitate a military response.

Moscow bureau chief Anton Troianovski describes Russia's tensions with the U.S. and how state media are covering the alleged chemical weapons attack in Syria. (Sarah Parnass, Anton Troianovski/The Washington Post)

"I rule out a scenario in which the United States will intentionally strike a facility in Syria where Russian servicemen are located," Military Sciences Academy Vice President Sergei Modestov said in Thursday's edition of the government newspaper Rossiyskaya Gazeta.

The Kommersant newspaper quoted anonymous Defense Ministry sources as saying that Russia's General Staff was in touch with the U.S. Joint Chiefs of Staff and expected to receive coordinates on airstrike targets from the Pentagon to avoid Russian casualties.

"Right now, the talk is about the necessity of de-escalation," said Alexander Golts, an independent military analyst in Moscow. "We've practically come to the brink of war."

On the ground, fighters from the hard-line Jaish al-Islam group have trickled out of Douma in recent days under the terms of a deal that followed Saturday's suspected chemical attack. Local residents said Wednesday that the militants had insisted on emptying their magazines into the air instead of handing them to the Syrian military, and that they wounded civilians in the process.

But by Thursday morning, a monitoring group reported that they had surrendered their weapons altogether. Russia says that more than 13,000 militants and their families have left Douma since April 1.

Negotiations for the group's withdrawal had taken months, stalling and resuming as the fighting ebbed and flowed. But Jaish al-Islam's political chief said Thursday that the suspected chemical attacks had been the final straw.

"Of course, the chemical attack is what pushed us to agree," Yasser Dalwan told the Agence France-Presse news agency.

The World Health Organization has said that during the shelling of Douma on Saturday, about 500 patients exhibited "signs and symptoms consistent with exposure to toxic chemicals."

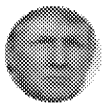
A network of local flight monitors said they had tracked several helicopters heading southwest from a government air base on Saturday evening. The same models of aircraft were then seen circling over Douma at 7:26 p.m. and 7:38 p.m.

Reports of a suspected gas attack began circulating minutes later. In one apartment block, rescuers would later find rooms filled with tangled bodies and the stench of chlorine. Some people had died foaming at the mouth, according to video footage.

Russia, however, says that its specialists who have visited Douma have found no evidence of a chemical attack. Instead, Saturday's incident represented the latest example of rebel trying to stage such an attack to undermine the Assad regime, Lt. Gen. Viktor Poznikhir, deputy chief of operations of the Russian General Staff, said Wednesday.

Rebel supporters on Saturday “once again tried to imitate in front of video cameras a staged chemical attack on civilians in the town of Douma,” he said.

TRUMP TWEETS



Donald J. Trump @realDonaldTrump · 4h

Good luck to Mike Pompeo during his Confirmation Hearing today. He will be a great Secretary of State!

5.9K 6.0K 29K

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Donald J. Trump @realDonaldTrump · 4h

Never said when an attack on Syria would take place. Could be very soon or not so soon at all! In any event, the United States, under my Administration, has done a great job of ridding the region of ISIS. Where is our “Thank you America?”

29K 14K 55K

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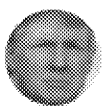

Donald J. Trump @realDonaldTrump · 4h

California Governor Jerry Brown is doing the right thing and sending the National Guard to the Border. Thank you Jerry, good move for the safety of our Country!

4.3K 8.1K 45K

Donald J. Trump @realDonaldTrump · 4h

If I wanted to fire Robert Mueller in December, as reported by the Failing New York Times, I would have fired him. Just more Fake News from a biased newspaper!

10K 10K 45K

Message

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Unilever Admits to Struggle With Plastic Wrapping

By Stephen Gardner

Posted June 21, 2018, 3:01 AM

Dealing with plastic packaging is proving tough for the world's largest consumer goods company.

Pruitt's Ethics Allegations Dog Nominees for EPA Posts at Hearing

By Sylvia Carignan

Posted June 20, 2018, 12:54 PM

Members of a Senate panel pressed two nominees for EPA posts, including Superfund program chief, for assurances they wouldn't fall prey to unethical behavior.

Senate GOP Ally of Pruitt's Says Concerns Allayed After Meeting (1)

By Ari Natter

Posted June 20, 2018, 10:46 AMUpdated June 20, 2018, 12:27 PM

EPA Administrator Scott Pruitt's longtime friend and political ally on Capitol Hill is walking back his criticism of the embattled agency leader after the two met June 19 evening.

INSIDEEPA.COM ARTICLES

Pruitt's Scandals Complicate Path For EPA Waste, International Nominees

Ongoing concerns about EPA Administrator Scott Pruitt's ethics scandals, the agency's limited responses to oversight requests and other issues will make it difficult for President Donald Trump's nominees to head the agency's waste and international affairs offices to gain Senate approval, Democratic senators told a June 20 environment committee hearing.

Reversing Course, Inhofe Defends Pruitt, Calling Accusations 'Lies'

Sen. James Inhofe (R-OK) is strongly defending EPA Administrator Scott Pruitt against numerous allegations of unethical conduct, calling them "outrageous lies," an apparent reversal from a week ago when the senator said he was upset by Pruitt's missteps and suggested the administrator might need to step down.

ATSDR Seeks To Downplay Effect Of PFAS Risk Levels Stricter Than EPA's

A federal health agency has released its much-anticipated draft toxicological profile for perfluorinated chemicals that recommends risk values more conservative than EPA's, but the agency is downplaying potential health concerns from exposures above its limits, cautioning the public not to read its levels as cleanup or health effects standards.

GREENWIRE ARTICLES

Inhofe defends Pruitt, despite 'questionable judgment'

Geof Koss and Kevin Bogardus, E&E News reporters

Published: Wednesday, June 20, 2018

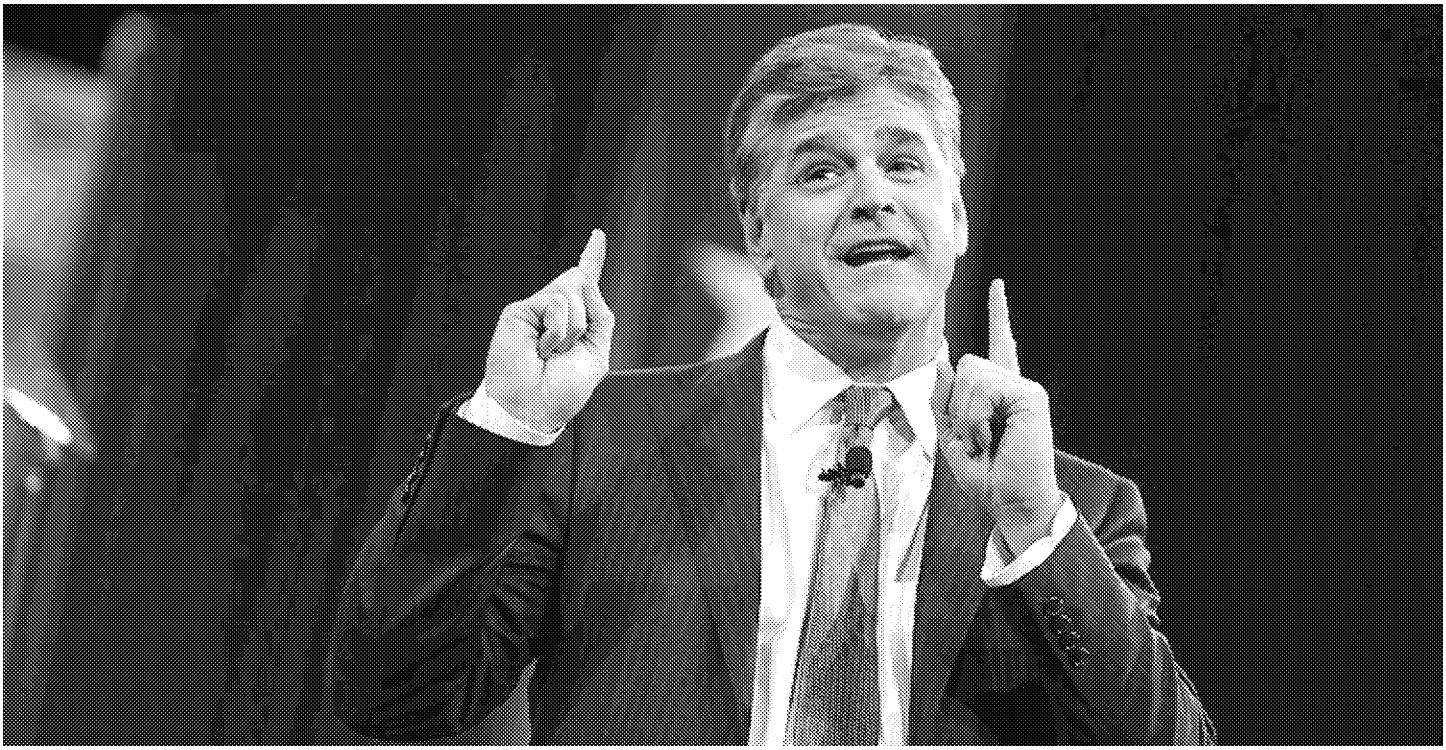
EPA Administrator Scott Pruitt (left) and Sen. Jim Inhofe (R-Okla.) are shown here in 2010 during Pruitt's campaign for Oklahoma attorney general. Pruitt/Facebook

Following a lengthy meeting with EPA Administrator Scott Pruitt yesterday evening, Sen. Jim Inhofe (R-Okla.) is dismissing the host of ethics questions surrounding his onetime political protégé as "misrepresentations."

In an interview with E&E News and other media outlets in his office this morning, Inhofe pinned blame for Pruitt's ethics scandals on California billionaire Tom Steyer, "disgruntled" former employees, the media and what he described as unprecedented security threats against the former Oklahoma attorney general.

Sean Hannity declined jet ride with Pruitt

Zack Colman, E&E News reporter Published: Wednesday, June 20, 2018



Fox News talk show host Sean Hannity was invited to ride on a jet with EPA Administrator Scott Pruitt last summer. Gage Skidmore/Flickr

EPA officials asked Sean Hannity to hop into a jet with agency chief Scott Pruitt when he barnstormed farming communities to promote changes to a water pollution rule.

The Fox News host ultimately didn't join Pruitt for a jaunt across Oklahoma to talk about the Waters of the United States rule, emails shared with E&E News by the Natural Resources Defense Council showed. But the communications, obtained via Freedom of Information Act request, shed more light on EPA's media strategy.

https://www.eenews.net/greenwire/2018/06/20/stories/1060085237

Federal study sounds alarm on nonstick materials

Ariel Wittenberg, E&E News reporter

Published: Wednesday, June 20, 2018

Health and Human Services headquarters in Washington. Matthew G. Bisanz/Wikipedia

The Trump administration has released a politically charged toxicology report about nonstick chemicals showing they can endanger human health at significantly lower levels than EPA has previously called safe.

The draft report from the Department of Health and Human Services' Agency for Toxic Substances and Disease Registry is a toxicological profile of four types of stain- and water-resistant chemicals.

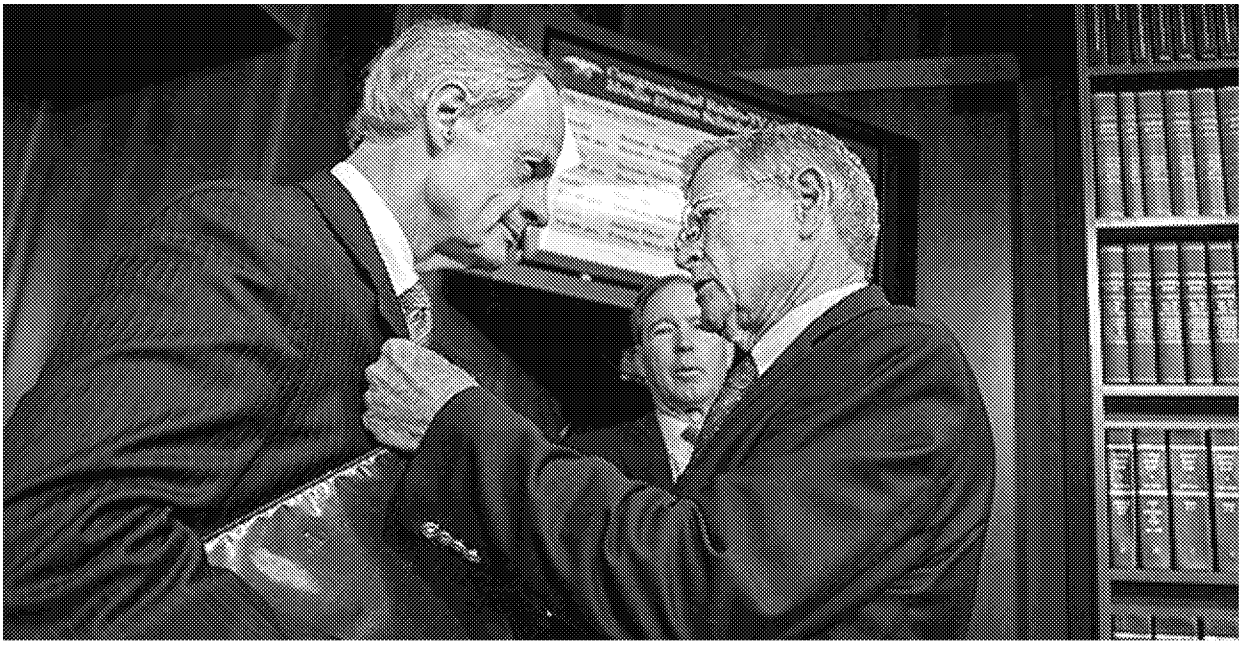
It finds that so-called "minimum risk levels" for the toxins should be seven to 10 times lower than standards set by EPA in 2016.

https://www.eenews.net/greenwire/2018/06/20/stories/1060085217

Carper, Inhofe spar over Pruitt at confirmation hearing

Corbin Hiar, E&E News reporter

Published: Wednesday, June 20, 2018



Sens. Tom Carper (D-Del.) and Jim Inhofe (R-Okla.) are shown here in a 2015 file photo. The two lawmakers this morning squared off during a hearing over EPA Administrator Scott Pruitt's alleged actions. Tom Williams/CQ Roll Call/Associated Press

Arguments over EPA Administrator Scott Pruitt's scandals, and the media's coverage of them, overshadowed a Senate confirmation hearing this morning for two nominees who hope to help him lead the agency.

Delaware Sen. Tom Carper, the top Democrat on the Environment and Public Works Committee, used his opening statement to criticize Chairman John Barrasso (R-Wyo.) for failing to promptly call Pruitt to testify as news reports raised questions about work that staffers have allegedly done for his family, his spending on travel and a secure phone booth, and his use of sports tickets secured by executives with business before the agency, among other issues.

Career staff warned cuts would cripple research office

Corbin Hiar, E&E News reporter

Published: Wednesday, June 20, 2018

EPA headquarters in Washington. Tim Evanson/Flickr

EPA career officials warned the Trump administration last year that its proposed staffing changes and budget shortfalls could undermine the agency's scientific research, documents show.

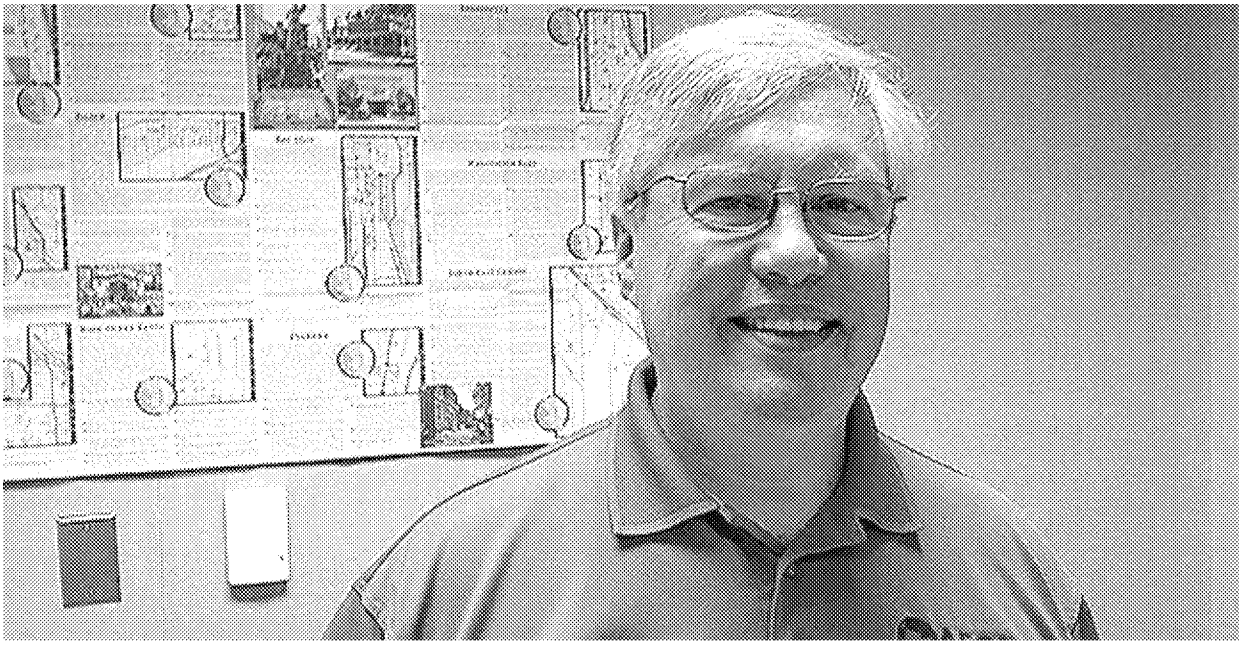
As political appointees began assembling a strategic plan to guide the agency through 2022, staffers in the Office of Research and Development alerted them to risks facing their programs.

The most serious risk — in terms of both its likelihood of happening and the extent of its potential impact — was that ORD would be unable to maintain a "sustainable workforce," says the undated draft assessment staffers had to provide to EPA's Office of Program Accountability and Resource Management by Aug. 2, 2017.

Union chief heads for the exit

Kevin Bogardus, E&E News reporter

Published: Wednesday, June 20, 2018



John O'Grady is president of the American Federation of Government Employees Council 238, EPA's largest union. O'Grady/Flickr

John O'Grady, head of EPA's largest employee union, is retiring.

As president of American Federation of Government Employees Council 238, he represents about 8,000 EPA employees through 14 local unions nationwide. O'Grady said he will retire from EPA and resign from his position as head of the council at the end of this month.

In an interview with E&E News, O'Grady, 66, said the time was right to depart, noting his wife was also retiring as a teaching assistant job in the Naperville, Ill., school district.

"I looked at all the financial numbers, and it just made sense," O'Grady said. "I wanted to enjoy some things."

Denise Morrison, executive vice president for the council, will be its acting president after O'Grady's departure. A special election will be held later on to fill the job permanently.

CHEMICAL WATCH ARTICLES

US senators demand release of controversial PFAS report

Bill would continue current EPA funding, differing little from House plan

20 June 2018 / PFCs, United States

A US Senate committee has ordered the release of controversial toxicological profiles for four per- and polyfluoroalkyl substances (PFASs).

The demand comes in a report accompanying a fiscal 2019 spending bill, approved by the Senate Appropriations Committee on 14 June. It directs the Agency for Toxic Substances and Disease Registry (ATSDR) to release its analyses within 15 days of the final approval of the EPA's 2019 spending plan.

Adoption of the plan is unlikely to occur before the autumn, so the instruction may end up having little practical effect. Nevertheless it does amount to a public statement.

A row erupted after the public release of internal EPA documents showed that the ATSDR assessments propose safe exposure levels for PFASs significantly below the EPA's non-enforceable drinking water guidelines. In internal agency emails, officials called this a "public relations nightmare" and NGOs have claimed the Trump administration is blocking release of the assessments.

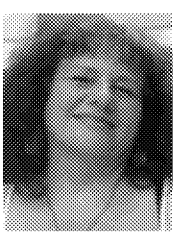
The Senate committee not only demands release of the study, but also asks for a report "identifying any changes made" to the toxicology profiles after 30 January.

Spending bill

The Senate spending bill would continue current funding for the US EPA and its programmes in chemical research and management, differing only slightly from legislation approved earlier by the House Appropriations Committee.

Both bills reject Trump administration proposals for huge spending cuts. They provide the same $92.5m for the "toxics risk review and prevention" funding category as in fiscal 2017 and 2018.

The senators instruct the EPA to follow lawmakers' 2018 order to continue operating the Integrated Risk Information System (IRIS) programme under the Office of Research and Development. The House bill does not mention IRIS, and so the programme appears to be safe.



Julie Miller

Reporter

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- Pruitt downplays EPA role in PFAS study row

- Congress rejects Trump plan to slash EPA budget
- US Congress likely to reject EPA cuts again
- Trump proposes slashing EPA budget again

Further Information:

- Senate appropriations report

National Academies forms flame retardant committee

20 June 2018 / Built environment, Children's products, Electrical & electronics, Halocarbons, United States

The National Academies has appointed a new committee to assess potential chronic health hazards, posed by organohalogen flame retardants.

Its findings will ultimately inform a Consumer Product Safety Commission (CPSC) assessment of the risk that additive, nonpolymeric organohalogen flame retardants (OFRs) pose to human health from four consumer products categories.

These are: children's products, upholstered residential furniture, mattresses and the external casings of electronics devices.

The CPSC's work on the products comes after its September decision to grant an NGO petition to begin a rulemaking that could see OFRs banned from these applications.

The National Academies of Sciences, Engineering, and Medicine (NASEM) is tasked with producing a hazard assessment plan that the CPSC-convened Chronic Advisory Panel (CHAP) will use when completing its risk assessment.

The committee's provisional slate – pending a public comment period and final approval by the National Academies – comprises:

- David Dorman (chair) – professor of toxicology, North Carolina State University;
- Hugh Barton – associate research fellow, Pfizer, Inc;
- Karen Blackburn – Victor Mills Society research fellow, The Procter and Gamble Co;
- John Bucher – senior scientist, National Toxicology Program (NTP);
- Julie Daniels – professor, University of North Carolina at Chapel Hill;
- Jennifer Freeman – associate professor, School of Health Sciences at Purdue University;
- Kamel Mansouri – lead computational chemist, Integrated Laboratory Systems;
- Carmen Messerlian – research scientist, Harvard TH Chan School of Public Health;
- David Reif – associate professor, North Carolina State University;
- Gina Solomon – principal investigator, Public Health Institute; and
- Chihae Yang – chief scientific officer, Altamira LLC.

Comments on the committee appointments are being accepted for 20 days, following the original posting of membership.

Related Articles

- US body seeks nominees for flame retardant hazard assessment
- US CPSC investigates possible action against organohalogen flame retardants

Further Information:

- NAS release
- Plan overview
- Committee membership

Campaigners secure third paint stripper victory with Home Depot

Retailer to phase out NMP, methylene chloride products by year's end

20 June 2018 / Built environment, Retail, Solvents, United States

NGO campaigners are celebrating the latest "nail in the coffin" for paint strippers containing methylene chloride and N-methylpyrrolidone (NMP), following news that the world's largest home improvement retailer, Home Depot, will no longer sell them.

In recent weeks, retail giants Lowe's and Sherwin-Williams have pledged to phase out the sale of the products by the year's end. This week, Home Depot announced plans to do the same.

"To build upon our strategy to maintain continual improvement in health and environmental safety for products, we have added many alternative chemical paint removers, and will phase out paint removal products that contain methylene chloride and N-Methylpyrrolidone (NMP) by the end of 2018," says the store's website.

Mike Schade, Mind the Store campaign director at Safer Chemicals, Healthy Families, said that the action means "the time for hazardous paint strippers is over".

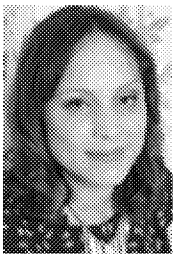
He urged the retailers which continue to stock these products – including Menards, Walmart and Ace Hardware – to phase out the products' sales by the end of the year.

Canadian NGO Environmental Defence similarly called for Canadian Tire and Home Hardware to follow suit.

Mike Belliveau, executive director of NGO, the Environmental Health Strategy Center, also urged the US EPA to take action on the two solvents in order to "sweep up the laggards".

The agency announced last month that it will finalise a rule on methylene chloride, after its proposal to ban or restrict methylene chloride and NMP in paint strippers appeared to be shelved last year.

But thus far, it has not indicated a timeline for this final rule, nor whether it will address NMP.



Tammy Lovell

Business reporter

Related Articles

- Lowe's to phase out methylene chloride, NMP paint removers
- Sherwin-Williams to stop selling methylene chloride paint removers
- Mind the Store campaign to target more US retailers in 2018
- Walmart aligns disclosure policy with Californian law
- US EPA commits to act on methylene chloride paint strippers
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA

Further Information:

- Home Depot announcement
- Mind the Store release

Andy Igrejas: 1970-2018

Campaigner and powerful voice in TSCA negotiations dies aged 47

21 June 2018 / North America, TSCA

Chemical Watch has learned of the recent passing of US public health advocate Andy Igrejas at the age of 47.

Founder of the NGO Safer Chemicals, Healthy Families, Mr Igrejas built a coalition of more than 450 organisations to advocate for stronger chemical safety laws and better protection of consumer health.

He was a powerful voice in the negotiations to reform the US's outdated federal TSCA law. And despite not endorsing the final bill, SCHF says Mr Igrejas "directly wrung more health-protective concessions even up through the final hours of negotiations."

Mr Igrejas also conceived the Mind the Store Campaign which has helped drive retailers to act on chemicals issues where the government has failed to do so. Just this week, the campaign played an instrumental part in convincing Home Depot to halt the sale of paint strippers containing methylene chloride, where the EPA has stalled on its own rule.

Beyond his legislative and grassroots efforts, Mr Igrejas will be remembered for his effective communication and sense of humour.

"His humour was infectious, and no one escaped his wit," an SCHF statement says. "Andy could have had a second career in stand-up comedy. But in those moments, he wasn't simply entertaining. For Andy, it was also a subversive organising technique that endeared him to allies and disarmed our opponents."

"He was a passionate, talented and committed advocate who dedicated his life to protecting children and families from toxic chemicals," said Sarah Vogel, vice president for health at the Environmental Defense Fund (EDF). "He will be greatly missed."

And Cal Dooley, president and CEO of the American Chemistry Council (ACC) said: "Over the years and through many hours of dialogue and negotiation, I and other members of the ACC team developed great respect for the commitment and passion Andy brought to his work to promote the safe use of chemicals.

"With Andy's passing, the environmental community has lost a tireless voice and dedicated advocate."

Related Articles

- Campaigners secure third paint stripper victory with Home Depot

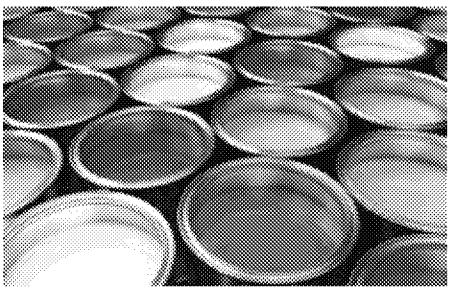
Further Information:

- SCHF tribute

Paint industry frustrated by Rac limit for paint preservative MBIT

Use will require skin sensitiser classification

21 June 2018 / Built environment, Classification, Classification, labelling and packaging Regulation, Europe, Risk assessment, Sensitisers



The European paint industry is "surprised" and disappointed that Echa's Risk Assessment Committee has agreed that the preservative MBIT should have a specific concentration limit (SCL) of 15 parts per million (ppm) for classification as a category 1A skin sensitiser.

The preservative is commonly used in cans of water-based products, such as paints, and the aim is to prevent skin sensitisation induction in exposed people.

Industry had hoped for a higher concentration limit for MBIT (2-methyl-1,2-benzisothiazol3(2H)-one), said Didier Leroy, technical director at the European Council of the Paint, Printing and Artists' Colours Industry (Cepe). "It is a concerning development that all isothiazolinones that go through Rac get lower [than expected] thresholds," he added.

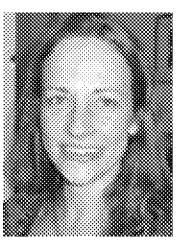
In 2016, the committee also decided on a 15ppm specific concentration limit for MIT and a mixture of CMIT and MIT. During its meeting on 4-8 June, Rac decided that MBIT is in the same "bracket of potency" as MIT and CMIT. "We came to the conclusion that it was very similar," said Rac chair Tim Bowmer.

MBIT prevents bacteria, yeast and moulds from growing in products but is not effective at 15ppm, said Mr Leroy. "Should our members want to use it, they would have to classify their paint or printing inks."

"That does not send a good signal to those adventurous biocide suppliers who would still try to get a new biocide substance on the market. Innovation is quasi non-existent and we observe the continuous reduction of availability of efficient preservatives," he said.

MBIT, CMIT and MIT are described as "product-type 6" biocides under the biocidal products Regulation (BPR); MBIT was approved as a new active substance last year.

Industry has long voiced concerns about the "uncertain" availability of active substances. Only a handful of substances can preserve products without affecting performance, it says.



Dr Emma Davies

Reporter

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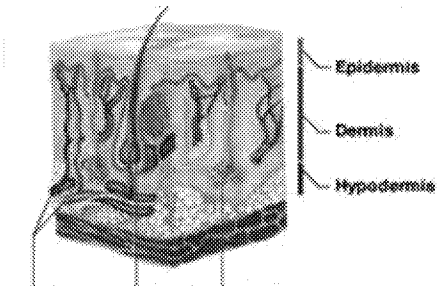
- Echa biocides committee supports approval of two exclusion candidates
- Authorities block industry appeal for holistic preservatives evaluation

Tattoo ink restriction 'complicated', says Echa's risk assessment committee

Some 3,000 chemicals must be addressed

21 June 2018 / Europe, REACH, Risk assessment



Echa's risk assessment committee (Rac) is continuing to review information on around 3000 chemicals used in tattoo inks and permanent make-up (PMU), for a proposed REACH restriction. "It's complicated – there are a lot of groups of substances that need to be addressed," said chair Tim Bowmer, following the Rac's meeting on 4-8 June 2018.

Chemicals requiring review include carcinogens, mutagens, reprotoxic substances, sensitisers and irritating or corrosive substances. The Rac is currently considering concentration limits, in the context of current analytical methods' detection limits, said Dr Bowmer. Levels that protect consumers are required but analytical restraints mean that setting levels too low may make harmonised enforcement across the EU difficult.

"In most cases, we are rather looking for a concentration limit that will reasonably regulate a substance in tattoo inks and will relatively easily allow enforcement to check."

Some of the substances come under the cosmetics products Regulation or are subject to harmonised classification under CLP. Most are covered by a Council of Europe recommendation on tattoo inks, on which seven member states have based national legislation.

Unique exposure route

The intra-dermal exposure route for both tattoo inks and PMU is unique among REACH risk assessments, according to the restriction proposal. It contains one exposure scenario, based on a "realistic worst case situation". This consists of single, full-colour, tattoo sessions on 300cm^2 skin, repeated until most of the body is covered.

Rac has access to quantitative risk assessments for some of the compounds but for others has to rely on semi-quantitative or qualitative evaluations. The restriction dossier proposes that a qualitative risk assessment will often suffice, given the exposure route, and makes the "important assumption" that injecting substances will give more severe adverse effects than applying them to the skin's surface. The dossier also describes the "major challenge" of a lack of harmonised analytical methods for analysing some of the components of tattoo and PMU inks, such as azo dyes. "There is a need for such methods to be developed," it states.

The restriction proposal was under public consultation until 20 June 2018. In their comments, NGOs the Health and Environmental Alliance (HEAL) and the European Environmental Bureau (EEB) point out that intra-dermal exposure is

"very poorly understood" and that ingestion "isn't necessarily or obviously predictive" of adverse outcomes. They support including tattoo workers in the restriction. Estimating workers' exposure would be "dramatically" simpler than estimating recipients' exposure because it requires a simple risk assessment involving inhalation and dermal exposures, they add.

In its comments, Sweden advocates listing all ingredients on ink labels. In particular, it suggests that products containing chromium VI should come with a warning such as: "Contains chromium. Can cause allergic reactions".

The Rac and the committee for socio-economic analysis (Seac) have until the end of 2018 to give their opinions on the restriction proposal for tattoo inks and PMU, put together by Echa, Denmark, Italy and Norway.

"I think this is a serious restriction. We are not trying to ban tattoo inks or drive it underground. We just want whatever is there to be safe," Dr Bowmer said.

Dr Emma Davies

Reporter

Related Articles

- Echa's Rac discusses restriction proposal for tattoo substances
- Echa opens consultation on tattoo ink substances restriction

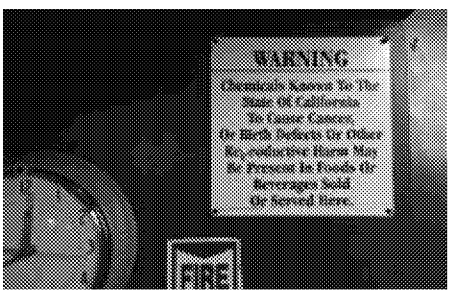
Further Information:

- Restriction report
- Restriction

California court upholds Proposition 65 lead limit

Federal judge affirms injunction against glyphosate warning mandate

21 June 2018 / California Prop 65, Labelling, Metals, United States



A court in California has found that the state "did not abuse its authority" in setting a permissible exposure level for lead, leaving in place the "safe harbour" level used to decide when warnings are required under Proposition 65.

In 2015, the NGO Mateel Environmental Justice Foundation sued the state's Office of Environmental Health Hazard Assessment (Oehha), seeking to invalidate the maximum allowable dose level (MADL) the agency had set for lead in 1989.

The NGO argued that the MADL does not set a standard at which there would be "no observable effect" from lead exposure. This is a requirement under Proposition 65.

However, on 5 June, the California Court of Appeal for the First District agreed with a lower court's decision in favour of Oehha. It said that data presented by the NGO does not prove that the existing MADL is invalid.

If the courts had ordered its repeal, there would have been no "safe harbour" in place. Employees and consumers would have had to be warned about any potential exposure to lead, until Oehha could set a new standard.

Lead and related chemicals are listed under Prop 65 for cancer and reproductive toxicity (male reproductive, female reproductive and developmental toxicity endpoints).

Mateel was one of three NGOs that separately petitioned Oehha to expand the basis for listing lead as a female reproductive toxicant. The agency rejected that petition in 2016.

Glyphosate injunction

In a separate 12 June proceeding, a federal judge has refused to change his ruling that temporarily blocks California from requiring labelling of products containing the herbicide glyphosate. This is while a trial continues on the constitutionality of Proposition 65 warning requirements.

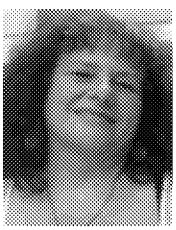
District Judge William Shubb issued a preliminary injunction in March. He said Monsanto is likely to win on its claim that requiring a statement on labels that the herbicide is a carcinogen is a violation of the company's free speech rights, if the required warning is not an "undisputed fact".

The injunction does not bar California from listing glyphosate as a carcinogen, but does block it from enforcing warning requirements. If Judge Shubb's interpretation sticks, the state could be forced to defend the scientific basis underlying the listing of chemicals under Prop 65, in lieu of accepting the findings of any one "authoritative body" referenced in the law.

Monsanto is backed by a coalition of industry groups in that case and a separate lawsuit brought under state law. In the latter, two courts have ruled against it on the issue of whether Prop 65 can rely on outside standards.

The state courts have held it is not an "unconstitutional delegation of authority" to list chemicals under Prop 65 based on determinations by the World Health Organization's International Agency for Research on Cancer (Iarc).

Inclusion on the Proposition 65 list triggers requirements that consumers and employees exposed to the substance are warned, primarily through labelling.



Julie Miller

Reporter

Related Articles

- California to update chromium VI, nickel public health goals
- US court rules on glyphosate labelling, threatening reach of Prop 65
- Judge rules against Monsanto in Prop 65 case

Further Information:

- Appellate decision on lead
- Order affirming injunction
- March glyphosate ruling

EU Commissioners urge greater action on SVHCs in imported articles

Level playing field needed, REACH Review conference hears

21 June 2018 / Alternatives assessment & substitution, Europe, REACH, SVHCs

The EU Commissioner for environment, maritime affairs and fisheries has urged Echa to assess the need for a restriction of SVHCs in imported articles earlier in the regulatory process.

Action 11(1) of the REACH Review calls upon Echa to consider developing systematically a restriction dossier before the sunset date for substances listed on Annex XIV – the authorisation list.

Speaking to delegates at last week's conference on the second Review of the Regulation, Karmenu Vella said that when companies point out that articles imported into the EU can still contain substances for which they have had to obtain authorisation "they do have a point".

It is an "understandable concern" for domestic companies which want a level playing field for EU and non-EU companies, he added. It is also "a very obvious concern" to citizens because of the potential impact on the environment and human health.

He said he would be following the outcome of Echa's assessment "very, very closely".

Mr Vella's calls are related to the requirement in REACH Article 69(2), which states that Echa must assess the need for a restriction on substances included in Annex XIV for their use in articles (EU produced and imported) and propose such a measure – if the risks are not adequately controlled – once the sunset date for the substance has passed.

The agency told Chemical Watch it has already assessed five substances and concluded that no restriction is required. For another four substances – the phthalates DEHP, DBP, DIBP and BBP – Echa proposed a restriction, which was supported by the Committees for Risk Assessment and Socio-economic Analysis (Rac and Seac) and is currently being discussed in the REACH Committee.

Meanwhile, restriction dossiers are being prepared for TCEP and lead chromates. For the remaining substances, Echa said it will carry out screening reports to assess if a restriction is required over the next six to 12 months.

The agency added that it is also assessing what can be done to speed up the process in the future, "such as gathering information on use of Annex IV substances in articles whilst the application for authorisation process is ongoing".

However, it said, the outcome of the application for authorisation process and whether an authorisation is granted "is an important issue to be clarified before any restriction is proposed".

Market protection

At the REACH Review conference, Elżbieta Bieńkowska, commissioner for internal market, industry, entrepreneurship and SMEs, said authorities needs to ensure that substances subject to authorisation in the EU will not bring risks when they are used in articles that are imported into the single market.

"On the other hand," she added "whenever we restrict the use of substances or their presence in articles, we have to make sure that this applies to imports as well."

The Review, she added, identifies the need to enhance enforcement, in particular at the border. Establishing closer cooperation of authorities responsible for REACH and customs authorities will be "vital", she said.

And Ms Bieńkowska also reiterated her previous calls for the simplification of the authorisation process. The Review found companies are investing in substitution of SVHCs and improving risk management measures when substitution is not possible, she said. However, authorisation is a "resource- and time-intensive process that should be simplified" and must be made more predictable for companies, she said.

Echa's Enforcement Forum will conduct a third pilot project on authorisation in 2019. This will check whether companies that are using Annex XIV substances, or marketing them, have the required authorisation.

Luke Buxton

Europe desk editor

Related Articles

- EU publishes delayed second REACH Review
- Incentives needed to trigger REACH dossier updates – Bjorn Hansen
- Echa's Seac adopts restriction proposals on four phthalates
- Echa recommends restriction on flame retardants in polyurethane foams
- Echa round-up
- EU Commissioner Bieńkowska calls for authorisation simplification
- EU enforcement project to check REACH registrations in 2019

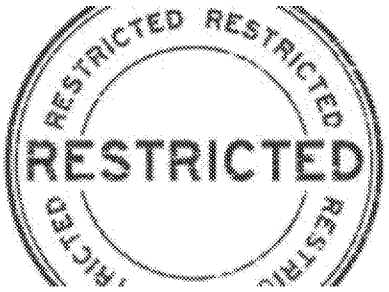
Further Information:

- REACH Review conference programme
- Echa restriction activities

ChemSec disputes Echa has 'addressed' all relevant SVHCs

Agency head urged to 'clean up' candidate list process

21 June 2018 / Alternatives assessment & substitution, Europe, REACH, SVHCs



NGO ChemSec is challenging Echa's claim that it has "addressed all relevant currently known" SVHCs.

The agency most recently stated this in its fourth progress report on the implementation of the SVHC roadmap.

The NGO is questioning Echa's use of the words 'addressed' and 'relevant' and will be raising the issue in a letter to agency head Bjorn Hansen next week.

"We don't agree they are addressed because they are not [all] on the candidate list. They are somewhere in the system," ChemSec senior toxicologist Anna Lennquist tells Chemical Watch.

She says she sees the need to put high priority substances in the system "because we know they are used and in that sense relevant". But, she adds: "You cannot just sit back and say that's it, that's done."

In Echa's automated SVHC roadmap process, Ms Lennquist says, unregistered substances are "usually filtered out". It does not mean that the agency can say the non-registered are not relevant, she adds, because they may well be.

There are "very many substances" Echa needs to look at that are not yet regulated. "They are just somewhere in some expert group."

And when the agency uses the words 'relevant substances', she says, it's really whatever they think is so. "It's time to move beyond that now for Echa and member states."

In November last year, Echa analysis identified seven substances on ChemSec's Substitute It Now (SIN List) that are not yet under regulatory scrutiny but that may be potentially harmful to humans or the environment.

The SIN List contains publicly available information on substances from existing databases and scientific studies, as well as new research. At the end of last year, the NGO produced a report which said the list shows the REACH process is too slow. It cited the wide disparity between it and the candidate list of substances.

'Political' process

The second REACH Review acknowledges that the process of adding SVHCs to the candidate list is "extremely slow", Ms Lennquist says, and that the precautionary principle is "not yet used".

The process is 'politicised' and there is "so much manufacturing of doubt from industry, so much insecurity from member states", which she says are too cautious. "They want to nominate something they know is certain to get through because it is costly."

Many of the last year's nominated substances, she adds, were degradation products of a substance already on the candidate list, or a mixture with something closely related to a substance on the list.

"All the time they are trying to take the very secure ones people can agree on rather than perhaps the most important ones that we can protect human health and the environment from."

There is a need to work on many different levels, she says, to "take back the candidate list and its role".

Overall, she adds, there is a "common understanding" that this is an important list. The actors need to "work harder to get it populated and this letter to Bjorn is one way of doing that. We hope he can have an overview and clean that up because it is difficult on a member state level to have this."

Ms Lennquist talks more on the issue in this month's Global Business Briefing.

Luke Buxton

Europe desk editor

Related Articles

- Echa: improvements needed in group screening approach
- Echa finds unregulated substances on ChemSec SIN List
- EU publishes delayed second REACH Review
- The usual suspects: time to move beyond the most obvious SVHCs

Further Information:

- Echa SVHC roadmap report
- ChemSec report comparing SIN list with REACH processes

US ATSDR releases 'suppressed' PFAS tox profile

Study confirms EPA guidelines 'woefully underestimate risk', says NGO

21 June 2018 / PFCs, Toxicology, United States

ATSDR
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

The US Agency for Toxic Substances and Disease Registry has released a controversial draft toxicological profile on four per- and polyfluoroalkyl substances (PFASs). The move comes amid uproar over allegations that other federal agencies were suppressing its release.

Last month, internal EPA emails released under a public records request showed concern that the ATSDR was planning to publish a study with minimal risk levels (MRLs) for the PFASs far below those set by the EPA. One White House staffer feared this would result in a "public relations nightmare".

Congress and the consumer advocacy community responded with outrage over the delay, and called for the ATSDR – which is housed under the US Department of Health and Human Services (HHS) – to release the draft toxicological profile.

Now the "very, very low" MRLs values referenced in the January email exchange have been confirmed in the toxicological profile for four of the 14 assessed substances: PFOS, PFOA, PFHxS, and PFNA.

The limits are set out on a body-weight basis (mg/kg/day), intended to serve as estimates of daily human exposure unlikely to cause an appreciable risk of adverse non-cancer health effects.

Environmental Working Group researchers tell Chemical Watch that using the EPA's methodology for translating these figures into drinking water advisory values results in the following levels:

- PFOS: approximately 7 parts per trillion (ppt);
- PFOA and PFNA: approximately 11ppt; and
- PFHxS: approximately 74ppt.

This contrasts with the EPA's non-enforceable lifetime health advisory level for PFOA and PFOS of 70ppt in drinking water. This makes its level seven to ten times higher than that recommended by the ATSDR, says the EWG.

And it "confirms that the EPA's guidelines for PFAS levels in drinking water woefully underestimate risks to human health," said Olga Naidenko, senior science adviser at the group.

NGOs push for further action

Michael Halpern of the NGO Union of Concerned Scientists praised the ATSDR for "finally doing the right thing" by releasing the "suppressed" assessment.

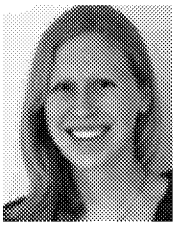
He requested that Congress "step up oversight into political interference in science that causes direct harm to public health and the environment."

And the EWG used the document's release to reiterate a call made by 40 NGOs for US states to continue taking the lead on eliminating the use of PFASs.

"It will largely fall to state and local governments to step in and take the necessary action to deliver results for the public," said EWG president Ken Cook.

The American Chemistry Council (ACC) told Chemical Watch it looked forward to reviewing the draft and providing feedback.

The ATSDR will accept comments on the document for 30 days. It is particularly seeking "additional information, reports and studies about the health effects of these substances" for possible inclusion in the final profile.



Kelly Franklin

North America editor

Related Articles

- White House fears PR 'nightmare' over PFAS risk level
- US senators demand release of controversial PFAS report
- US NGOs press for release of PFAS tox profile
- NGOs in US push for state-level action on PFASs

Further Information:

- Profile
- Federal Register
- EWG release
- UCS release

Greenpeace finds PFAS and microplastics in the Antarctic

Polyester fabric is likely source of microfibres, says report

21 June 2018 / Global, Microplastics, PFCs, Textiles & apparel

A Greenpeace study, has revealed the presence of microplastics and per- and polyfluorinated alkylated substances (PFASs) in seawater and snow samples from the Antarctic.

The samples were gathered during a three-month expedition from January to March this year.

In its recently published report, *Microplastics and persistent fluorinated chemicals in the Antarctic,* Greenpeace says the study shows "even the most remote and pristine habitats of the Antarctic are contaminated with microplastic waste and persistent hazardous chemicals".

The study found:

- seven out of eight seawater samples contained microplastics;
- microplastics were detected in two samples of seawater taken using a manta trawl (a net system for sampling the surface of the ocean);
- seven out of nine snow samples tested contained detectable concentrations of PFASs.

'Fast fashion' risk

Microplastics are defined by Greenpeace, as pieces of plastic "with a diameter of 5mm or less" which are likely to come from microbeads in personal care products, fragments from land-based sources such as tyres, or fibres from synthetic clothes, which are released into wastewater systems when consumers wash them.

The most likely sources of microplastic fibres in the Antarctic ocean, the report says, are fishing nets and polyester from textiles.

"Synthetic fibres, especially polyester, are widely used in textile products. For example, 60% of the material currently used in clothing is polyester, much of it in short life 'fast fashion' items of clothing," the report says.

Last year, Greenpeace warned about the industry's use of large quantities of polyester and its contribution to pollution of the oceans with microplastic fibres. Its Fashion at the crossroads report called for industry to slow down its plans for expansion - which include plans to nearly double its annual use of polyester by up to 76 million tonnes annual by 2030.

According to the report the "synthetic nature and their propensity to absorb or attract chemicals from seawater on to their surfaces" of microplastics means they can also carry "substantial concentrations of a range of chemical additives and contaminants, contributing to the exposure of marine species to hazardous chemicals".

The European apparel and textile confederation, Euratex declined to comment.

'Global spread'

The most commonly detected chemical was PFOA, which was found in "significant concentrations" in five out of nine snow samples.

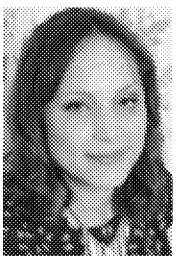
Greenpeace says the findings confirm its conclusion from previous expeditions, that once PFAS are released they "are spread globally by long distance transport through the atmosphere and are deposited as snow in all remote regions."

PFASs are widely used in many industrial processes and consumer products, such as in waterproof and dirt-repellent finishes by the outdoor apparel industry.

Jon Corley, spokesperson for the chemical industry trade association, FlouroCouncil, said it was difficult to comment on the report without knowing more about the underlying data and methodologies used.

"It is important to note they provide no risk context for the extremely low levels of PFAS detected in their report," he said.

In response, Kirsten Brodde, project lead for Greenpeace's Detox my Fashion campaign said: "The FluoroCouncil should be aware that persistent chemicals such as the PFAS found in Greenpeace's study can be hazardous at extremely low levels – they should be concerned by the fact that they've been found in habitats as remote as the Antarctic."



Tammy Lovell

Business reporter

Related Articles

- Italy to ban microplastics used in rinse-off cosmetics products
- Greenpeace: Premature circular economy threatens Detox campaign
- Gore and Greenpeace target 'PFCs of environmental concern'

Further Information:

- Greenpeace report
- Fashion at the crossroads report

Walmart considers blockchain technology for tracing chemicals

Potential to create 'a new era of transparency'

21 June 2018 / Confidentiality & right-to-know, Data, United States, Voluntary action

US retail giant Walmart is assessing whether the digital technology 'blockchain' can be used to trace chemicals across some of its products and packaging.

Blockchain is a digital record keeping system that enables the creation and maintenance of a growing number of records, allowing fast tracking of information. It was originally created to manage transactions through the crypto-currency Bitcoin, but has since shown potential for sharing and retrieving many other forms of data.

In its 2018 global responsibility report, the company says the technology holds a lot of promise for "enabling a new era of transparency and enhanced trust".

A Walmart spokesperson told Chemical Watch that,"the beauty of blockchain is that it lets us shine a light on a range of data attributes".

"We have certainly thought about how we could trace chemicals in foods and food packaging among these," she added.

Blockchain, she said, lets companies confidently and precisely pinpoint ingredients and suppliers, with dates, times, locations, temperatures, certificates and more.

"It can provide an extraordinary level of detail that we would definitely like to see include chemical ingredients, direct and indirect additives and colours," she added.

Pilot projects

Last year, Walmart collaborated with Chinese online retailer JD.com, IBM, and the Tsinghua University National Engineering Laboratory for E-Commerce Technologies to create a 'Blockchain Food Safety Alliance'. This aims to enhance food tracking, traceability and achieve greater transparency across the food supply chain.

In a trial of the technology, the company first asked a team to trace a package of sliced mangoes back to their source using current methods. Because of paper-based record keeping commonly used in the industry and multiple layers in produce supply chains, it took six days, 18 hours and 26 minutes.

However, using blockchain it was able to trace a mango in a US store back to its origin on a farm in Mexico in 2.2 seconds.

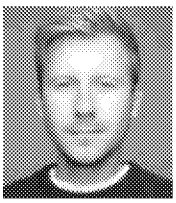
"Such capability would help enable rapid processing of recalls and help limit potential exposure to affected products," it said.

It also ran a blockchain pilot in China on pork, significantly reducing the time needed to trace products back to the farm.

Its potential has sparked the formation of a coalition comprised of the suppliers and retailers Danone, Dole, Driscolls, Golden State Foods, Kroger, McCormick, Nestlé, Tyson, Unilever and Walmart. The aim is to identify new areas where the global supply chain can benefit from blockchain.

The technology is a hot topic and has been linked with its potential use for a number of materials and products, including the tracking of conflict minerals and nanomaterials.

In a 2017 report on the mining industry, service provider PwC says through its use, materials could be tracked and traced from the "moment of extraction to the point of sale". This, it says, would satisfy increasing consumer demand for both improved supply chain transparency and more environmentally sound products.



Leigh Stringer

Global Business Editor

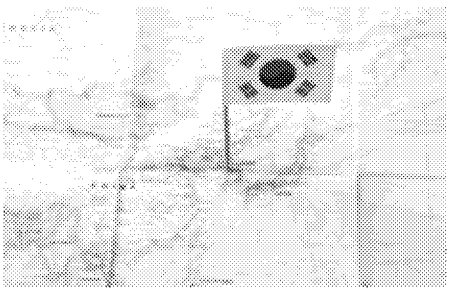
Further Information:

- Walmart 2018 report
- PwC report
- IBM press release

As deadline approaches, details emerge on K-REACH enforcement rules

Animal testing and polymer requirements are revealed

21 June 2018 / K-REACH, South Korea



With less than two weeks to go until the first K-REACH registration deadline of 30 June, 286 of the 370 substances expected have been submitted, with 109 of them completed, according to sources close to South Korea's Ministry of Environment.

And the MOE has provided extensive draft K-REACH enforcement rules. They include:

Animal testing

Duplicate vertebrate animal testing must be avoided. However, by presidential order, it can be carried out if:

- new findings suggest hazardousness and risk concerns;

- where existing data has low credibility; and
- when considering existing data costs and whether it can be shared.

When the owner of vertebrate animal testing data does not agree to share this, a company can apply to the MOE for an exemption from submitting the data. However, this only applies where the data owner is either registered or intends to register under K-REACH.

Polymers with hazardous monomers

A polymer can be not hazardous, but still subject to registration. This is if it contains a monomer that is subject to registration and the unreacted monomer persists at 0.1% or more of weight.

Abolition of risk concern products Regulation

The ministry guidelines also note that the "products of risk concern" Regulations under Article 34 of the initial K-REACH have been abolished; as have enforcement decrees and rules, including reporting on manufacturing. Regulation of these products has moved to K-BPR, where required.

Other sections of the enforcement rules include:

- registration outcomes;
- joint registration exceptions;
- research exemptions; and
- domestic representatives' obligations.

The public consultation on the draft rules runs until 9 July.

More details available on CW+AsiaHub

Sunny Lee

Asia editor

Related Articles

- South Korea's draft implementation rules arrive for updated K-REACH
- South Korea approves prioritisation of K-REACH alternative tests
- South Korea publishes decree on biocides law
- More detail on K-REACH enforcement rules as first deadline approaches

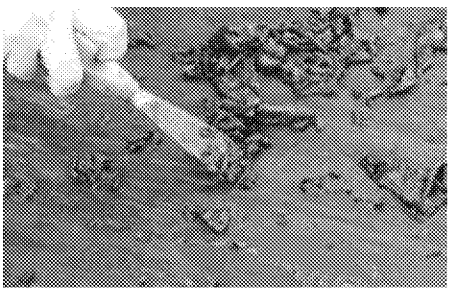
Further Information:

- MOE announcement (in Korean)
- Pecs registration status

US industry defends methylene chloride despite retailer bans

Consumers will buy paint removers in smaller hardware stores, says HSIA

21 June 2018 / Built environment, Retail, Solvents, United States



US industry groups have continued to defend the need for methylene chloride paint removers, despite three major retailers announcing plans to phase them out.

In recent weeks, retail giants Home Depot, Lowe's and Sherwin-Williams have pledged to stop selling products containing the solvent by the end of this year. The actions follow campaigning from consumer advocacy groups for a ban, after a number of deaths over the last few years.

But a spokesperson for the Halogenated Solvents Industry Alliance (HSIA) insisted that methylene chloride products still had an important place in the marketplace, and "are the best products for efficient and effective paint removal".

Alternative formulations have not been widely accepted in the market, the spokesperson told Chemical Watch. "They do not work as well and many of them are flammable, unlike methylene chloride."

They are frequently returned to the store and exchanged for the methylene chloride-based products, the spokesperson added. "To the extent the big stores stop carrying these, I would guess contractors [and] knowledgeable consumers will go to smaller local hardware stores."

The US paint and coatings trade group, American Coatings Association, also defended the use of methylene chloride and alternative solvent N-methylpyrrolidone (NMP) in paint removal products.

A spokesperson said the association "opposed outright bans of these compounds in the absence of environmentally safer alternatives."

ACA "strongly endorses following the precautionary labelling guidelines of using proper personal protective equipment (PPE) and ensuring proper ventilation," they said.

The US Consumer Product Safety Commission (CPSC) recently expanded its labelling guidance for paint strippers containing methylene chloride to address acute inhalation hazards.

Decoupling NMP from methylene chloride

Meanwhile, the NMP Producers Group told Chemical Watch it believes the US EPA should decouple its approach to NMP and methylene chloride in regulating the products.

In 2017, the EPA proposed a single rule under section 6 of TSCA to ban methylene chloride paint strippers, and either to ban or impose restrictions on products containing NMP.

But Kathleen M Roberts, manager of the NMP Producers Group, said that assessing them as a single category had "led to confusion in the marketplace, by giving the impression these products present a comparable risk profile."

Methylene chloride is "very volatile and most of the exposures occur via inhalation", she said. NMP is "mildly volatile and most of the exposures would occur through dermal exposure".

The fact that the agency put forward a proposal for NMP that considers labelling and other restrictions in place of a ban "demonstrates that EPA does not intend for the two chemicals to be treated the same", Ms Roberts added.

Apparently shelved, the EPA announced last month that it will finalise a rule on methylene chloride. But the EPA's recent problem formulations suggest the agency might not be moving forward with its rulemaking on NMP.

Tammy Lovell

Business reporter

Related Articles

- Campaigners secure third paint stripper victory with Home Depot
- Lowe's to phase out methylene chloride, NMP paint removers
- Sherwin-Williams to stop selling methylene chloride paint removers
- NGOs push Lowe's on methylene chloride paint strippers
- CPSC updates methylene chloride labelling policy
- NMP producers urge withdrawal of TSCA section 6 rule
- US EPA proposes prohibitions on methylene chloride, NMP
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA
- US EPA commits to act on methylene chloride paint strippers
- US 'problem formulations' raise fears for TCE, NMP rules

US EPA updates TSCA new chemical submission guidance

21 June 2018 / Substance notification & inventories, TSCA, United States

The US EPA has published an updated copy of its guidance for submitting new chemicals for agency review under TSCA.

The newest version of the document – *Points to consider when preparing TSCA new chemical notifications* – incorporates comments received on a November draft, including those made at a December public meeting.

Formation of the document came amid ongoing industry frustration at the slow pace of review of pre-manufacture notices (PMNs) since TSCA was amended in 2016. It provides non-binding information to assist submitters in preparing PMNs, significant new use notices (Snuns) or exemption notices under section 5 of TSCA.

The agency says the guidance "promotes early engagement and communication, and enhances overall understanding of EPA's technical review and analysis to better move chemicals through the evaluation process."

EPA Administrator Scott Pruitt said this will "increase manufacturers' certainty, improve submissions, and get new, safer chemicals on the market faster and more efficiently".

Alongside the guidance, the agency has published responses to more than 100 comments raised by stakeholders.

Related Articles

- US EPA explains new chemicals decision-making process
- OPPT director defends US agency plans for new chemical evaluation
- Halt on TSCA 'non 5(e) Snurs' raises industry concerns
- Industry groups seek changes to TSCA new substance reviews
- TSCA new chemicals programme named a top regulatory burden

Further Information:

- Points to Consider EPA page
- Comment responses
- Points to Consider document

Echa round-up

21 June 2018 / Classification, labelling and packaging Regulation, Europe, REACH, Safety data sheets

Testing proposals

Echa has invited third parties to submit scientifically valid information and studies on 13 testing proposals for nine substances. The deadline for providing information is 2 August.

CLH intentions

The agency has received new intentions to harmonise the classification and labelling of:

- multi-walled carbon nanotubes (fibres fulfilling the WHO definition: diameter <3µm, fibre length >5µm and aspect ratio ≥3:1, with a diameter >xx nm), [MWCNT]. Additional lower cut-off value for the diameter of the MWCNT will be clarified in the final CLH proposal. Germany proposes a harmonised classification of carcinogen 1B, specific target organ toxicity-repeated exposure (Stot Re) with submission expected by 31 December;
- 2,4,6-tri-tert-butylphenol; and
- 6-[(C10-C13)-alkyl (branched, unsaturated)-2,5-dioxopyrrolidin-1-yl] hexanoic acid.

Echa closure

Echa will be closed on 22 June.

Video on updating REACH-IT contact details

The agency has reminded registrants of the importance of keeping contact details up to date in its REACH-IT tool. There is a video with practical advice on how to do this, which is through the REACH-IT menu (Menu/Manage company/Contacts).

It is also important, Echa says, to make sure the email address in the 'Email notifcation settings' is up to date (Menu/Manage company/Contacts). An email is sent to this account every time an action is required in REACH-IT by the registrant, for example, updating a dossier, it says.

Update to interactive guide on SDSs

Echa has updated its interactive guide on safety data sheets and exposure scenarios. The guide is to help suppliers and SDS recipients to compile and understand substance and use information.

The agency has fixed some minor bugs and updated links. Translated versions will be corrected in coming weeks.

Consultation on new guidance on Annex VIII to CLP

The agency has sent its new draft guidance on harmonised information related to emergency health response for Forum consultation (Annex VIII to CLP).

Further Information:

- Current testing proposals
- Registry for CLH intentions
- Video on contact details for REACH-IT
- Interactive guide on SDSs

Echa opens consultation on derogation request for PFOA restriction

21 June 2018 / Alternatives assessment & substitution, Europe, PFCs, REACH

Echa is inviting comments on a proposal for an additional derogation to the restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (entry 68 of Annex XVII to REACH).

The agency's Committees for Risk Assessment and for Socio-economic Analysis (Rac and Seac) have been requested to prepare an opinion.

Echa says this assessment is not being carried out under the normal restriction procedure as it is a specific request from the European Commission for a derogation on an existing restriction. The opinions will be sent to the Commission by 1 December 2018.

The restriction entered into force in June 2017 and includes several derogations for different industrial sectors and uses.

The derogation review request came from pharmaceutical company AstraZeneca, which uses perfluorooctane bromide (PFOB) for the manufacturing of pharmaceutical products for the treatment of pulmonary diseases.

PFOB is excluded from the scope of the PFOA restriction, but it contains perfluorooctane iodide (PFOI) as an impurity in concentrations above the threshold in the PFOA restriction. PFOI is a PFOA-related substance that is covered by the restriction.

The public consultation ends on 20 August.

Further Information:

- Consultation page

US legislators seek changes in Iarc procedures

Threat to bar funding continues a long campaign

21 June 2018 / Toxicology, United States

Members of the House Appropriations Committee have demanded assurances that the International Agency for Research on Cancer (Iarc) will make specified changes in the way it conducts research reviews as a condition of receiving US funding.

Fiscal 2019 spending legislation contains a provision barring funding for Iarc's monograph programme unless the US National Institutes of Health (NIH) submits to Congress a report which describes "that grants, contracts or cooperative agreement awards to Iarc will require":

- a "transparent review process" in which drafts and revisions are publicly available online;
- a process to "address conflicts of interest in the selection of individuals involved with monograph programme assessments;"
- use of "the best available science" in developing assessment conclusions; and
- summaries of "relevant and significant" studies and reports that do not support assessment conclusions.

The legislation, approved on 15 June by a House appropriations subcommittee, covers the fiscal year beginning on 1 October. But spending bills are not likely to be finalised for several months, and Senate appropriators would have to agree for the provision to be included in the final version.

Long-simmering row

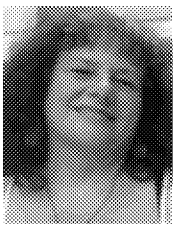
The appropriations rider is the latest salvo in a long-running feud between the international agency and Republicans in the US Congress.

Members of the House Committee on Science, Space and Technology recently wrote to Elisabete Weiderpass, the incoming Iarc director, asking her to testify at a July hearing. The letter described the monograph programme as "an affront to scientific integrity" and accused Dr Weiderpass of having aligned herself with "shoddy and politics-driven science".

Iarc's decisions have regulatory implication in the US because they lead to substances being listed as carcinogens under California's Proposition 65.

Critics have taken aim at Iarc's procedures generally, but their primary focus has been its 2015 review of glyphosate – the primary ingredient of Monsanto's Roundup herbicide – which Iarc classified as "probably" carcinogenic to humans. Litigation over the substance's listing under Prop 65 is currently underway.

The NIH has given nearly $48m to Iarc since 1985. More than $22m of this went to the monographs programme.



Julie Miller

Reporter

Related Articles

- Incoming Iarc boss gets hearing request from US Republicans

Further Information:

- Appropriations bill

EU presidency to 'finalise' POPs recast

21 June 2018 / Europe, Persistent organic pollutants

Austria said it aims to finalise the recast of the persistent organic pollutants (POPs) Regulation during its presidency of the Council of the EU, which starts on 1 July.

The recast provides for adjustments to the Treaty of Lisbon and to the definitions of EU chemicals and waste legislation, as well as an adaptation of the monitoring system.

In May, NGO the Health and Environment Alliance (HEAL) sent a letter to Austrian chancellor Sebastian Kurz urging the country to seize "significant opportunities" to improve chemicals regulations and push for better controls of hazardous substances during its presidency.

Related Articles

- Austrian EU presidency urged to act on chemicals controls

Further Information:

- Document

NGO launches Brexit and chemicals blog

21 June 2018 / Europe, REACH, United Kingdom

UK NGO CHEM Trust has set up a blog containing perspectives and news on chemicals regulations as Britain prepares to leave the EU.

In it, the NGO say it agrees with Cefic's calls for a post-Brexit bilateral chemicals regulations agreement, advocating continued membership of Echa and the retention of REACH in the UK.

Speaking at Chemical Watch's second Brexit conference in April, CHEM Trust executive director Michael Warhurst said the remaining 27 countries might come to recognise the benefits to the EU of allowing the UK to stay in REACH.

Related Articles

- Cefic calls for post-Brexit bilateral chemicals regulations agreement
- UK chemicals industry sees progress, but Brexit 'clock ticking furiously'

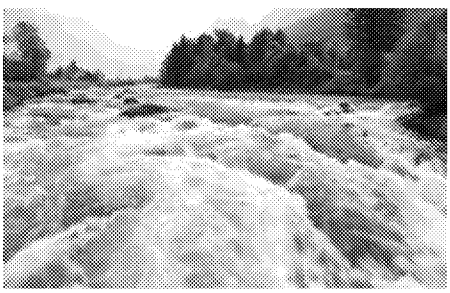
Further Information:

- CHEM Trust blog

Echa's MSC agrees that D4, D5 and D6 are SVHCs

Strong reaction from industry

21 June 2018 / Built environment, Ecotoxicology, Europe, Persistent, bioaccumulative & toxic, REACH



Echa's Member State Committee has agreed that the siloxanes D4, D5 and D6 are all REACH substances of very high concern (SVHCs), based on persistent, bioaccumulative and toxic (PBT) properties. Industry has voiced strong criticism of the decision.

Based on intrinsic properties, D4 is both PBT and "very persistent, very bioaccumulative" (vPvB), while D5 and D6 are only considered vPvB. The use of D4 and D5 is already restricted in wash off personal care products - at a concentration equal to or greater than 0.1% by weight - to reduce emissions to the aquatic environment.

The MSC agreed that D5 and D6 can be considered PBT and vPvB because of D4 impurities, when present at "relevant concentrations" above or equal to 0.1% by weight.

"If D5 and D6 get into the environment, the impurity D4 will have its own fate and behaviour," said Watze de Wolf, MSC chair. D5 and D6 products without D4 impurities would not be considered PBT, he added.

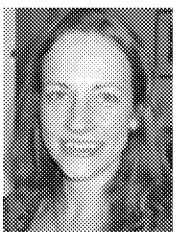
Germany compiled the SVHC reports for D4 and D5, while Echa prepared D6's Annex XV report, at the European Commission's request. In its reports, Germany recommends not immediately including the substances on the authorisation list (Annex XIV). Once included, they would no longer be subject to targeted restrictions, it says.

However, Pierre Germain, secretary general of trade organisation CES-Silicones Europe, said: "The silicones industry strongly believes that the Member State Committee has not taken full account of the whole body of scientific evidence."

"It should have recognised that measured levels in the real environment are extremely low; taken into account already applicable or ongoing regulatory activities; and that it will cause considerable uncertainty for customers on a global level," he added.

A recent US industry-funded study suggested that D4 poses a "negligible risk to the environment", based on data collected under an Environmental Protection Agency enforceable consent order.

On 2 April, the Global Silicones Council, US, together with European silicones producers, launched legal action against the European Commission. They argue that criteria in Annex XIII of REACH should not have been used to decide on the persistence and bioaccumulation of D4 and D5. The applicants describe concerns over hazard assessment, risk assessment and the use of weight of evidence.



Dr Emma Davies

Reporter

Related Articles

- Echa seeks views on SVHC identification proposals
- D4 poses negligible risk to environment, says industry

Further Information:

- D4 Annex XV report
- D5 Annex XV report

- D6 Annex XV report
- Action brought by the Global Silicones Council et al

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Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

U.S. Companies Split Over Global Chemical Classifications

Posted: Nov 24, 2017, 9:01 AM EST

By Sylvia Carignan

A United Nations proposal for a single, global classification list for chemicals used in trade is getting support—and some skeptical looks—from U.S. companies navigating the conflicting standards.

Companies in favor of a single, harmonized, global list of chemicals that would classify things like flammability and carcinogenicity, say it would reduce compliance costs and trade barriers by resolving conflicts between countries' chemical classifications. But, skeptics say there is an overwhelming amount of work to be done to create such a list.

Hach Co., which manufactures and distributes water quality testing technology, is in favor of the proposal.

"For a multi-national company like Hach, it is very difficult to keep up with national classification lists," James Lee, senior compliance analyst for chemicals at Hach Co., said.

In U.S. workplaces regulated by the Occupational Safety and Health Administration, hazard communication citations are among the most common violations, according to the agency. In fiscal 2015, hazard communication, which governs the evaluation of chemicals in the workplace, was the second most frequently cited standard.

The United Nations committee considering the chemical list proposal is scheduled to meet Dec. 6 through Dec. 8 in Geneva. But the committee needs to reach an agreement to take action on the list.

"There are concerns about how it should be developed, politics involved, how much work and time, and whether major players like [the European Union], China, and Japan will pay much attention to this list, or even oppose it," Lee said.

Lagging Behind

The "Globally Harmonized System of Classification and Labelling of Chemicals" is a framework a U.N. committee built to help countries classify the hazards of individual chemicals used in trade.

OSHA was involved with the system at its inception, and has been taking public input on the U.N. proposal for a global list based on the system's framework. The U.N. committee first started studying the possibility of a global list in 2008.

The classifications range from a chemical's carcinogenicity to flammability to environmental contamination risk. But, since countries have based their classifications on differing studies, or interpreted them differently, a single chemical's classification can vary from country to country.

One country may designate a chemical as a known carcinogen, while another may designate it as a suspected carcinogen.

Companies know that communicating chemical hazards is a clear priority, but the classifications are not well understood, Glenn Trout, president and chief executive officer of VelocityEHS, told Bloomberg Environment. "There's really a lot of confusion around how to label chemicals in the work environment," Trout said.

A global list proposed by the U.N. committee would align those classifications.

"Theoretically, it sounds like a great idea, but when you think about how it would be implemented, practically speaking, it is very complicated," Melissa McCaffrey, marketing communications director for VelocityEHS, told Bloomberg Environment.

A pilot program involving three chemicals, facilitated by the Organization for Economic Co-operation and Development, found that international bodies could reach a consensus on nonbinding classifications, but "substantial" effort was required. It would take potentially 18 to 20 months from selecting a chemical to finalizing its classifications, according to Edmund Baird, counsel for standards at the U.S. Department of Labor.

"It just seems like—not an insurmountable task, but there has to be a serious commitment," McCaffrey said.

OSHA has its own separate hazard communication rule, and doesn't plan to make changes to the rule as a result of global list feedback, according to an agency spokeswoman.

Weighing In

The American Petroleum Institute supports developing a list, as long as its classifications are not binding or mandatory. The institute's members include Alcoa Oil and Gas, Belle Fourche Pipeline, and Hess Corp.

A global list would help countries that don't have the resources to develop their own classifications, the institute said in a statement. But, the U.N. committee would need to determine how it chooses chemicals for the list and how it justifies each classification.

"These two key considerations become particularly salient when the available data are apparently conflicting," the institute said in a statement.

The U.N. committee has already agreed that the list be developed transparently and that the classifications be non-binding.

The American Cleaning Institute, which represents companies such as Cargill, Inc., Unilever, and Colgate-Palmolive, isn't supporting the list.

The list isn't a priority for the institute's members, and the effort necessary to build a list is a significant roadblock, Richard Sedlak, executive vice president for technical and international affairs at the American Cleaning Institute, said.

It's unclear whether the U.N. committee will set a timeline if it decides to build a list.

GREENWIRE ARTICLES

Buyout stories: 'We are kind of being hollowed out'

Three hundred seventy-two U.S. EPA employees took buyouts this year, with the enforcement and research offices among the hardest hit, according to agency data obtained by E&E News. "We are going to be able to hang a shingle on the outside of the building and still call it EPA," a union official said, "but we're not going to be able to still do what EPA used to do."

Federalist Society project hunts for burdensome rules

Maxine Joselow, E&E News reporter

Published: Wednesday, November 22, 2017

The Federalist Society has launched a project to identify regulations whose costs exceed the benefits.

The Regulatory Transparency Project, which kicked off this month, seeks to find rules and guidance that place an undue burden on the American economy.

Despite the best of intentions, government regulations can cause harm," said Devon Westhill, director of the project. "What we're trying to do is examine rules and guidance and the regulatory process itself to find areas where regulation seems to be doing more harm than good."

It's a frequent conservative talking point that red tape should be cut and the sprawling regulatory state should be trimmed. But Westhill said the project is nonpartisan, noting that the Federalist Society doesn't take a stance on specific law or policy initiatives.

The project comes as President Trump has made deregulation a top priority for his administration. Trump signed a January executive order requiring that two rules be revoked for every new one issued, followed by a February executive order requiring that agencies set up regulatory reform task forces.

But Westhill said the Regulatory Transparency Project has been in the works since spring 2016.

"While we're just announcing this, this is something that's been in the hopper since before the election of President Trump," Westhill said. "There's no idea that there would be a sympathetic ear at the federal level."

The project will consist of 12 working groups that each focus on an area of rulemaking, including antitrust and consumer protection, energy and environment, intellectual property, and labor and employment.

The energy and environment working group has eight members. All have academic credentials, and some have conservative pedigrees, with two previously serving in the George W. Bush administration and one having served in the Reagan administration.

Jeff Holmstead, chairman of the energy and environment working group and former assistant administrator of U.S. EPA's Office of Air and Radiation under President George W. Bush, said he hopes to foster meaningful conversations about regulatory reform.

"When this opportunity came along, I really viewed it as a way to help create the intellectual framework for regulatory reform," Holmstead said. "Regulations are basically a bad deal for society if the costs outweigh the benefits. And even when the benefits outweigh the costs of a particular regulation, that doesn't make it a good thing if there are less costly ways to achieve the same result."

So far, the group has produced two papers. The first criticized EPA's "expansive regulatory approach" to the Waters of the U.S. rule and called for "restoring meaningful limits" to the statute. The second called for repealing the Jones Act to unfetter American oil and gas production.

Richard Belzer, a member of the energy and environment working group and former staff economist in the Office of Management and Budget under President Reagan, said he hopes the group turns its attention next to the Safe Drinking Water Act.

"The last time it was reauthorized was 1996," he said. "What's going on, I think, is that the 1996 amendments to the law finally told EPA that they had to do benefit-cost analysis. And I think what they're discovering is that the costs outweigh the benefits."

CHEMICAL WATCH ARTICLES

Swiss chemical giant, Lonza, rolls out global preservatives strategy

Aims to defend ingredients for personal care and household products

22 November 2017 / Active substances, Biocides, Cleaning products, Global, Personal care

Swiss multinational Lonza has rolled out a global strategy, dedicated to ensuring a broad palette of preservatives remains available to the household and personal care products industries in the years ahead.

The chemical giant's consumer care division is investing in short-, medium- and long-term preservation programmes. The move comes partly in response to increasing regulatory scrutiny of traditional preservatives, which has thrown the cosmetics industry in particular into a crisis.

An ongoing goal is to defend existing ingredients, which are "supported by robust data packages and underpinned by regulatory compliance", Lonza says.

The company is working with relevant trade bodies and regulators to argue for keeping these on the market. Often this means addressing negative media attention, says Lonza's head of global marketing for preservation, Phil Hindley.

"It is inevitable that some companies in the market will be more sensitive towards such controversy than others, with a continuing dilemma being the battle between negative PR and actual regulatory restrictions," he says.

"We recognise there is a move away from certain 'controversial' chemistries, but equally that many formulators and personal care companies are continuing to use these, given their familiarity and longstanding adoption."

Bans and restrictions on widely used substances have come into force over the last two years in Europe and in the US, including for several parabens and the mixture of methylchloroisothiazolinone and methylisothiazolinone (MCI/MI). Other compounds are facing scrutiny from authorities and NGOs.

Innovation

Meanwhile, Lonza is future-proofing its portfolio by formulating new preservative systems, based on options including organic acids and multifunctional additives.

A growing trend in the personal and home care sectors - blending recognised actives with inert ingredients or other co-formulants - can improve a preservative system's efficacy and reduce the content of single ingredients in the final formulation. This can help in complying with restrictions, or reducing the potential for allergies.

Multifunctional additives are not regulated as preservatives, but can contribute towards the effectiveness of the final product. They can be used as either standalone systems that offer a preservation effect in addition to other benefits, or as potentiators that boost the activity of existing active substances.

Although multifunctionals can add a level of complexity to a product, they have a "solid place" in the preservation market, says Mr Hindley. Nevertheless, they are also beginning to give concern to authorities and NGOs. Sweden's EPA has flagged up that with a lack of research on their use, these additives could come with unknown human health risks.

Organic acids, meanwhile, are growing in popularity and adoption, particularly in personal care markets, he says.

Lonza's long-term goal is to develop two new preservative active substances for a number of applications. A "significant investment" for the company, it is expecting to progress these within the next few years.

Joint efforts

Mr Hindley adds that Lonza's strategy fits into a joint effort by industry to defend preservatives. "There are trade bodies working to [do this] on behalf of their members; some of our competitors are making efforts too. And outside of that we are also communicating with the regulators about this issue."

The European Commission acknowledged earlier this year that reducing the palette of preservatives available to formulators "creates real public health problems" because it means that consumers are exposed to higher levels of those remaining.

And Cosmetics Europe has been vocal in its defence of preservatives, calling the shrinking pool of substances available "a crisis".

Meanwhile, US business group the Green Chemistry and Commerce Council (GC3) has run a competition with the aim of identifying promising safe preservation systems for personal care and household products, and help bring them to market. It closed in the summer with 48 submissions for potential new systems.

Judges from 11 companies, including Lonza, are currently evaluating them.

Related Articles

- The big preservatives 'crisis'
- EU bans five parabens, restricts triclosan in cosmetics
- European Commission restricts three cosmetics preservatives
- Swedish government considers action on preservatives in cosmetics
- Industry must avoid stigmatising preservatives, says EU Commission
- The big preservatives 'crisis'
- US business group evaluating 48 potential new preservation systems

Further Information:

- Lonza preservatives web page

Niceatm invites scientists to build oral toxicity models

22 November 2017 / Alternative approaches to testing, United States

The US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (Niceatm) has invited researchers to take part in a global project to develop *in silico* models to predict acute oral systemic toxicity, using available rodent data.

Acute oral toxicity is one of the US EPA "six-pack" tests, which result in high animal use worldwide. Tests are for acute oral, dermal and inhalation systemic toxicity, as well as eye and skin irritation and skin sensitisation.

The Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam) is organising the international modelling project through its acute toxicity workgroup. One of Iccvam's "high-priority efforts" is to develop alternative test methods for the six-pack.

Niceatm and the EPA National Center for Computational Toxicology have collected a large body of rat acute oral lethality data. Researchers interested in joining the project should build and test models, using this. A 'training' data set is already available on the Niceatm website and prediction data will be released in December.

Models that meet certain criteria will be used to generate consensus predictions for acute oral toxicity endpoints of particular interest to regulatory agencies, according to Niceatm.

Toxicity predictions generated by the models will also be made publicly available on the EPA's chemistry dashboard.

Prediction results should be submitted by 9 February 2018. The results will be presented at a workshop in April.

Further Information:

- Niceatm call

Thailand's draft chemical inventory expected by year end

Limited searches possible, based on Cas numbers

22 November 2017 / Safety data sheets, Substance notification & inventories, Thailand

The first draft of Thailand's existing chemical inventory is expected before the end of the year, delegates at Chemical Watch's Regulatory Summit Asia have heard.

Dr Piyatida Pukclai, regulatory policy director at consultancy Dr Knoell Thailand, said that it will include data collected up until December 2016. However, she noted, there is currently no date for the official first full version.

Dr Pukclai also covered recent announcements on confidential business information (CBI) by the Department of Industrial Works (DIW). These include a minimum period for CBI requests of eight-12 months and the rules for rejecting a CBI submission, which are currently published in Thai.

She also discussed changes to Thailand's Hazardous Substance Act. The updated law is "expected soon" and will include 22 new substances.

Dr Pukclai told delegates that from October, the ministry has allowed a Thai subsidiary company of a manufacturer – or an authorised agent – to consult with them on behalf of importers.

She also reported on a new online tool, called the hazardous substance single submission (HSSS), that can be used for the registration of type two and three hazardous substances and for the licensing of type three substances.

Sunny Lee in Singapore

More on this on CW+AsiaHub

Related Articles

- Thailand's draft chemical inventory expected by year end

Further Information:

- Hazardous substance single submission (HSSS) online

Vietnam sets limits on formaldehyde and azo colourants in textiles

23 November 2017 / Textiles & apparel, Vietnam

Vietnam's Ministry of Industry and Trade has published limits on the amount of formaldehyde and azo colourants in textiles. The new regulation takes effect on 1 May 2018.

Under the new rules, the limits of formaldehyde are:

- 30mg/kg in textile products for children under three;
- 75mg/kg in textile products in direct contact with the skin; and
- 300mg/kg in textile products with no direct skin contact.

It also specifies the limit of 30mg/kg for 22 aromatic amines converted from azo colourants.

The ministry published a draft on the limits earlier this year. The new rules will be introduced under Circular No 21/2017/TT-BCT: "the national technical regulation on the content of formaldehyde and certain aromatic amines derived from azo colourants in textile products."

More on this on *CW+AsiaHub*

Related Articles

- Vietnam to limit formaldehyde and azo colourants in textiles
- Vietnam sets limits on formaldehyde and azo colourants in textiles

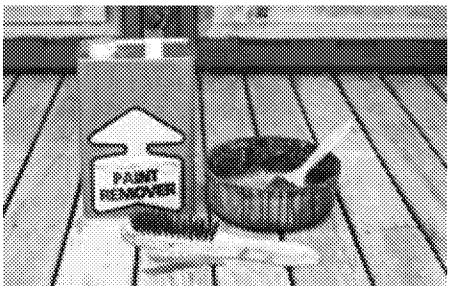
Further Information:

- MIT announcement (in Vietnamese)

California moves on methylene chloride paint strippers under SCP programme

'Priority product' designation will require 'alternatives analysis'

23 November 2017 / Alternatives assessment & substitution, Built environment, TSCA, United States



California's Department of Toxic Substances Control (DTSC) has proposed regulations to name paint strippers containing methylene chloride a "priority product". The move comes under the state's Safer Consumer Products (SCP) programme and is the next step in a process that could lead to the products being restricted or banned in California.

The agency said it will accept written comments until 18 January, and will hold a public hearing on 8 January.

Once the regulation is finalised, manufacturers of such products sold in the state will have 60 days to register with the department and begin an analysis to determine if a safer alternative is possible.

The DTSC named the first three chemicals to be scrutinised under the programme in 2014. And children's sleeping items containing the flame retardants TDCPP or TCEP officially became the first "priority product" on 1 July. Alternatives analyses for this should be underway. The public comment period on the second priority product – spray polyurethane foam (SPF) containing MDI – ended on 6 June.

It took more than eight months to move from consultation to finalised regulations on the flame retardants, so it is likely alternatives analyses for methylene chloride paint strippers will not begin until the end of 2018.

Methylene chloride paint strippers are not only carcinogenic and neurotoxic, the DTSC says, but "high-level acute exposures can be fatal and there are numerous worker and consumer deaths" associated with their use.

The requirements will apply to any methylene chloride product sold in California "as a chemical substance designed to break down paint, varnish, or any other surface coating to facilitate its removal from any surface."

Separate California regulations already ban the use of methylene chloride in a variety of consumer cleaning products.

Listing as a priority product "sets in motion a strategy to reduce human exposure," the DTSC said in its current proposal, but it is unknown what regulatory action might be taken in response to alternatives analyses.

"Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that paint or varnish manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles," the agency said.

EPA considering federal ban

In the last days of the Obama administration, the US EPA issued a proposed rule to ban all consumer, and most commercial, use of methylene chloride as a paint stripper. And the agency solicited feedback on whether to additionally ban n-methylpyrrolidone (NMP), or impose rules on concentration, workplace protections and labelling.

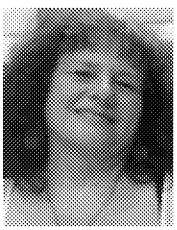
The January proposal specifically excluded furniture refinishing, indicating that the EPA would "propose such a regulation at a later date."

At a September EPA stakeholder workshop, manufacturers and industrial users argued for requiring protective measures and possibly restricting the use of methylene chloride to commercial products, arguing that an outright ban would make furniture stripping unprofitable.

The workshop could be a clue that the Trump administration might follow through on some methylene chloride regulation. In addition, the semiannual regulatory agenda the EPA published on 24 August indicated that the agency plans to publish a supplemental notice of proposed rulemaking, amending its original proposal.

There is no requirement that the EPA act on that rule. However, methylene chloride is also being reviewed separately as one of the first ten priority substances subject to mandatory risk evaluation under the new TSCA. Furniture refinishing is included in the scope of that evaluation.

Sale of paint strippers containing methylene chloride is restricted in the EU under REACH.



Julie A Miller

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- Science advisers question California AA guidance lack of specificity
- California names first priority products for alternatives assessment
- California designates first priority product under SCP programme
- Industry speaks out against California spray polyurethane foam proposal
- US EPA proposes prohibitions on methylene chloride, NMP
- Industry urges US EPA against full paint stripper ban
- EPA may progress proposed methylene chloride and NMP restrictions
- EPA names first ten chemicals for new TSCA evaluations

Further Information:

- DTSC documents on methylene

EU enforcement pilot to target phthalates, flame retardants

Substances in articles project to include electrical products, building materials

23 November 2017 / Built environment, Electrical & electronics, Enforcement, Europe, Halocarbons, Phthalates, REACH

Echa's Enforcement Forum has started work on a pilot project to verify compliance with the notification and communication obligations of substances in articles in REACH. It will specifically target seven substances, or groups of substances, including flame retardants and phthalates.

National enforcement actions, reports from authorities and NGOs, and the low number of notifications being made to Echa indicate that industry is failing to meet its obligations.

The pilot was first announced in November 2015, two months after the European Court of Justice (ECJ) ruling that the 0.1% threshold for notifying SVHCs in articles applies to each component of a complex product rather than the entire product.

The project aims to:

- check compliance of producers, importers and suppliers of articles with their obligations (REACH Articles 7 and 33);
- raise awareness and understanding of legal obligations and the level of compliance among duty holders;
- build a better picture of the actual level of compliance by suppliers of articles;
- identify reasons for non-compliance and decide whether Echa, the Commission and/or member states competent authorities need to do more, such as providing support to duty holders; and
- gather experience and establish enforcement methods for a potential future large-scale check of these obligations.

Echa says electrical products, building materials and interior articles are examples of consumer goods that may be inspected. The substances, or groups of, that it will focus on are:

- brominated flame retardants;
- phosphorous flame retardants;
- short-chain chloroparaffins;
- phthalates;

- aprotic polar solvents;
- perfluorinated substances; and
- phenolic benzotriazoles.

The project runs from from October 2017 to June 2018. A report of the results is expected by the end of next November.

At the end of June, Echa published the long awaited revision of its guidance on substances in articles. The agency said the "comprehensive update", which was expected in 2016, gives more clarity on communication and notification obligations when articles contain SVHCs. It includes new examples, which it says are in line with the judgement of the ECJ ruling.

Forum meeting

Textile articles will also be addressed in the pilot, Forum chair Katja vom Hofe told Chemical Watch. This subject was raised at the November Forum meeting by Mauro Scalia, manager of sustainable business at European textiles industry association Euratex. He said the association has faced challenges with some non-compliant companies and asked if there was any enforcement activity around textiles.

"We said we have a number of enforcement projects, which – among other types of articles – are looking into textiles," Ms vom Hofe said. This includes the recently concluded fourth REACH-En-Force (Ref-4) project, which had "quite a high number" of checks for textiles.

Cefic REACH director Erwin Annys also spoke at the meeting about the enforcement of imported substances and how to protect competition for European manufacturers, which face strict controls inside the EU. Robust checks of imported substances are needed because, he said, Cefic believes some non-EU manufacturers are potentially not following the rules of REACH.

The Forum has "a very high percentage" of checks that address imports, Ms vom Hofe said, and added that "at least half" of the substances or products that it inspects are imported because it knows there is "a fairly high chance" they might not be compliant.

The third authorisation pilot project to be carried out by EU national enforcement authorities (NEAs) in 2019 will cover chromates with sunset dates that have passed.

In June, the Forum announced that NEA inspectors will focus on registration obligations – including substances registered as intermediates – under Ref-7. It also launched its first joint action agreement with its accredited stakeholder organisations (ASOs) – trade bodies and NGOs – to improve the quality of safety data sheets.

The working group is now set up and there is "lots of willingness" among its members, who will report at the end of next year on their findings, Ms vom Hofe says.

The next Forum meeting will take place in March 2018.

Luke Buxton

Europe desk editor

Related Articles

- National authorities 'committed to coordinating enforcement' of substances in articles
- European Court of Justice rules on SVHCs in articles
- Echa issues updated guidance on substances in articles
- REACH enforcement project finds phthalates in toys a 'big problem'
- Third EU authorisation enforcement project to cover chromates
- EU enforcement project to check REACH registrations in 2019

Further Information:

- Echa press release
- Enforcement Forum

EPA lists chemicals reported under TSCA inventory notification rule

23 November 2017 / Substance notification & inventories, TSCA, United States

The US EPA has published an updated list of more than 10,000 chemical substances that have been reported under the TSCA inventory notification rule.

The rule requires manufacturers and importers to report by 7 February 2018 all nonexempt substances that they used in the ten-year 'lookback period' ending 21 June 2016.

Processors (downstream users) have until 5 October 2018. They are not required to report but must do so to avoid having a chemical labelled "inactive".

Agency officials said last month that a final inventory would be published within two months of the October deadline.

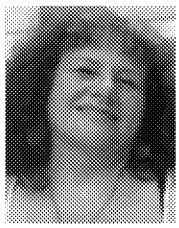
The list will be the starting point for identifying high and low priority substances for assessment under TSCA.

The list of 10,370 chemicals published on 22 November includes reports received by 10 November, and the agency plans to update it regularly.

"This list is for informational purposes only" and the listed substances "are not exempt from retrospective reporting by other manufacturers" unless they have obtained a Central Data Exchange (CDX) receipt from the manufacturer who has reported it, the EPA's notice says.

It will probably be most useful to processors, who are not required to report but may want to ensure that chemicals they deal with are on the active inventory.

The EPA has developed a separate list of 13,209 active chemical substances that are exempt from reporting. They are substances reported under the 2012 and 2016 Chemical Data Reporting (CDR) rule, and in Notices of Commencement received during the ten-year lookback period.



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Related Articles

- Final TSCA inventory notification rule eases reporting burden
- Downstream users express concern at TSCA inventory requirements

Further Information:

- Substances reported through 10 November
- Substances exempt from reporting

Canada will not regulate 2-MBS

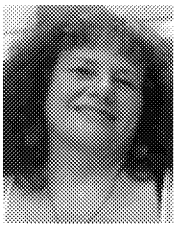
23 November 2017 / Canada, Environmental Protection Act, Personal care

The Canadian government has decided that 2-MBS (benzenesulfonamide, 2-methyl) does not pose health or environmental risks, sufficient to warrant regulation under the country's environmental protection act (Cepa).

The substance is used primarily as an intermediate for fluorescent pigments and plasticiser resins, and as a plasticiser for hot-melt adhesives. It is also used as an ingredient in nail polish, and may be formed in small amounts during the manufacture of the food additive saccharin.

The risk assessment of these substances, and the proposal to take no action on them, was published for public consultation in February.

The final determination was published in the 18 November *Gazette*.



Julie A Miller

North American Desk Editor

Related Articles

- Canada publishes draft screening assessment for 2-MBS

Further Information:

- Canada Gazette

US Senate spending bill would eliminate IRIS programme

Appropriations measure would restore more than half of Trump's proposed cuts

23 November 2017 / TSCA, United States

The Senate Appropriations Committee has released a proposal that would eliminate the US EPA's Integrated Risk Information System (IRIS) programme. Such a move would potentially give control of chemical research directly to political appointees who run the agency's regulatory agenda.

The Senate committee's version of the fiscal 2018 appropriations bill covering the EPA was published on its website on 20 November. It would cut the agency's overall funding by $149m. But it provides $3.8bn more than the counterpart legislation approved by the House in September and $22.5bn above the 30% cut called for in the Trump administration's requested budget.

The Senate bill includes $111.6m for the "chemical safety and sustainability" line item that funds chemical research. This would be a $15.3m cut, but is more generous than the House and restores more than half of the $27m cut proposed by the administration.

Eliminating IRIS

However, the report accompanying the bill's text says the committee has not provided funding for IRIS. "In order to ensure that important chemical assessment work is completed, the Committee has transferred resources within the agency from IRIS to help implement the Lautenberg Chemical Safety Act," it said.

Chemical safety and sustainability is one of six thematic research programmes managed by the Office of Research and Development (ORD). Actual research is carried out by seven laboratory organisations. IRIS is part of one such laboratory, the National Center for Environmental Assessment (NCEA), which has facilities in Ohio and North Carolina.

"The bill imposes the IRIS workload onto the recently-reformed Toxic Substances Control Act (TSCA) programme, which was not designed to accommodate the breadth of the IRIS programme's responsibilities," minority Democrats on the Senate Appropriations Committee said in a statement.

It is not clear exactly how the committee's majority envisions redistributing funding and responsibilities, but the office in charge of "implementing" the Lautenberg Act's TSCA reforms is the Office of Chemical Safety and Pollution Prevention (OCSPP). That is the regulatory division that would be headed by Michael Dourson if his nomination is not defeated in the Senate.

"At best a small fraction of its responsibilities — and only one-third of its funding — would be re-allocated" to the OCSPP, Jennifer McPartland, a senior scientist at the Environmental Defense Fund (EDF), wrote in criticising the Senate bill's treatment of IRIS.

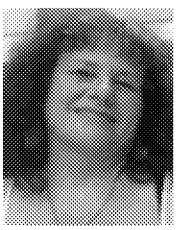
Moving IRIS staff from the non-regulatory ORD into the OCSPP would cost the EPA "scientific expertise that serves the entire agency, severely undermining the legal responsibilities Congress has given it," and would "sever the independence between scientific review and regulatory decisions informed by such reviews," Dr McPartland wrote.

She noted that the EPA's website says placing the IRIS programme within ORD "ensures that IRIS can develop impartial toxicity information independent of its use by EPA's program and regional offices."

Alternative test methods

The Senate panel's report also included unusually specific language regarding development of a strategic plan to promote alternative test methods that is required under TSCA. EPA officials discussed the emerging plan at a recent public meeting. The process of developing the plan should involve public meetings, consultation with "the scientific community and the public" and a final version "documenting response to, and disposition of, public comments". The committee asked for a progress report by 30 September 2018.

Finally, the report addresses a TSCA provision allowing the EPA to collect fees from manufacturers. The bill would earmark $10m in federal funds that would be replaced by the fees that are anticipated to come in during fiscal 2018.



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Related Articles

- House approves 2018 spending bills, rejects further US EPA cuts
- Trump budget proposal would cut EPA funding by a third
- Opposition by Republican senators casts doubt on Dourson nomination
- US EPA has first public input on alternative test methods for TSCA

Further Information:

- Senate appropriations report
- Democrat news release

Russia sends implementation plan to Stockholm Convention

23 November 2017 / Persistent organic pollutants, Russia

The Russian Federation has submitted its national plan on implementing the Stockholm Convention on persistent organic pollutants (POPs).

Each party to the convention is required to develop such a plan, which the Secretariat then presents to the next Conference of the Parties.

The national implementation plan (NIP) was approved by the country's Ministry of Natural Resources on 3 October.

The NIP consists of two sections. The first deals with activities to be implemented by 2020, and includes seven objectives:

- improved legal regulation of POPs;
- an improved management system for POPs;
- the destruction/disposal of accumulated pesticides, industrial wastes and equipment containing POPs;
- cleaning of contaminated territories;
- monitoring of the pollutants in the environment and population health in relation to their effects;
- improved information and education; and
- exchange of information with the Secretariat and Parties to the Stockholm Convention.

The second section deals with long-term versions of these activities for the years 2021-2028.

Further Information:

- NIPs

US children's products trade group refutes NGO chemical ranking

Mind the Store defends retailer report card

23 November 2017 / United States

US trade group the Juvenile Products Manufacturers Association criticised an NGO report — which grades retailers' on their efforts to tackle chemicals of concern — for implying children's products could be toxic.

Kelly Mariotti, executive director of the JPMA, told Chemical Watch that children's products "cannot present either acute or chronic hazards to children" because they are "heavily regulated" under the Federal Hazardous Substance Act and Consumer Product Safety Act, and most products were tested by government-accredited laboratories before sale.

She said: "We are extremely confident these products are safe and would be verified as safe by any board-certified toxicologist. The claims here are false and misleading, which is why we urge all responsible parties to either verify them or retract them from publication."

The 'report card' by the Mind the Store coalition of NGOs ranked 30 retailers across 11 sectors on their chemicals policies.

The eight baby and children's products retailers assessed received an average D+ grade, matching the average retailer performance on safer chemicals.

Co-author of the report and executive director of the Environmental Health Strategy Center, Mike Belliveau, told Chemical Watch: "We did find that the baby product sector is a laggard in ensuring the chemical safety of the products they sell. That should be a wake-up call to action for most consumers and the retailers."

In a Mind the Store press release, Bobbi Wilding, coordinator of the Getting Ready for Baby campaign, called on Toys R Us subsidiary Babies R Us, and Buybuy Baby to make "vast improvements" in 2018.

However, Frederick Locker, attorney at Locker Greenberg & Brainin LLP, the independent general counsel for JPMA, told Chemical Watch: "The premise of the reports and supporting campaigns is a claim the mere presence of a substance or material renders products toxic; rather than a toxicological assessment of hazardous exposure. There is a significant distinction."

'Drop in the bucket'

In response to the JPMA's comments, Mr Belliveau said: "This report is not an assessment of the safety of an individual product, it is a comparison of leaders and laggards in the retail sector regarding policies and practices that are designed to ensure that chemical safety in the products they buy and sell."

He added: "There are thousands of dangerous chemicals and untested chemicals in commerce. The US government has only outright banned two classes of chemicals in toys in recent times, which is lead compounds and phthalates. That's a drop in the bucket."

Ms Wilding said in response to the JPMA: "Baby products retailers were evaluated with the same criteria looking at their corporate practices. You don't need to look any further than the Washington State database on chemicals of concerns in children's products to realise that there are chemicals of concern being reported by manufacturers in products made for children."

She added: "We stand by our concern in making sure that products made for children are made without chemicals of concern, because we are concerned about eliminating the hazards."

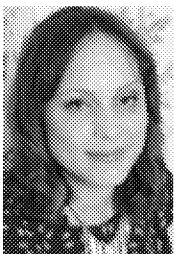
Toys R Us

Toys R Us and its subsidiary Babies R Us, received an F grade, scoring five out of a possible 135 points and ranking 22nd out of 30 retailers.

The report says the store is "failing to publicly address toxic chemicals in the products they sell". Toys R Us missed out on points because it does not publish a corporate responsibility report or other public facing documents that summarise their efforts to address chemicals of concern.

A spokesperson for Toys R Us said that, because the report based its grades on publicly available information, it did not reflect its actual policies or programmes.

Buybuy Baby did not respond to Chemical Watch's request for comment by the time of publishing.



Tammy Lovell

Business Reporter

Related Articles

- Apple comes top in US retailer chemical ranking

Further Information:

- Retailer report card
- Getting Ready for Baby campaign

Head of UN Environment calls for 'targeted intervention' on hazardous chemicals

Executive director sets out framework ahead of global environment meeting

23 November 2017 / Global

In his vision to combat the rise in global pollution, UN Environment executive director, Erik Solheim (pictured), has set out measures to address hazardous chemicals.

Mr Solheim's report, *Towards a Pollution-Free Planet*, outlines actions to tackle the issue around the world and highlights chemicals of concern as a "hard-hitting" target. The report has been prepared for the third United Nations Environment Assembly (Unea-3) in Nairobi, Kenya between 4 and 6 December which has the overarching theme of pollution.

The framework targets substances already addressed through multilateral agreements — such as those covered by the UN's Basel, Rotterdam, Stockholm and Minamata Conventions. The aim will be to identify — and take action on — areas where implementation and enforcement of these substances needs to be strengthened and scaled up. Examples of where action can be taken include:

- identifying alternatives;
- providing additional finances to curb risks;
- capacity building; and
- encouraging industry support.

A second target category will be pollutants where scientific evidence already exists to justify new interventions to reduce the risk that they pose, for example for heavy metals. Actions, it says, could include enforcing new emissions standards and improving chemical labelling schemes.

A third category focuses on substances where the emerging scientific evidence of the "nature and magnitude of their risk to human health and the environment points to the need for further investigation and better understanding of those risks", such as endocrine-disrupting chemicals.

"There is a need to step up research into, and build understanding of, the potential risks of these substances, especially in developing countries," the report says.

Chemicals and waste

The report sets out 50 broad policy options to address air, water, land/soil, marine and coastal, and chemicals and waste pollution. Of these, 19 come under chemicals and waste.

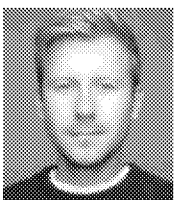
These include:

- adopt sound chemicals management and advance sustainable chemistry within business approaches, policies and practices;

- increase efforts to deploy locally safe, effective, affordable and environmentally sound alternatives to chemicals of concern, including DDT (dichlorodiphenyltrichloroethane), PCBs (polychlorinated biphenyls), asbestos, lead and mercury;
- accelerate the implementation of the Basel, Rotterdam and Stockholm conventions, the Minamata Convention and the Strategic Approach to International Chemicals Management in a coordinated manner at the national level;
- improve knowledge relating to chemicals in products throughout their life cycle (production, use, consumption and disposal); and
- increase publicly available information and monitor data on the presence of chemicals in the environment, in humans and in pollution hotspots.

Last month, the EU Council of Ministers called on UN member states to help increase knowledge of hazardous substances, encourage the exchange of information on chemicals in products and replace hazardous chemicals with safer alternatives.

It called upon the assembly meeting to decide upon concrete measures to deal with specific issues such as endocrine disruptors and heavy metals.



Leigh Stringer

Global Business Editor

Related Articles

- EU Council calls on Unea to increase hazardous chemicals knowledge

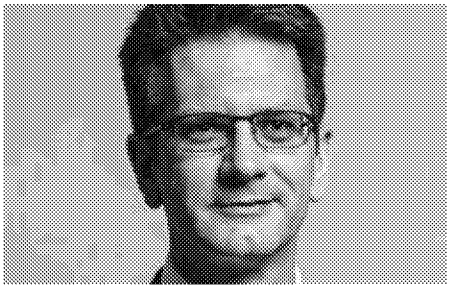
Further Information:

- UN report

UK government wants Brexit deal validity for REACH registrations

Chemicals regulations 'key topic in opening phase of negotiations', minister says

23 November 2017 / REACH, Substance registration, United Kingdom



The UK government has reaffirmed its position that it wants existing REACH registrations and authorisations to remain valid in both the EU and UK markets after Brexit.

And, according to a government spokeperson, the matter has been a key topic of the opening phase of Brexit negotiations.

The comments were due to be made in a speech by Steve Baker, a junior minister in the Department for Exiting the European Union at last week's Brexit conference, which was hosted by the Chemical Industries Association (CIA). Mr Baker was forced to pull out at the last minute but supplied his speaker's notes to the organisation.

"The UK's position is clear," the notes say. "We want existing registrations, authorisations and approvals to remain valid in both the EU and UK markets. Clearly, this is in the interests of businesses in the UK and the EU. [The government] recognises the complex compliance activity that takes place through supply chains.

"We understand the concerns of businesses regarding the validity of their REACH registrations, as well as the costs that industry have already invested to comply with REACH," he says. "We have been listening to what businesses and others have been telling us about their concerns for the future and the potential impacts and opportunities of EU Exit. We will continue do this.

"I can assure you that this matter has been a key topic of the opening phase of negotiations. Our position paper on this in August sets out the UK's principles for ensuring goods continue to be available on UK and EU markets."

The CBA, CIA and Cefic have all called for regulatory consistency and for the country to remain in REACH. Failure to do so, they say, might result in British registrations and authorisation applications becoming invalid.

Continuity

In the short-term, Mr Baker's notes say, the EU Withdrawal Bill will provide "continuity" for the chemicals sector, because it is "designed to ensure" that the UK exits the Union with "certainty, continuity and control".

According to the notes, the UK wants:

- high standards of protection of human health and the environment;
- to make sure it can respond to emerging risks; and
- to make sure it can minimise barriers to trade.

Britain and the EU start from "the unique position" of regulatory alignment, Mr Baker says. "So the question for us now, in building a new economic partnership, is not how we bring our rules and regulations closer together, but how we manage our interdependence in a way that maintains the balance of rights and obligations that flow from this regulatory relationship."

It is in the "mutual interests" of the UK and EU chemicals industries to agree a deal that allows the greatest possible tariff-free and barrier-free trade in chemicals.

In the "unlikely scenario" that no mutually satisfactory agreement can be reached, the government will "make sure we continue to have a functioning chemicals regulatory and enforcement system".

Earlier this month, CIA and Cefic said failure to secure a transition period and a new UK/EU trade agreement after Brexit could cost the chemicals industry an extra €1.5bn a year.

Collaboration

The chemicals sector, Mr Baker's notes say, is "the industry of industries", and one of the UK's "core objectives" is to continue to collaborate with European partners on major science, research and technology initiatives.

"The UK will look to build on its unique relationship with the EU and establish an agreement on science and innovation that ensures the valuable research links between us continue to grow."

And the notes say "stakeholder engagement is a central element" of the government's plan to build its negotiating positions.

Industry and NGOs have both called for business to "speak up" for a better Brexit, through cooperation and more visibly communicating their concerns.

Luke Buxton

Europe desk editor

Related Articles

- UK minister wants REACH 'mutual recognition' accord
- Chemicals industry 'must work together' to limit Brexit damage
- Cefic, CIA spell out 'hard' Brexit costs to chemicals industry
- Cefic, CIA spell out 'hard' Brexit costs to chemicals industry

- Businesses 'need to speak up' for a better Brexit

Further Information:

- Steve Baker speaker's notes

Echa round-up

23 November 2017 / Classification, labelling and packaging Regulation, Europe, SVHCs

Extension of public consultation on CLH

Echa will extend the public consultation comment period on harmonised classification and labelling (CLH) proposals from 45 to 60 days from 1 January 2018. The reason for this is to allow more time for the parties concerned to prepare and submit their comments, the agency says.

Testing proposals

The agency has received twelve testing proposals for eight substances. The deadline for submitting information is 8 January 2018.

Translations:

- **Guidance on labelling and packaging**

Translations of the updated Guidance on labelling and packaging (version 3.0) published in July, are now available in 23 EU languages on Echa's website.

- **Information on manual verification**

The agency's advice for manual verification at the completeness check was updated in October. Translations in 22 EU languages are now available.

Survey of SVHC Roadmap tools

Echa is reviewing, with member states and the European Commission, implementation of the roadmap for SVHC identification and REACH risk management measures from now to 2020 (the SVHC Roadmap).

In particular, the agency is looking for ideas on how to improve current tools that have been developed to enhance and support the transparency and predictability of the work of authorities.

Survey of poison centres website

Echa is planning an update of the poison centres website and would like users' opinion on the current content. Its online survey will take about five to ten minutes to complete, it says.

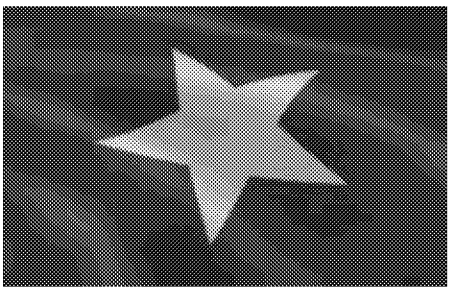
Further Information:

- Current testing proposals
- Guidance on labelling and packaging

- Manuals
- Online survey: SVHC Roadmap and tools
- Online survey: poison centres website

Vietnam to introduce national database by 2019 at earliest

23 November 2017 / Vietnam



Vietnam aims to complete its first comprehensive national chemical inventory and database by 2019, an official at its chemicals agency Vinachemia said.

Speaking at the International Chemical Management Conference earlier this month, Nguyen Thi Ha, head of the organisation's Conventions and International Cooperation Division, said that one of its priorities is the development of a national chemical database and inventory.

The government is funding the project with support from Japan's Ministry of Economy, Trade and Industry (Meti). The agency published a draft inventory in March 2017.

The new database and inventory aim to reach an effective list of between 300 and 400 chemical substances.

"We expect that we can complete this task at the earliest by 2019," she said.

Details of Decree 113/2017/ND-CP unveiled

During the conference, Ms Ha also introduced the key points of Decree 113/2017/ND-CP which regulates the declaration of manufacturing/import of chemicals. The rules take effect on 25 November and include:

- adding requirement for the bottling and packaging of chemicals;
- adding clear criteria for each list of chemicals based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) classification;
- removing the current list of toxic chemicals;
- removing the requirement for the registration for the use of chemicals; and
- mandating that reporting requirements to be integrated in general reports on all chemical activities.

The aim is to ease numerous onerous or unnecessary restrictions and make some tasks for self-management.

More on this on *CW+AsiaHub*

Dennis Engbarth (Taipei City)

Related Articles

- Vietnam updates draft existing chemicals inventory
- Vietnam publishes new chemical decree
- Vietnam to introduce national database by 2019 at earliest

Spanish initiative targets child poisoning from 'everyday' products

23 November 2017 / Accidents, emergency response & poison centres, Cleaning products, Labelling, Spain

The Spanish consumers federation, CECU, has launched a new initiative to raise awareness of chemicals contained in glues and paints, used daily by children. It will also target household products, such as detergents, to prevent incidents of poisoning.

The project – Ojo a la Etiqueta (Watch the label) – will promote knowledge about the labelling and safe use of stationery items, including markers and correctors, as well as cleaning products and insecticides used at home.

"Every year thousands of accidents related to poisoning occur, of which more than 93% happen in the home and more than 45% affect children under ten years," CECU said in a statement.

The project, to be carried out in collaboration with the Spanish chemicals industry association (Feique), will be presented in Madrid today. Mercedes Vinas, Echa's head of unit for dossier submission, will be at the launch.

The CECU says it has prepared ten training sheets for parents, tutors and teachers with advice on what to do if a child swallows paint, glue or medication, and how to act in case of poisoning. The material will also be available on the CECU website.

It has also created a mobile app with:

- access to the sheets;
- rapid advice in case of poisoning; and
- a direct dial button to the Toxicological Information Service.

The initiative, subsidised by the Spanish agency for consumer affairs, food safety and nutrition (AECOSAN), will be disseminated in social networks and has the hashtag #OjoALaEtiqueta.

Earlier this year, soap and detergents trade body Aise said some of its members plan to undertake voluntary measures, to help reduce child exposure to liquid laundry detergent capsules (LLDCs). These will include superior child-impeding closures and an advertising code of conduct.

It followed European Commission's LiquiCaps study, which highlighted an increase in the numbers of accidental exposure or poisoning in children under five, when compared with traditional detergents.

Related Articles

- Aise proposes measures to reduce detergents poisoning in children

Further Information:

- Press release (Spanish)

Echa: non-animal tests for complex endpoints remain distant

Regulatory applicability 'not foreseen' in near or medium term

23 November 2017 / Biocidal products Regulation, Classification, Classification, labelling and packaging Regulation, Europe, GHS, REACH, Test methods

Non-animal approaches for the prediction of higher-tier hazard endpoints that would be applicable under EU chemical legislation are "not foreseen" in the near or medium term, according to analysis by Echa.

Non-animal approaches in general are the subject of "very active ongoing research", the agency said in a report on the current status of regulatory applicability of such approaches under the REACH, CLP and biocidal products Regulations. Furthermore, those for the prediction of certain lower-tier endpoints, such as skin irritation, corrosion and sensitisation, have become standards, as defined by the legislation.

But non-animal approaches for the prediction of more complex endpoints, such as repeated dose or reproductive toxicity, remain far off, the report said.

Challenges

The report outlines several challenges to the development of such approaches and their uptake in regulatory contexts.

First, they do not always provide the same levels of information as their animal equivalents in terms of the dose- or concentration-response relationship and adverse effects, it says. Some still under development could provide higher levels of information than current ones. These include approaches based on *in vitro* microsystems and high-throughput or high-content approaches. But these will still require standardisation and validation before they can be used in regulatory contexts.

Second, standardisation and validation is complicated by the plurality of approaches required, compared with animal equivalents. Regulators must work out how data generated by non-animal approaches that do not have a direct relationship with an endpoints specified in CLP, can be used for classification and for the derivation of safe use levels.

The agency suggests that an inventory of non-animal approaches that shows stage of development and regulatory applicability would help to identify gaps and determine future steps to enhance use.

The report, requested by Echa's management board, is the first of its kind. In previous reports, requested by the European Commission and published in 2011, 2014 and 2017, Echa provided data on companies' use of non-animal approaches under REACH.

In contrast, for each relevant information requirement, the new report provides:

- the potential non-animal approaches;
- the challenges to achieving their use in regulatory contexts; and
- future perspectives, including of those approaches that could be close to regulatory applicability.

In a foreword, outgoing Echa executive director Geert Dancet says he hopes the report will act as a guide for the scientific community.

Animal rights NGO Humane Society International (HSI) questioned "the continued emphasis on animal methods as the basis for comparison of the viability of new methods". Such emphasis presumes that toxicology studies on animals are the only valid approach, it said.

"These words must now be backed-up by more positive practical action and financial support for the promotion of non-animal approaches."

Furthermore, future reviews should be led by "mandated bodies", such as the European Commission Reference Laboratory for Alternatives (EURL-Ecvam), HSI said.

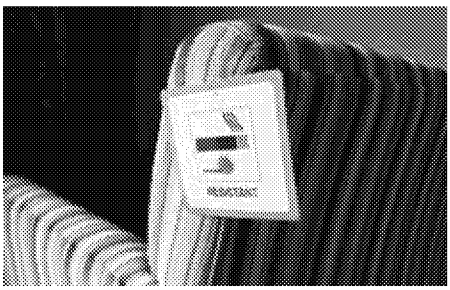
Further Information:

- Report

Furniture trade body welcomes EU warning on flame retardants

Member states urged to evaluate testing methods for upholstered items

23 November 2017 / Built environment, Europe, Substances of concern



The European Furniture Industries Confederation (Efic) has welcomed a warning, included in the revised EU Green Public Procurement criteria, on the negative effects of flame retardant use.

GPP criteria for furniture are voluntary guidelines, which aim to help public authorities purchase products and services with reduced environmental impacts.

In the staff working document on the EU GPP, the European Commission notes that the open flame test for upholstered furniture (EN 1021-2) requires a lower level of flammability than the European 'smoulder ignition test' (EN 1021-1).

It says the open flame test can lead to use of flame retardant chemicals which "may have negative effects for the environment, health, durability and quality of products, and may lead to cost increases".

The guidelines urge public authorities to "therefore consider, according to the intended use and location of the furniture items, what levels of flammability it needs to require."

'A first step'

Efic general secretary, Roberta Dessi, told Chemical Watch that the association was glad the Commission had adopted this recommendation.

She said: "It is a first step. We believe that this can help raise awareness among member states about the consequences of choosing certain flammability tests for furniture."

But she added that the "sustainability part" of public tenders is often accompanied by demands for very stringent flammability standards. This leads to widespread use of flame retardants "in contradiction with the aim of having truly green procurements".

She urged member states to "use this feedback to re-evaluate the need for such stringent standards for furniture in their national requirements, in the light of the overwhelming scientific evidence on risks connected to flame retardant use."

The UK and Ireland are the only EU countries to have national regulations requiring an open flame test for domestic furniture, which effectively necessitates the use of flame retardants. Last year, Efic lodged a complaint with the Commission on the basis that these standards pose a barrier to trade in the single market.

For furniture for the public market there are different national regulations in force, some of which also impose open flame tests.

Furniture design

The GPP criteria technical report acknowledges that the need for flame retardants can potentially be avoided by "careful choice of materials and product design". But it says that this type of upholstered furniture "can be considered to only represent a niche market at this stage and, unlike California, current fire safety standards in Europe for public furniture are currently not well set up to embrace this approach."

California removed its open flame test in 2013. Prior to that, California's Technical Bulletin (TB) 117 had served as the de facto national standard, which effectively required the use of flame retardants.

The report adds that the lack of a harmonised approach to fire safety standards, at the European level, means that "any potential restrictions on flame retardants, recommended in EU GPP criteria, may conflict with specific member state legislation."

Ms Dessi responded: "Our campaign is aimed at having a more proactive approach from European institutions, in making the case for flame retardant free furniture possible."

She also noted: "In addition to the environmental and health impact, there is a growing concern that flame retardants may increase fire toxicity. This would also seriously question any concrete fire safety benefit from their use."

Efic is a member of the Alliance for Flame Retardant Free Furniture in Europe, a coalition of stakeholders including industry associations and environmental NGOs.

Last year, the coalition published a paper, *The Case for Flame Retardant free Furniture,* calling for the EU to harmonise fire safety regulations so that the chemicals were not required for them to be met.

Efic have argued that the use of flame retardants and other chemicals may prevent the furniture sector from fully entering the circular economy.

Earlier this year, San Francisco banned the sale of upholstered furniture and children's products, "made with or containing an added flame retardant chemical". More than a dozen US states have banned some categories of the chemicals.

Tammy Lovell

Business Reporter

Related Articles

- EU Commission publishes green public procurement criteria for furniture
- Industry challenges UK and Irish furniture standards
- Industry challenges UK and Irish furniture standards
- Furniture trade body calls for clarity on recyclable chemicals
- San Francisco bans sale of furniture treated with flame retardants

Further Information:

- GPP working document
- EU GPP technical report
- The Case for Flame Retardant Free Furniture report

ToxCast and Tox21 high-throughput data identify potential EDCs

Fifra SAP set to discuss androgen receptor model

23 November 2017 / Alternative approaches to testing, EDCs, United States

ToxCast and Tox21 high-throughput screening data provide a "rapid and effective resource" for identifying substances with the potential to activate human oestrogen (estrogen) receptors (ERs), according to a top US Environmental Protection Agency (EPA) official.

Stan Barone, acting director of the EPA's Office of Chemical Safety and Pollution Prevention, was describing progress in using ER high-throughput assays for tier 1 of the Endocrine Disruptor Screening Program (EDSP) at a workshop on toxicity testing and decision making.

The EDSP uses an oestrogen receptor model that integrates data from 18 high-throughput assays. The agency has recently been looking into whether it actually needs all of the tests to get the same predictive validity from the model, and has a publication in press. "The short answer is we don't need 18 assays," said Dr Barone.

The EDSP is making good progress on an androgen receptor model, which integrates 11 *in vitro assays*, he added.

The Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (Fifra SAP) is set to discuss the tests between 28 and 29 November.

Limitations

Like most alternative approaches, the high-throughput assays have limitations, Dr Barone explained. These include metabolism and solubility issues. False negatives can result from low solubility, which limits test chemical concentrations. Furthermore, reactive compounds, metals and particulates tend not to work well in the low volume, high-throughput assays, he added. The EPA is conducting research to address these issues.

The agency is also looking into "critical performance criteria" to include in a performance-based guideline to help stakeholders understand data and documentation requirements.

One of the lessons learned is that annotating assays is "critically important for acceptance", said Dr Barone.

Understanding pathways to a paradigm shift in toxicity testing and decision making was held by the National Academies of Sciences, Engineering and Medicine in Washington DC between 20 and 21 November.

Related Articles

- NICEATM and EPA publish androgen receptor model

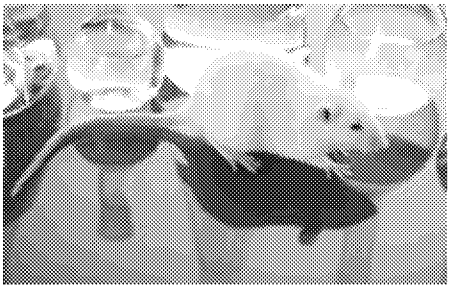
Further Information:

- Understanding pathways to a paradigm shift in toxicity testing and decision making
- Fifra SAP white paper

US NAS workshop raises issue of animal tests as 'gold standard'

Greatest progress where human data available

23 November 2017 / Test methods, United States



The issue of whether animal test methods should be used as as a "gold standard" against which to judge the alternatives was raised by multiple attendees at a recent US workshop on toxicity testing and decision making.

"It is one of the big challenges that we face," said Anna Lowit, co-chair of the Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam) and senior science adviser at the US EPA's Office of Pesticide Programs.

"One of the things that we are finding is that we are having the most success in areas where human data exists to make those comparisons," she added. As an example, she pointed to recent research suggesting that OECD test guidelines for skin sensitisation may give better predictions of human toxicity than the local lymph node assay (LLNA) in rodents.

Maurice Whelan, head of the EU Reference Laboratory for Alternatives to Animal Testing (EURL Ecvam), described the relevance and variability of animal test results as the "elephant in the room". In the case of alternative skin sensitisation test methods, discussing it with regulatory committees resulted in an important step forwards. "What's the variability of the LLNA data? ... From the human data that we have, we know it's not perfect."

Rodent retreat

Meanwhile, Dr Lowit spoke of progress in moving away from rodent tests for skin irritants, and effects in the nasal cavity and lung tissue.

"Industry partners are working towards actually eliminating the 28-day and 90-day rate inhalation study, just because it's not really relevant to humans," she said. "We can do better with animal 3D tissues combined with sophisticated pharmacokinetic modelling and just avoid the animal completely."

She predicted that: "When we start to tackle complicated things, like cancer and developmental reprotoxicity, we will have enough experience under our belt, in a way that we won't have to hold up the rat and the mouse models as a gold standard."

The importance of uncertainty

Finally, workshop participants agreed on the need to understand the uncertainties associated with alternative test methods.

The skin sensitisation case "highlights the importance of something that we have neglected for many years: appreciating that, in fact, understanding uncertainty, describing it, talking about it, is extremely important for moving towards people using new approaches," said Professor Whelan.

"The good news is that we won't have to start from scratch. There is an awful lot of rigorous scientific-based work being done on how to go about describing uncertainties."

Understanding pathways to a paradigm shift in toxicity testing and decision making was organised by the US National Academies of Sciences, Engineering and Medicine and held in Washington, DC on 20-21 November.

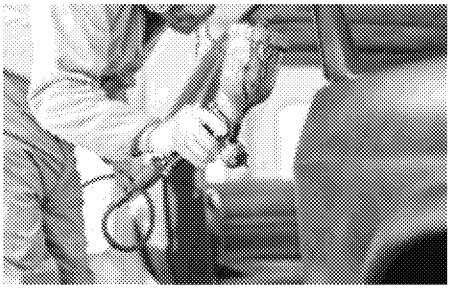
Further Information:

- Understanding pathways to a paradigm shift in toxicity testing and decision making

REACH exposure scenario group looks for improvements

New batch of updated use maps to be published soon

24 November 2017 / Europe, Exposure scenarios



Stakeholders of the REACH Exchange Network on Exposure Scenarios (Enes) have been discussing a draft programme that will take its work through until 2020, at its eleventh meeting in Helsinki this week.

The network aims to improve the content and use of exposure scenarios generated under REACH. They are a key element of safe use communication through the supply chain through the extended safety data sheet.

Erwin Annys, REACH director at Cefic, told stakeholders – including representatives from Echa, up and downstream industry and member state authorities – the programme aims to tackle six issues:

- promotion of the Enes tools to various stakeholders;
- support for downstream sectors developing use maps;
- support for registrants in applying new use information in their chemical safety reports, and communicating safe use information through the supply chain. Proposed activities include adapting the software tool Chesar and building a common practical framework for various estimation tools relating to worker exposure;
- improving tools for formulators;
- further market research especially to help downstream users; and
- improving the interface between REACH and occupational safety and health controls.

The programme will be finalised early next year, and presented to the Competent Authorities for REACH and CLP (Caracal) in March.

Updated sector use maps

Meanwhile, a raft of updated REACH sector specific use maps are expected to be published shortly on Echa's website. The agency's Laure-Anne Carton de Tournai, said that 13 sectors are currently active in the programme.

So far six groups have published the standardised information. This aims to provide realistic descriptions of chemical uses and, depending on their relevance, inputs for worker, consumer and environmental exposure, in their industries.

Another five sector groups – paints and coatings, plastics additives, petroleum products, solvents and fertilisers – will be published soon.

Ms Carton de Tournai also gave figures for how many files had been downloaded from the Echa use map library.

The detergents sector, represented by Aise, which had its documents published in October 2016, has had nearly 5,800 downloaded; and the adhesives and sealants industry (Feica) has had more than 3,500 documents downloaded since November 2016.

Ambition

Echa is unclear on exact use of the documents. Originally the ambition was for the updated use maps to be implemented in 2018 dossiers. However, this has not occurred, and the hope now is they will be used to update dossiers after the deadline.

Speaking for the European Solvents Industry Group (Esig), Cornelia Tietz said assessment of generic exposure scenarios developed for solvent uses for the 2010 REACH deadline showed good alignment with the new batch of use maps and specific worker exposure determinants.

Dook Noij of Dow outlined a pilot project trying to quantify the benefits of the harmonised communication package ESCom XML, and standard ESCom phrases. The project indicated that manual exposure scenario data input takes between 2-4 hours, compared to five minutes to quality check electronic submissions – if all phrases exist in ESCom. If there are phrases missing, the estimated time is up to an hour.

Mr Noij noted that the initial effort needed to implement ESCom XML can be significant, but he said the benefits included improved use of resources and expertise, and faster processing.

Emma Chynoweth

Chief Customer Officer

Further Information:

- Enes 11
- Use map library

OTHER ARTICLES

Jennifer Jelinek: Finalize EPA toxic chemical rules

Madison.com

Dear Editor: Thanks to the 2016 update of U.S. chemical policy, the EPA now has the authority to protect us from toxic chemicals. EPA proposed rules ...

Vt. toxics law provides data, but not clarity, about kids' toys

BurlingtonFreePress.com

Companies reporting any of the 66 chemicals to Vermont included ... has worked for years to help Vermonters know more about **toxic chemicals**.

Toxic chemical found in children's products

KIMT 3

Toxic chemical found in children's products ... The toxin is a cheap chemical some companies use instead of lead. It's been linked to bone damage, ...

Toxic chemical found in children's products

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Toxic chemical found in children's products ... The toxin is a cheap chemical some companies use instead of lead. It's been linked to bone damage, ...

Group finds many consumer products still contain **toxic chemicals**

ConsumerAffairs

Photo (c) gilaxia - Getty Images In a report on **toxic chemicals** contained in consumer products, a consumer group finds two thirds of retail companies it ...

Advocacy group Safer **Chemicals**, Healthy Families rates **toxic** retailers

CosmeticsDesign.com USA

A Report Card on Retailer Actions to Eliminate **Toxic Chemicals** purports to rate stores based on their efforts to limit or regulate "**toxic chemicals** in ...

Letter: A **toxic** EPA pick

Concord Monitor

But he is not someone you can trust to protect your children from **toxic chemicals**. In fact, it is his extensive background as a paid researcher for the ...

Annual 'Trouble in Toyland' report highlights dangerous small parts and confusing labels

KOMO News

... from toys and other children's products made with harmful **toxic chemicals**. ... But there are numberous chemicals that must still be addressed.

California should expand on San Francisco's flame retardants ban

San Francisco Examiner

A lack of statewide action to eliminate **toxic**, flame retardants continues to jeopardize their health, along with the health of all Californians. “We're long overdue for bold statewide policy prohibiting the unnecessary use of flame-retardant **chemicals**,” Debbie Raphael, director of the San Francisco ...

Touching receipts can lead to lengthy pollutant exposures

Science News for Students

Over the next several days, the researchers measured how much of the tagged BPA came out in the mens' urine. This showed how quickly the body was processing and removing the chemical. (Waste products, including BPA and other **toxic chemicals**, are filtered out of the bloodstream by the kidneys.

Explainer: Store receipts and BPA

Science News for Students

By the early 2000s, Warner was teaching **green chemistry** at the University of Massachusetts in Boston and Lowell. “I'd send my students out to local stores to get their cash register receipts.” Back in the lab, they'd dissolve the paper. Then they'd run it through a mass spectrometer. This instrument could ...

Message

From: Hamernik, Karen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02BBE1896C484C03A2D02DD496640B3A-KHAMER02]
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To: Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Lowit, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d3428a2c0b84d5099124a0460babd53-Anna B. Lowit]; Barone, Stan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4f8618acbba418da24c110f3123a2af-Barone, Stan]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Keigwin, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=151baabb6a2246a3a312f12a706c0a05-Richard P Keigwin Jr]
CC: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Hanley, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]
Subject: RE: STPC September Meeting
Attachments: 1_Agenda Sep 12 STPC Meeting_0905.docx; 2a_Strengthening Transparency in Regulatory Science presentation v4.pptx; 2c_STPC_Pbslides_09-12-18mtg_HH-VZ_DraftInternal.pptx; 3_EPA_NTTAA-Coordination_20170310.pdf; 3_NTTAA_CoP-Roster_by-AAship-Region_2018.pdf; 3_NTTAA_VCS-Participants_20180116.pdf; 3_Standards Participation Guidance - 1-page summary - 20180723.pdf; 3_STPC - NTTAA Participation Guidance - 20180827.pptx; 4_Draft Charge for Citizen Science workgroup under STPC_081518.docx; 4_epaoig_20180905-18-P-0240_cert.pdf; 4_STPC meeting Citizen Science 9-04-2018.pptx

All,

OSA has released materials for the September 12, 2018 STPC meeting:
1) Agenda
2) Agenda Item 1a: Slide set: Strengthening Transparency in Regulatory Science Rulemaking
3) Agenda Item 1c: Slide set: Status of Draft Federal Lead Strategy
4) Agenda Item 3: Voluntary Consensus Standard (VCS) Development materials (5 items)
5) Agenda Item 4: Citizen Science IG report, Sept 5, 2018 and Slide set
6) Agenda Item 4: Citizen Science Draft Workgroup Charge

More items may be added prior to the meeting.

Thanks,

Karen

-----Original Appointment-----
From: Science and Technology Policy Council Staff
Sent: Wednesday, September 05, 2018 3:08 PM
To: STPC Members
Cc: STPC_SSP; Greene, Mary; Sinks, Tom; Amon, Dan; Griesinger, Mark; Poeske, Regina; Best-Wong, Benita; Mazza, Carl; O'Farrell, Thomas; Armstead, John A.; Anand Mudambi; Carpenter, Thomas; Kumar, Manisha; McNaughton, Eugenia; Newton, Cheryl; Orme-Zavaleta, Jennifer; Ohanian, Edward; Firestone, Michael; Duncan, Bruce; Henry, Tala; Bussard, David; Morton, Michael; Shields, Amy; Greenblott, Joseph; Minoli, Kevin; Raffaele, Kathleen; Mundrick, Doug; Teichman, Kevin; ORD-OSA; Martin, Lawrence; Broder, Michael; Vogel, Dana; Rodan, Bruce; Sonich-Mullin, Cynthia; Siciliano, CarolAnn; Weber, Robert; Zartarian, Valerie; Doa, Maria; Owen, Elise; Frithsen, Jeff; Hughes, Hayley; Guiseppi-Elie, Annette; Ali Goldstone; Schumacher, Alessandria
Subject: STPC September Meeting
When: Wednesday, September 12, 2018 2:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DC Location - Ronald Reagan Building Room 41213

AGENDA

SCIENCE & TECHNOLOGY POLICY COUNCIL MEETING

Wednesday, September 12, 2018
2:00 – 4:00 PM ET

Conference Room (DC): Ronald Reagan Building 4th Floor Room 41213
Audio Conference Call-in Number: 1-202-991-0477
Conference Code: 312-3584

Adobe Connect Information: http://epawebconferencing.acms.com/amudambi/

1. **Introductory Remarks and Roll Call** (10 minutes, to 2:10)
   Lead: Jennifer Orme-Zavaleta (Science Advisor)
   Roll Call: Anand Mudambi, STPC Coordinator (OSA)

2. **Updates:** (40 minutes, to 2:50)
   a. Strengthening Transparency Rule (Response to comment and rulemaking): Maria Doa (ORD)
   b. PFAS Coordination : OW
   c. Pb Coordination : Hayley Hughes and Valerie Zartarian (ORD)
   d. Contaminants of Emerging Concern Project : Jeff Frithsen (ORD)
   e. Standing Groups Status : Anand Mudambi (OSA)

3. **Voluntary Consensus Standard (VCS) Development - Draft EPA Guidance** (20 minutes to 3:10)
   Lead: Elise Owen (EPA Standards Executive, housed in OCSPP)
   Purpose: Brief the STPC on the development of Agency guidance regarding EPA personnel participation in private sector Voluntary Consensus Standards (VCS) development
   Outcome: Inform STPC input on the draft guidance

4. **Citizen Science** (25 minutes, to 3:35)
   Lead: Jay Benforado (OSA)
   Purpose: Discussion of Draft Charge to Implement NACEPT and OIG Recommendations
   Outcome: Get STPC input on the charge activities

5. **RAF Cumulative Risk Assessment (CRA) Technical Panel Products** (20 minutes, to 3:55)
   Lead: Lawrence Martin (OSA)
   Purpose: Inform STPC about the CRA Guidelines on Planning and Problem Formulation, and the Document updating Chemical Mixtures Additivity
   Outcome: Preparation for STPC concurrence on the RAF's CRA products for external peer review

6. **Summary of Action Items** (5 minutes, to 4:00)
   Report: Anand Mudambi (OSA)

Next STPC Meeting: Wednesday, December 5, 2018

AGENDA

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Next STPC Meeting: Wednesday, December 5, 2018

STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE RULEMAKING

OVERVIEW

- Proposed on April 30, 2018
- The proposed rule would require that for significant regulatory actions, the underlying data for pivotal regulatory science be made publicly available to support independent validation of the studies
- OPD is leading the Agency workgroup for this Tier 1 action
- Representatives from OAR, OGC, OLEM, OP, OW, OCSPP, R4, R5 and R7
  - Have started assessing some issues
- ORD team representatives from OSP, OCA, NHEERL, NERL, OSIM, NCEA

PUBLIC COMMENT

- Public Hearing was held on July 17, 2018
  - 150 attendees and 91 speakers
- Public comment period closed August 16, 2018
  - Comments are still being processed but as of August 21, 2018 there were almost 600,000 public comments of which more than 9,500 are unique comments
- In the process of organizing and reviewing the comments

- Comments submitted by
  - Professional organizations and journal editors
    - E.g. SOT, ACS, AAAS
  - States, Tribes and Localities
  - State associations
  - Industry
  - Environmental groups
  - Health groups
  - Labor Unions
  - Universities
  - Public
    - Federalregister.gov/documents/public_submissions

PUBLIC COMMENT

PUBLIC COMMENT

- Major categories of comments
  - Comparison of the proposed rule requirements with statutory findings and procedures in environmental statutes
  - What problem is the proposed rule intended to fix?
  - Consistency with the Administrative Procedures Act
  - Degree of consistency with scientific norms
  - Types and extent of data that would be excluded
  - EIS
  - Quality of regulatory text
  - Costs
  - Peer review
  - Does the process work?

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
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To: Askinazi, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f11a6972234134ae9b2f59a4a26709-Askinazi, V]; Barkas, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=808724835d8a457fb0c5333e62b34291-Barkas, Jessica]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; Brown, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da0a099605514dbeb3ebab7aaf253de6-Brown, Sam]; Buster, Pamela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0d03c8a52440b7a95343287b8928c5-PBuster]; Canavan, Sheila [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5453ba7f3d4582a0eff06ed80a5e79-Canavan, Sheila]; Caraballo, Mario [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e9d657e48042fea4bb7c68f78a023c-Caraballo, Mario]; Carroll, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882c7705ed3f4d50aba9a7870f9eb6cc-MCarr03]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Christian, Myrta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=207ad12497b04bcf8e80a0024b35a18a-MChris02]; Corado, Ana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb9257919594061b763f306c2f8be60-ACorado]; Davies, Clive [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eca39ab66ea413993d7355fd46b1008-Davies, Clive]; DeDora, Caroline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e587cd3b59b46f59a369df26390fd9f-Newton, Caroline]; Devito, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be78622515bd451e96e948786357fb45-SDevito]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Drewes, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1107458a6d814a61ab24b605aff2c7ba-Drewes, Scott]; Dunton, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ffa0e71e87448cc9fd86ba1379ea93a-Dunton, Cheryl]; Ebzery, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5729928cba7e4025bbdcd3504c791095-JEbzery]; Edelstein, Rebecca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9549e6e2f43e4a3c88cc3bea8f7220f5-Rebecca L Edelstein]; Edmonds, Marc [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed31dcc62754411aae5e1be96ed01f1d-MEdmonds]; Eglsaer, Kristie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5365adea6f9a4f3397bdc735dafe4c32-Friesenhahn, Kristie]; Elwood, Holly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc14ca33efe94036a4b406c9951eb70a-HElwood]; Farquharson, Chenise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b240335cb7b41d79edb4ef922386a23-Farquharson, Chenise]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: News Articles (For EPA Distribution Only))

BNA DAILY ENVIRONMENT REPORT ARTICLES

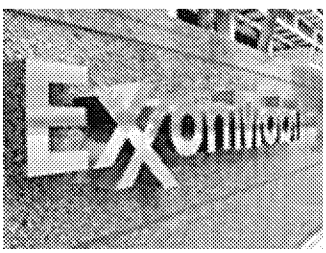
Security Detail Added $30K More to EPA Chief's Italy Trip

Travel costs for security personnel accompanying EPA Administrator Scott Pruitt to Italy tallied $30,554, bringing the grand total for the trip to $120,249, according to documents obtained by the Environmental Integrity Project.

Trump EPA Plans New Restrictions on Science Used in Rulemaking

The Environmental Protection Agency is preparing to restrict the scientific studies it uses to develop and justify regulations, making it harder to rely on research when its underlying data are shielded from view.

Exxon Says U.S. Gulf Coast Plastics Project Could Begin by 2021



Snapshot

• Final investment decision due to be taken later this year

• U.S. shale boom has spurred hundreds of chemical investments

By Kevin Crowley

Exxon Mobil Corp. said a project to expand plastics manufacturing along the U.S. Gulf Coast could start up by 2021 as the oil explorer boosts investment in a business that accounted for almost one-fourth of last year's profit.

Engineering work has begun on a facility that would increase Exxon's ability to produce polypropylene, a resin used to make lightweight and durable plastics, by as much as 450,000 tons a year, the Irving, Texas-based company said in a statement March 20.

The project will cost "several hundred million dollars" with a final investment decision due later this year.

Hundreds of U.S. chemical projects valued at $188 billion have been announced since 2010, according to the American Chemistry Council, as the U.S. shale boom slashed the cost of oil, natural gas, and byproducts used as feedstocks.

"Most of our planned investment in the Gulf Coast region is focused on supplying emerging markets like Asia with high-demand products," John Verity, who heads Exxon's chemical business, said in the statement.

Exxon's polypropylene project is one of the company's 13 new facilities planned to expand chemical output in North America and Asia.

—With assistance from Jack Kaskey.

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To contact the editors responsible for this story: Reg Gale at rgale5@bloomberg.net

Bid for FDA Ban of Formaldehyde Hair Products Stalled

Two environmental groups can't force the Food and Drug Administration to begin rulemaking to regulate or ban formaldehyde in hair-straightening products, the U.S. District Court for the District of Columbia said March 19.

GREENWIRE ARTICLES

Negotiators aim to settle policy fights, post omnibus tonight

George Cahlink and Geof Koss, E&E News reporters

Published: Tuesday, March 20, 2018

Congressional leaders hope to have massive omnibus spending legislation on the House floor by Thursday. Wikipedia (money); Ed Uthman/Flickr (Capitol)

Congressional leaders hope to have massive omnibus spending legislation on the House floor by Thursday, assuming they can resolve a few dozen outstanding policy fights.

House Speaker Paul Ryan (R-Wis.) said this morning he's "hoping" to file the $1.3 trillion spending bill late tonight, paving the way for the House Rules Committee to consider the bill tomorrow and then floor action Thursday

https://www.eenews.net/greenwire/2018/03/20/stories/1060076859

Pruitt aide didn't have to sign Trump ethics pledge

Kevin Bogardus and Amanda Reilly, E&E News reporters

Published: Tuesday, March 20, 2018

U.S. EPA headquarters in Washington. EPA/Flickr

One of U.S. EPA Administrator Scott Pruitt's top aides wasn't required to sign President Trump's ethics pledge.

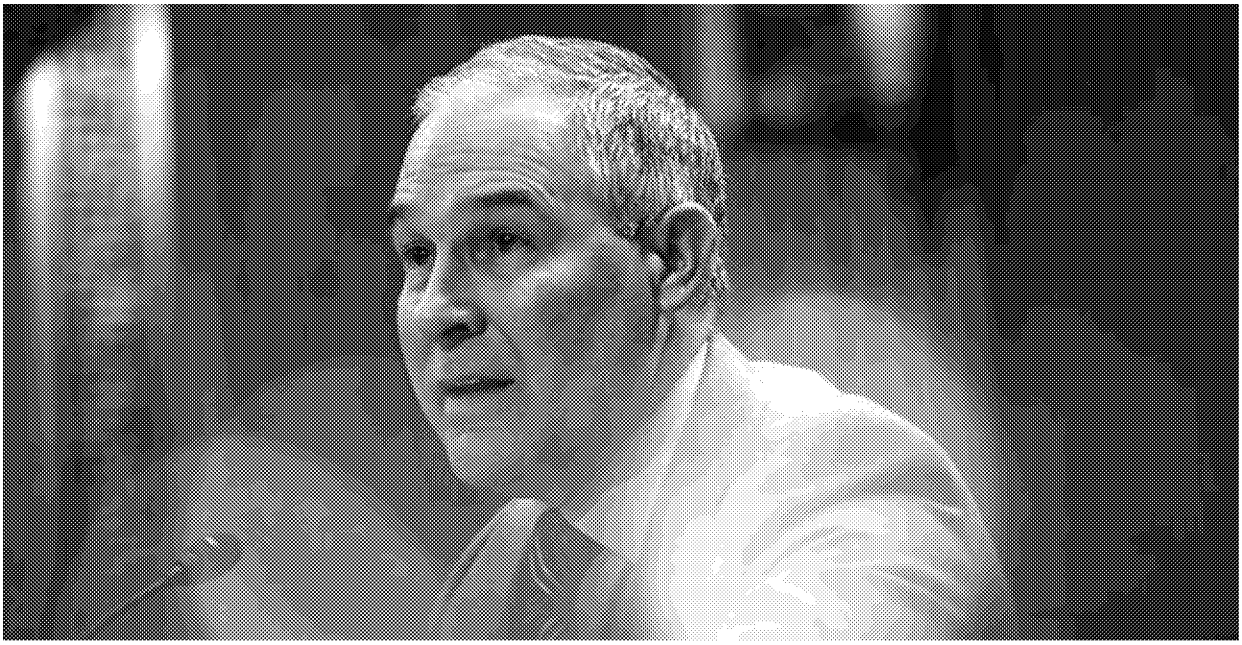
Byron Brown, deputy chief of staff for policy, was hired in an "administratively determined" position — a unique hiring authority held by the agency under the Safe Drinking Water Act. Consequently, Brown was not designated as a political appointee and didn't have to abide by the pledge.

https://www.eenews.net/greenwire/2018/03/20/stories/1060076851

Details lacking as Pruitt attacks 'secret science'

Scott Waldman, E&E News reporter

Published: Tuesday, March 20, 2018



U.S. EPA Administrator Scott Pruitt is sharing few details about his plan to make agency science more transparent. Pablo Martinez Monsivais/Associated Press

U.S. EPA is not releasing details of its plan to make science at the agency more transparent.

EPA will require that data and methodology from studies used to craft regulations be made public. In addition, studies that receive EPA funding must make data public.

EPA spokesman Jahan Wilcox would not release additional information about the plan and referenced Administrator Scott Pruitt's comments to the conservative news organization *The Daily Caller*. The agency sent that publication the article as a press release but did not otherwise lay out any details.

https://www.eenews.net/greenwire/2018/03/20/stories/1060076849

EPA plans summit on politically toxic nonstick chemicals

Corbin Hiar, E&E News reporter

Published: Tuesday, March 20, 2018

U.S. EPA Administrator Scott Pruitt has invited governors from every state and territory to a two-day meeting on a class of stain- and water-resistant chemicals after concerns about their health effects sank the nomination of his chemical safety adviser.

The National Leadership Summit, as EPA is referring to it, will take place in Washington on May 22 and 23. Governors or their representatives will share information on ongoing efforts to evaluate and respond to contamination from per- and polyfluoroalkyl substances, or PFAS.

https://www.eenews.net/greenwire/2018/03/20/stories/1060076861

Consensus forming around TSCA unique identifier provision

Industry and NGO lend tepid support to 'third option'

20 March 2018 / Confidentiality & right-to-know, TSCA, United States

Stakeholders from industry and public advocacy groups have backed a single proposed approach to applying a 'unique identifier' to confidential information submitted under TSCA.

The US EPA has been grappling for more than a year with a requirement under the new TSCA that it develop a system for applying a unique identifier (UID) to a substance, whose identity is protected as confidential business information (CBI).

It made two proposals aimed at addressing the challenge of consistently identifying information, while maintaining confidentiality.

Industry had initially rallied around the second option – a company-specific approach – until it became apparent that once the agency published the UIDs and their corresponding chemical accession numbers, it would inadvertently create linkages that could divulge CBI.

Last month, the EPA consulted on a third approach. This called for giving a single UID to each confidential chemical substance, and applying it to pertinent information, both confidential and non-confidential. In cases, however, where the application of the identifier would allow the public to work out the identity of the CBI substance, the agency would omit the UID and simply identify the substance by its name.

In comments to the agency, a majority of industry groups – including the American Chemistry Council, Socma, the American Fuel & Petrochemical Manufacturers (AFPM) and the International Fragrance Association North America (Ifrana) – endorsed this latest option.

Meanwhile, NGO the Environmental Defense Fund has also agreed this is the "preferable" of the three options. "If implemented narrowly, as promised in the *Federal Register*," the EDF said in its comments, the third approach would "result in substantially fewer violations of the statute as compared with the earlier alternatives proposed by EPA."

The is a significant development. Previously the NGO had vehemently opposed the industry-backed second option.

Concerns persist

Nonetheless, the EDF continues to argue that even the third option is "flawed". It has called on the agency to "follow the plain text of the statute" and to require UIDs to be applied "consistently to all information relevant" to the chemical substance.

And industry has also raised concerns. The ACC was among groups that highlighted a risk of the EPA erring in its assessment of whether application of a UID would result in CBI disclosure, and applying it where it should not. It called on the agency to use caution and "implement a robust system of quality control and quality assurance to mitigate any risk of error".

And the American Petroleum Institute said it does not support the third option, because it "does not offer enough protection against CBI disclosure".

The approach, said the API, requires the EPA to screen non-confidential information for possible disclosure of CBI before determining whether to omit the UID – a "resource-intensive" process that carries a risk that the agency "would not be thorough" in its determinations.

The Lautenberg Act requires the EPA to annually publish a list of substances for which it has approved claims of protected chemical identity, together with those substances' unique identifiers.

The EDF pointed out in its comments that the agency's failure to do so – together with its apparent failure to begin applying any unique identifiers to date – has "already resulted in innumerable statutory violations". It has called on the agency to "act expeditiously" to address this.

Unique identifier

TSCA allows companies to request to keep a substance's identity confidential. If the EPA grants this, the substance is listed in the public portion of the TSCA inventory by an accession number and a generic chemical name that masks the specific substance identity.

Under section 14 of the new TSCA, the EPA must:

- develop a system to assign a UID to each specific chemical identity, for which it has approved a confidentiality request;
- apply that identifier consistently to all information relevant to the applicable substance;
- annually publish a list of confidential substances with their UIDs, including the expiration date for the claim;
- ensure that any non-confidential information received uses them to identify the substance; and
- for any expired confidentiality claim, link the chemical identity back to its unique identifier.

But in a May *Federal Register* notice, the agency said that two requirements – to apply the unique identifier to all non-confidential information related to the substance, while ensuring the identity is protected from disclosure – "do not appear to be completely reconciled in the statute". And it cited several examples where universally applying them to every information submission could result in CBI, including the chemical identity, being revealed.

Kelly Franklin

Editor, North America

Related Articles

- EPA to grapple with TSCA 'unique identifier' CBI requirement
- Industry, NGO disagree on TSCA confidential chemical identities
- 'Unique identifier' plan floated by US EPA for CBI data

Further Information:

- 2018 Federal Register notice
- Public docket

US EPA to convene PFAS summit

20 March 2018 / United States

The US EPA is convening a summit to identify risks associated with, and ways to take action on, per- and polyfluoroalkyl substances (PFAS). The agency says it plans to develop and release a PFAS management plan later this year, using information from the meeting.

In letters to state and US territory governors, EPA Administrator Scott Pruitt said that the substances have "emerged as a concern in communities across the nation, and it is time to come together to identify near-term actions to protect the health of all Americans."

The National Leadership Summit will take place on 22-23 May in Washington, DC. The EPA says it will include:

- discussion on characterising risks, monitoring and cleanup techniques of PFAS;
- identifying "specific near-term actions" that can be taken; and
- developing communications approaches to "address public concerns" with the chemical class.

The latest action follows the announcement late last year of a "cross-agency effort" to address PFAS substances, even as states continue to ramp up efforts to address the highly persistent substances.

Ongoing work by the agency includes the development of additional toxicity values, analytical methods, and treatment options for PFAS in drinking water.

The EPA has published drinking water health advisories for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), but has not formally regulated them.

Instead, the agency took the approach of working with industry to phase out their use, under a stewardship programme slated for completion by 2015. It proposed a significant new use rule (Snur) to codify the voluntary phase-out and apply it to manufacturers which were not party to that agreement, but the Snur has not been finalised.

Related Articles

- US EPA announces 'cross agency' initiative on PFAS
- California lists PFOA and PFOS as reproductive toxicants under Prop 65

- PFASs seen as biggest emerging chemical issue for US states

Further Information:

- Summit
- EPA PFAS page

Maryland considers NMP, methylene chloride ban

21 March 2018 / Built environment, Solvents, United States

Maryland is considering legislation to ban the sale of paint strippers containing N-methylpyrrolidone (NMP) or methylene chloride.

Introduced last month, the bill (HB 1138) calls for a prohibition on the sale or distribution of "any paint or coating removal product" containing either solvent. If passed into law, the ban would take effect from 1 January 2020.

A similar ban is being considered at the federal level. The US EPA proposed a rule under section 6 of TSCA in the final days of the Obama administration to ban paint strippers containing methylene chloride and prohibit or restrict such products containing NMP. However, the current administration appears to be delaying action on finalising it.

The NGO Center for Environmental Health has praised Maryland for taking up the issue "where the EPA has failed to act". It is calling on other states to follow suit.

In addition to the paint stripper legislation, Maryland lawmakers are also contemplating a cleaning product ingredient disclosure bill, similar to one passed last year in California.

The state is also one of more than half a dozen contemplating legislation to ban certain flame retardants from children's products.

Related Articles

- US EPA proposes prohibitions on methylene chloride, NMP
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA
- California cleaning disclosure bill unites NGOs and industry

Further Information:

- HB 1138

Amazon's e-commerce model a 'hurdle' for chemicals policy compliance

Company plans to make announcement this year

21 March 2018 / North America, Retail, United States, Voluntary action

Retail giant Amazon's promise of a chemicals management policy this year will have a big influence on the market, but its e-commerce business model will prove a challenge when it comes to getting third-party product sellers to adhere to it, say US NGOs and business groups.

The company announced in 2017 that it would launch its chemical policy – the first by a solely e-commerce business – this year, but it has not said exactly when it will do this.

Boma Brown-West, senior manager of the business programme at US NGO the Environmental Defense Fund (EDF), told Chemical Watch: "One of Amazon's biggest hurdles could be demonstrating that it can influence its large third-party seller population to adhere to its chemicals policy, when it doesn't have the traditional buyer-seller relationship that brick and mortar retailers have."

If, she added, Amazon is able to address this and establish a chemicals policy that commits to clear time-bound goals, then "I could see the retailer having a real impact on the marketplace."

Similarly, Joel Tickner, director of the Green Chemistry and Commerce Council (GC3), a cross-sectoral, business-to-business network of companies and other organisations, said: "The Amazon model of e-commerce, particularly of third-party sellers – that is becoming the norm with other retailers selling online – will create significant challenges in terms of extending chemicals policies beyond own brands to a dispersed network of smaller and larger resellers."

'Online retailers, like their brick and mortar peers, need to hold suppliers accountable for reducing the use of chemicals of high concern in the products they sell on their virtual shelves,' Mark Rossi, Clean Production Action

And Mark Rossi, executive director of US NGO Clean Production Action, the team behind the Chemical Footprint Project, said retailers that are successful in reducing their chemical footprints are setting clear goals for suppliers, both brands and private labels, to meet and then holding those companies accountable to the goals.

"Online retailers, like their brick and mortar peers, need to hold suppliers accountable for reducing the use of chemicals of high concern in the products they sell on their virtual shelves," he said.

Size and reach

The company's size and global reach in terms of product sales makes its development and implementation of a chemicals policy hugely significant. Amazon last year recorded net sales of almost $180bn.

However, it has been criticised for its lack of chemicals management and came bottom of a 2016 'report card', ranking US retailers on their actions to eliminate chemicals in consumer products. The report card has been produced for the past two years by Mind the Store, a campaign run by the coalition Safer Chemicals, Healthy Families.

In last year's report card, the company ranked 14th out of 30 companies and scored 30.5 points out of a possible 135.

Mike Schade, Mind the Store director, said: "We are confident that Amazon will develop a chemicals policy that ensures the products they sell don't contain harmful chemicals. Given the company's innovation, resources and market power, the company can have a big impact on the health of its consumers."

David Levine, co-founder and CEO of the American Sustainable Business Council (ASBC), a policy group representing a network of more than 250,000 businesses, told Chemical Watch Amazon's plan to launch a policy is part of a trend of more businesses creating products that meet safer chemical criteria – and the growing demand of consumers.

Retailer policies

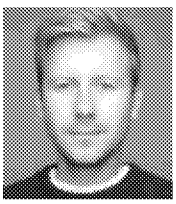
Amazon will follow several major retailers which have recently launched chemicals policies – such as Home Depot and Costco. Walgreens and Staples also plan to launch policies this year.

Professor Tickner said that those being developed by major retailers to date have played a significant role in signalling demand for safer chemistry. "This has in turn driven the growth of green chemistry initiatives within brands and chemical manufacturers."

"Amazon's chemicals policy – the first of a solely e-commerce retailer – will only augment these demand signals and hopefully investments in green chemistry," said Professor Tickner.

Ms Brown-West said an effective policy sets clear time-bound goals on ingredient transparency within the supply chain and to consumers, and on safer products via removal of chemicals of concern and prevention of regrettable substitutes. Equally important, she said, is a plan to measure and demonstrate progress to consumers and the business.

Amazon declined to respond to Chemical Watch's questions asking for details about its policy and how it plans to address the challenge of ensuring its third-party sellers adhere.



Leigh Stringer

Global Business Editor

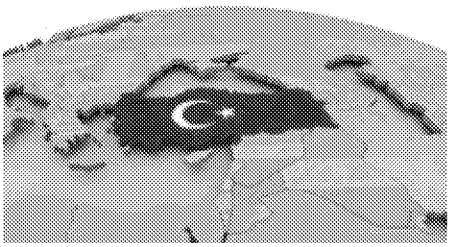
Related Articles

- Apple comes top in US retailer chemical ranking
- Treading lightly with chemicals
- Amazon ranked bottom in retailer chemical 'report card'
- Apple comes top in US retailer chemical ranking
- US retailer Home Depot announces chemicals management measures
- Costco to screen products for 'chemicals of concern'
- Walgreens pledges to launch long-awaited chemical policy

Industry moots 'Turcha' Turkish chemicals agency

But proposal for Echa-style agency may face political hurdles

21 March 2018 / KKDIK, Turkey



A Turkish consultancy has called on the country's environment ministry to establish a chemicals agency, modelled on Europe's Echa. Its purpose would be to support the implementation of KKDIK, the country's new REACH-like regulation.

The 'Turcha' proposal, led by DorukSistem consultancy, has been endorsed by a leading Turkish scientific research organisation, academic institutions, free trade zones and civil society organisations, according to managing partner Selçuk Bilgin.

Mr Bilgin says that due to the size of the industry and potentially large number of registrations, "we need an organisation that can work closely with Cefic, Echa and the OECD."

Stakeholders have expressed concerns over the Ministry of Environment and Urbanisation's (MoEU) ability to process a high volume of KKDIK registrations with its current team of five to six people.

The law came into effect in December last year and sets a registration deadline of 2023. Pre-registrations are due by the end of 2020 and already some 4,000 substances are in the system, most of them carried over from the previous chemicals legislation.

Around 10,000 companies are expected to submit pre-registrations, industry observers say.

Mr Bilgin plans to take the proposal to the MoEU and other ministries to secure formal approval. He told Chemical Watch that during informal conversations MoEU officials have been "keen" on the idea.

However, he added, the proposal is still in the "early stages" and it may be a while before it can get off the ground – mostly because of political hurdles.

Some industry representatives doubt an Echa-style agency can be established in Turkey. Mustafa Bagan, KKDIK training executive at industry association TKSD and formerly its general secretary, called the Turcha proposal "politically difficult".

And another industry consultant with close links to the ministry said such a proposal would need to originate from them to have any chance of success. An independently conceived Turcha "does not fit" the definition of Echa, the consultant said.

Taking shape

Turcha would mirror Echa's management structure, with similar risk assessment and socio-economic analysis committees and composition of the management board, Mr Bilgin said.

He has asked Cefic – the European chemicals industry council – to help set up a meeting with the agency to discuss the proposal.

Cooperation with Echa, he said, would "speed things up" and could attract more financial support for the idea.

It could also lead to possible mutual recognition of registrations between the two agencies, he added. This might allay the fears of the many Turkish and European companies, concerned about the duplicate cost of data-sharing arrangements under REACH and KKDIK.

Cefic said discussions about the topic are "still in the very early stages", while an Echa spokesperson said it has not had "any "formal cooperation" with Turkey on the subject.

The spokesperson added: "Any potential mutual recognition system cannot be initiated by Echa, but should first be based on formal agreement at political level."

MoEU officials did not respond to Chemical Watch requests for comment.

Meanwhile, another initiative in Turkey seeks to set up an only representative organisation, similar to the European ORO, to advise on reputable service providers for KKDIK.

Mr Bilgin said foreign companies were having difficulties appointing ORs in Turkey and an ORO platform would provide a secure environment for European companies trading in the country.

Clelia Oziel

Reporter

Related Articles

- Turkey publishes law modelled on REACH

Mexico consults on household cleaning product labels

21 March 2018 / Biocides, GHS, Mexico

Mexico's health ministry has released a proposed standard on the labelling and packaging of household cleaning products.

The proposal, which aims to promote customer choice and reduce health risks, lays down the labelling requirements for hygiene products and substances intended for the "washing or cleaning of objects, surfaces or buildings, and that release specific fragrances into the air".

Products affected include:

- soaps;
- detergents;
- cleaners;
- whiteners;
- starches for external use;
- stain removers;
- disinfectants;
- deodorisers and air fresheners; and
- other similar products, determined by the ministry.

The draft standard, published on 7 March, also mentions cleaning products for textiles, substances used to unblock sanitary conduits, and products such as waxes, used to apply glossy finishes.

In a non-exclusive list, it singles out the following substances for particular attention:

- phosphates;
- phosphonates;
- anionic surfactants;
- cationic surfactants;
- amphoteric surfactants;
- nonionic surfactants;
- oxygen-based bleaches;
- chlorine-based bleaches;
- EDTA;
- nitrilotriacetic acid;
- halogenated phenols and phenols;
- aromatic hydrocarbons;
- aliphatic hydrocarbons;
- halogenated hydrocarbons;
- waxes;
- silicones;

- sulphates;
- carbonates;
- silicate;
- zeolites; and
- polycarboxylates.

Consultation on the proposal will finish on 7 May. The final standard will then become law, three months after its publication in the country's official journal.

In a study last November, Mexico was identified as one of a number of countries to have only partially implemented the Globally Harmonized System (GHS) of classification and labelling of chemicals.

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- GHS study highlights worldwide implementation gap

Further Information:

- Draft standard (in Spanish)

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The Pew Charitable Trusts (blog)

Virginia Lyons, the lead sponsor on a piece of **toxic chemicals** legislation in Vermont. Lyons' proposal would go beyond individual chemicals and set up a mechanism to ban flame retardants from children's products if they are deemed unhealthy by the state Department of Health following a scientific ...

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Tulsa World: EPA Administrator Scott Pruitt says lack of clean up of Tar Creek Superfund site is 'unacceptable'
Administrator Scott Pruitt of the U.S. Environmental Protection Agency said his new push on the nation's Superfund program finally can provide clarity and accountability to the Tar Creek area, for decades one of the oldest, largest and most complex toxic sites in the nation. "It is really unacceptable," Pruitt said as he recalled the history of the Tar Creek area in far northeastern Oklahoma, whose Superfund legacy dates back to 1983, as well as the amount of money and time deployed there. "You don't list a site in the mid-1980s and you don't take the kind of steps we have taken historically and still have issues today in 2018."The area in Ottawa County is contaminated by lead and other heavy metals from long-closed mining operations and is undermined with caverns that are prone to cave-ins. The Picher and Cardin communities were bought out by a federal program and are now ghost towns, but the mine wastes remain.

Hot Air: EPA Ends The Use Of "Secret Science" In Crafting Regulations
Just in case liberals didn't already have enough reasons to pin EPA Administrator Scott Pruitt's picture to their dart boards, he's just rolled out another policy change which will force the "party of science" to rely on actual science when pushing for regulatory changes. Promising to eliminate "secret science" in EPA deliberations, Pruitt is ordering all scientific studies used when considering new regulations to include publicly available data and methodologies. This was announced in an exclusive interview with The Daily Caller News Foundation.

Detroit News: EPA chief wants to eradicate lead from drinking water
The head of the Environmental Protection Agency says eradicating lead from drinking water is one of his top priorities three years after the Flint water crisis, and he's worried Americans aren't "sufficiently aware" of the threat. "I really believe that we ought to set a goal as a country that, over the next 10 years, that we ought to work with respect to investments in our infrastructure to eradicate lead in our drinking water," EPA Administrator Scott Pruitt told reporters this week at the agency's headquarters. "It can be achieved. Some of the mental-acuity levels of our children are being impacted adversely as a result of this." Pruitt is concerned that parents and citizens don't understand the threat of lead in drinking water or toys, and "we're looking at ways we can contribute to that dialogue," he said, according to an audio recording provided by the New York Post.

New York Post: EPA head calls for 'coordinated' response to NYC lead crisis
EPA Administrator Scott Pruitt called for a "coordinated" response between New York State and City officials to address the ongoing lead crisis. Asked whether federal intervention is needed to protect New York children and tenants from lead poisoning, the Environmental Protection Agency chief urged action on all fronts. "I think a local, state and federal response that is very coordinated and collaborative is terribly important," Pruitt said in an interview. "We each play a role. I'd love to see steps taken at the local level to invest." Gov. Cuomo already announced an emergency declaration for New York Housing Authority buildings and pledged an additional $250 million for upgrades. But heated public squabbles over resources and responsibility with rival Mayor de Blasio have complicated progress.

The Philadelphia Inquirer: Philly has a smog problem. Will Scott Pruitt's EPA say so?
Whether Philadelphia is violating the federal Clean Air Act remains in bureaucratic limbo. Despite deadlines, the EPA has refused to say whether Philadelphia and some other cities, including Pittsburgh, have met a 2015 benchmark of 70 parts per billion or less of ground-level ozone in the ambient atmosphere. Being out of compliance, or in "nonattainment," has a real-world impact on the state, city, businesses and industry, and even motorists through increased regulation and funding. The EPA was supposed to state whether Philadelphia was in compliance by last Oct. 1. Last week, a federal court ruled that the EPA, under its administrator, Scott Pruitt, broke the law by missing the deadline, and gave the EPA until April. On Monday, Pruitt's office said it would meet the deadline.

National Morning News Highlights 03.21.18

Politico: Congress struggles to clinch spending deal

Congressional leaders are racing to finalize a spending bill by the end of Tuesday but find themselves still at odds over a host of controversial issues — delaying plans to unveil the proposal and raising the prospect of weekend votes to avoid a shutdown. Democrats, Republicans and the White House battled late into the night Monday and into Tuesday afternoon over whether to include provisions on President Donald Trump's border wall, a massive New York infrastructure project and the special counsel's Russia investigation, according to lawmakers and aides in both parties. There were still a number of unresolved issues as of Tuesday evening, and multiple sources were pessimistic that negotiators would reach a deal in time to release the bill before Wednesday.

Wall Street Journal: Trump to Ramp Up Trade Restraints on China

The White House is preparing to crack down on what it says are improper Chinese trade practices by making it significantly more difficult for Chinese firms to acquire advanced U.S. technology or invest in American companies, individuals involved in the planning said. The administration plans to release on Thursday a package of proposed punitive measures aimed at China that include tariffs on imports worth at least $30 billion. But the tariffs won't be imposed immediately. Rather, U.S. industry will be given an opportunity to comment on which products should be subject to the duties. As part of the package, the White House will announce possible investment restrictions by Chinese firms in the U.S. and will direct the Treasury Department to outline rules governing investment from China.

TRUMP TWEETS

Tulsa World

http://www.tulsaworld.com/homepagelatest/epa-administrator-scott-pruitt-says-lack-of-clean-up-of/article_4a3e4982-569e-5023-8141-392ebe629a65.html

EPA Administrator Scott Pruitt says lack of clean up of Tar Creek Superfund site is 'unacceptable'

By: Jim Myers, 3/21/18

Administrator Scott Pruitt of the U.S. Environmental Protection Agency said his new push on the nation's Superfund program finally can provide clarity and accountability to the Tar Creek area, for decades one of the oldest, largest and most complex toxic sites in the nation.

"It is really unacceptable," Pruitt said as he recalled the history of the Tar Creek area in far northeastern Oklahoma, whose Superfund legacy dates back to 1983, as well as the amount of money and time deployed there.

"You don't list a site in the mid-1980s and you don't take the kind of steps we have taken historically and still have issues today in 2018."

The area in Ottawa County is contaminated by lead and other heavy metals from long-closed mining operations and is undermined with caverns that are prone to cave-ins. The Picher and Cardin communities were bought out by a federal program and are now ghost towns, but the mine wastes remain.

Pruitt blamed inconsistency, even within the EPA's 10 regions, as well as a lack of attention and focus, for slowing remediation outcomes.

"It is one of the things that seemed to be languishing as we arrived," Pruitt said, making it clear that the lack of urgency was something he found "palpable" at Superfund sites across the country.

"When it takes you 27, 28 years to make a decision — make a decision, not clean it up, not remediate, but make a decision on how you are going to remediate — that is unacceptable."

His comments came during one of several reporter roundtables he has been holding at the EPA's headquarters to mark his first year as administrator, during which he also became a leading voice in the Trump administration's major push on regulation reform.

Those efforts have prompted applause from his supporters and alarm from his critics.

Recently Pruitt is rarely out of the headlines, with stories ranging from travel expenses to speculation over whether his political future might include bids for a U.S. Senate seat or even the White House.

When given the chance to comment on yet another story this week about his political options, he took a pass.

Pruitt also declined to comment when asked about a recent decision by an Oklahoma judge to allow a lawsuit filed by Campaign for Accountability to continue. The lawsuit seeks to force the release of a 2014 audit of the Lead-Impacted Communities Relocation Trust, which was created in an effort to help move residents out of communities affected by the Tar Creek contamination.

"That is during my time as attorney general," he said. "I think it is better that I just keep it focused on the EPA matters."

Pruitt, who was Oklahoma's attorney general before being tapped by President Donald Trump to lead the EPA, had declined to file charges based on the audit by state Auditor Gary Jones and also had taken steps to bar its release to the public.

According to reporting by The Oklahoman, legal action in the case continues and eventually could include an appeal to the Oklahoma Supreme Court.

Pruitt's emphasis on Tar Creek and the other Superfund sites across the country grew out of a task force he created in 2017, just months after being sworn in as administrator.

Members of the Superfund Task Force came back with a list of specific recommendations under major goals ranging from expediting cleanup and remediation to promoting redevelopment and community revitalization.

As part of that process, Tar Creek landed on a list Pruitt says he will use to keep the emphasis on the program.

Hot Air

https://hotair.com/archives/2018/03/20/epa-ends-use-secret-science-crafting-regulations/

EPA Ends The Use Of "Secret Science" In Crafting Regulations

By: Jazz Shaw 3/20/18

Just in case liberals didn't already have enough reasons to pin EPA Administrator Scott Pruitt's picture to their dart boards, he's just rolled out another policy change which will force the "party of science" to rely on actual science when pushing for regulatory changes. Promising to eliminate "secret science" in EPA deliberations, Pruitt is ordering all scientific studies used when considering new regulations to include publicly available data and methodologies. This was announced in an exclusive interview with The Daily Caller News Foundation.

> "We need to make sure their data and methodology are published as part of the record," Pruitt said in an exclusive interview with The Daily Caller News Foundation. "Otherwise, it's not transparent. It's not objectively measured, and that's important."
>
> Pruitt will reverse long-standing EPA policy allowing regulators to rely on non-public scientific data in crafting rules. Such studies have been used to justify tens of billions of dollars worth of regulations.

> EPA regulators would only be allowed to consider scientific studies that make their data available for public scrutiny under Pruitt's new policy. Also, EPA-funded studies would need to make all their data public.
>
> "When we do contract that science out, sometimes the findings are published; we make that part of our rule-making processes, but then we don't publish the methodology and data that went into those findings because the third party who did the study won't give it to us," Pruitt added.

In other words, science is not being excluded from any EPA studies. The agency is simply ensuring that groups conducting studies publish the data used to reach the conclusions they forward to the EPA so it can be examined and potentially challenged if it's found to be faulty. Surely nobody who's really interested in following the science could object to that, right?

Wrong. Democrats were immediately arguing against such a move, saying that forcing research organizations to publish their figures "would reveal confidential patient data." That's a rather odd argument in a couple of different ways. First of all, there's a lot of data collected for various studies used by the EPA which have nothing to do with medical records. Examples include all of the groundwater studies done when the Obama administration was considering banning fracking.

But even in cases where medical information is required, the groups conducting the study were able to obtain the patient data. As Steve Milloy, the publisher of JunkScience.com was quoted as saying, California regularly makes such data available under the name, 'Public Use Death Files.' Other medical information can be compiled and have the patients' names and other identifying personal information scrubbed. This is already done on a regular basis.

In fact, barring some subject which might compromise national security – such as the handling of tactical weapons materials – it's difficult to imagine many true, scientific studies which couldn't publish their underlying data, making it available for peer review. So if you're still opposed to federal agencies wanting to see such data, the next logical question to ask is precisely what it is that you're hiding.

The Detroit News

https://www.detroitnews.com/story/news/politics/2018/03/20/epa-pruitt-lead-water-flint/33125283/

EPA chief wants to eradicate lead from drinking water

By: Melissa Nann Burke, 3/20/18

The head of the Environmental Protection Agency says eradicating lead from drinking water is one of his top priorities three years after the Flint water crisis, and he's worried Americans aren't "sufficiently aware" of the threat.

"I really believe that we ought to set a goal as a country that, over the next 10 years, that we ought to work with respect to investments in our infrastructure to eradicate lead in our drinking water," EPA Administrator Scott Pruitt told reporters this week at the agency's headquarters.

"It can be achieved. Some of the mental-acuity levels of our children are being impacted adversely as a result of this."

Pruitt is concerned that parents and citizens don't understand the threat of lead in drinking water or toys, and "we're looking at ways we can contribute to that dialogue," he said, according to an audio recording provided by the New York Post.

"I do think that what happened in Flint is something that could happen elsewhere. We just simply need to take steps to do all that we can to address it prospectively and proactively," Pruitt said.

Pruitt said President Donald Trump's $1.5 trillion plan to bolster the nation's infrastructure over the next decade would include investments in aging water infrastructure.

Pruitt didn't describe a plan for replacing the thousands of lead service lines throughout the country – a cost estimated around $40 billion to $45 billion – but stressed the need for state and local governments to invest in such upgrades, perhaps with federal grant aid.

Pruitt added he would "love" to see local governments investing more in water infrastructure.

"These water treatment facilities – they have authority to bond out, to raise fees, to invest in corrosion control, the replacement of service lines and the rest," Pruitt said. "And some of them just aren't doing it."

Gov. Rick Snyder has proposed having water customers across Michigan pay a $5 annual fee to help upgrade aging infrastructure and replace lead pipes in their local communities, but the plan hasn't gained steam in the Republican-controlled Legislature.

U.S. Rep. Dan Kildee, D-Flint Township, said what Pruitt has described isn't really a plan.

"When it comes to Mr. Pruitt, nice words don't replace pipes. It takes money. What they have proposed is really nothing when it comes to infrastructure," Kildee said of the Trump administration.

Kildee said what would help is Pruitt putting his support behind Kildee's legislation that would reduce the acceptable amount of lead in drinking water to 5 parts per billion. The current federal action limit is 15 parts per billion.

"Force federal and state governments to stare this in the face by adopting a level that is science-based that says there is no acceptable level of lead," he said.

EPA has spent a decade trying to update the rule.

Snyder called the rule "dumb and dangerous" after the Flint disaster. The state has proposed draft rules to drop the acceptable amount of lead in drinking water to 10 parts per billion by 2024.

The New York Post

https://nypost.com/2018/03/21/epa-head-calls-for-coordinated-response-to-nyc-lead-crisis/

EPA head calls for 'coordinated' response to NYC lead crisis

By: Marisa Schultz, 3/21/18

EPA Administrator Scott Pruitt called for a "coordinated" response between New York State and City officials to address the ongoing lead crisis.

Asked whether federal intervention is needed to protect New York children and tenants from lead poisoning, the Environmental Protection Agency chief urged action on all fronts.

"I think a local, state and federal response that is very coordinated and collaborative is terribly important," Pruitt said in an interview. "We each play a role. I'd love to see steps taken at the local level to invest."

Gov. Cuomo already announced an emergency declaration for New York Housing Authority buildings and pledged an additional $250 million for upgrades. But heated public squabbles over resources and responsibility with rival Mayor de Blasio have complicated progress.

Pruitt declined to weigh in on the Cuomo/de Blasio feud but encouraged broad infrastructure investment from all levels to prevent children from getting sick.

"I think the governor's call for that is important and it's something we think is important as well and we need to contribute to it along with the states, local cities and towns," Pruitt said.

While the problems in NYCHA are centered on lead paint, Pruitt has primarily tackled the issue of eliminating lead poisoning from water. He raised concerns over high lead levels found at certain New York City school water fountains.

"I do think that what happened in Flint is something that could happen elsewhere," Pruitt said. "We just simply need to take steps to do all that we can to address it prospectively and proactively."

Pruitt estimated it would take $40 billion – $45 billion to replace lead service lines nationwide and suggested President Trump's $1.5 trillion infrastructure plan can assist states and cities with the costs.

"I really believe that we ought to set a goal as a country that, over the next 10 years, that we ought to work with respect to investments in our infrastructure to eradicate lead in our drinking water," Pruitt said.

He added: "It can be achieved. Some of the mental-acuity levels of our children are being impacted adversely as a result of this."

The Philadelphia Inquirer

http://www.philly.com/philly/health/pruitt-epa-smog-philadelphia-ozone-20180320.html

Philly has a smog problem. Will Scott Pruitt's EPA say so?

By: Frank Kummer, 3/20/18

Mollie Michel of South Philadelphia keeps her children inside some days because of air pollution, so she's particularly irked by a long delay by the U.S. Environmental Protection Agency to say officially whether Philadelphia has a smog problem. That designation could mean more regulation to help clean up the dirty air, she said.

"You have a city with a childhood asthma rate twice as high as the national average," Michel said to bolster her argument. A member of Moms Clean Air Force, she gathered Tuesday with a few dozen other activists and local officials at City Hall to mark the first day of spring by protesting Trump administration policies.

Whether Philadelphia is violating the federal Clean Air Act remains in bureaucratic limbo. Despite deadlines, the EPA has refused to say whether Philadelphia and some other cities, including Pittsburgh, have met a 2015 benchmark of 70 parts per billion or less of ground-level ozone in the ambient atmosphere. Being out of compliance, or in "nonattainment," has a real-world impact on the state, city, businesses and industry, and even motorists through increased regulation and funding.

The EPA was supposed to state whether Philadelphia was in compliance by last Oct. 1. Last week, a federal court ruled that the EPA, under its administrator, Scott Pruitt, broke the law by missing the deadline, and gave the EPA until April.

On Monday, Pruitt's office said it would meet the deadline.

Pruitt said during a meeting with reporters at EPA headquarters in Washington that the scope of monitoring required to answer the smog question had caused the delay.

"The agency has been running behind for a number of years," said Pruitt, who took office a year ago.

Pruitt, who said he didn't have data specific to Philadelphia in front of him, also took issue with how the monitoring program has been carried out in the past, saving money by "modeling" — using data from one area and applying it to another.

"Real data is terribly important," Pruitt said. "When we go forward, we need to focus more on monitoring as opposed to modeling … You shouldn't get data from one monitor and extrapolate it over a whole area because you're not dealing with real data at that point."

He said his office is "exploring ways" to pay for monitoring.

If Philadelphia is declared to have a smog problem, the Pennsylvania Department of Environmental Protection would be responsible for crafting a plan to reduce ground-level ozone. Ozone is formed when volatile organic compounds and nitrogen oxides — created by burning fossil fuels, and power plants and other industries — combine in sunlight. Long, hot, humid days act as smog factories, so smog is expected to increase as the climate warms up.

James Garrow, a spokesman for the city's Department of Public Health, said, "Philadelphia is indeed out of compliance" as of March 1. He said the trend for ground-level ozone has been going down for years and Philadelphia expects to meet requirements within a few years.

At the protest, Flora Cardoni, an organizer with PennEnvironment, joined Democratic State Reps. James R. Roebuck Jr. and Brian K. Sims, as well as members of Deep Green Philly and the Clean Air Council, in speaking out. Cardoni said it's already been too long a wait for action.

"Philadelphians want to walk along the Schuylkill, play in Fairmount Park, and wander the historic city without worrying about choking on smog and soot," she said.

Politico

https://www.politico.com/story/2018/03/20/omnibus-vote-house-thursday-473010?lo=ap_e1

Congress struggles to clinch spending deal

By: Burgess Everett, Rachel Bade, Sarah Ferris and Heather Caygle, 3/20/18

Congressional leaders are racing to finalize a spending bill by the end of Tuesday but find themselves still at odds over a host of controversial issues — delaying plans to unveil the proposal and raising the prospect of weekend votes to avoid a shutdown.

Democrats, Republicans and the White House battled late into the night Monday and into Tuesday afternoon over whether to include provisions on President Donald Trump's border wall, a massive New York infrastructure project and the special counsel's Russia investigation, according to lawmakers and aides in both parties.

There were still a number of unresolved issues as of Tuesday evening, and multiple sources were pessimistic that negotiators would reach a deal in time to release the bill before Wednesday.

Asked how confident he was that the Senate would avoid weekend work, Sen. John Thune (R-S.D.) replied: "I'm not real confident at this point."

Dragging the talks into Wednesday would increase the chance that lawmakers pass a short-term spending bill to prevent a temporary shutdown when funding lapses Friday evening.

Several issues remain open after administration officials participated in a lengthy meeting Tuesday afternoon with top leadership and appropriations staffers that did little to break the logjam.

“Everything that remains is going to be pulling teeth to resolve,” said a senior congressional aide with knowledge of the meeting, which included representatives from the White House and the Office of Management and Budget.

The New York-area Gateway project is a primary issue for the White House, according to the aide, but several other provisions are also still up in the air.

Trump is likely to support the bill if the Gateway project is excluded, the military receives a major budget boost and there is a significant infusion of border security funding, White House legislative affairs director Marc Short said at the Capitol Tuesday.

House Speaker Paul Ryan (R-Wis.) told his conference that he is planning to pass the massive, $1.3 trillion omnibus on Thursday, according to House Republicans.

"I'm hoping today," Ryan told reporters when asked Tuesday morning when leaders would wrap up negotiations. He said lawmakers were not yet considering a short-term funding patch to buy more negotiating time. "There are some unresolved issues. We're working through them as we speak."

Senate Majority Leader Mitch McConnell (R-Ky.) said he would keep the Senate in until the bill is passed.

"We anticipate the House filing later today, which will give the Senate plenty of time to take a look at it and see what’s in it," McConnell said on Tuesday afternoon.

Still, on the House's current schedule, the Senate would have just a day to pass the bill before government funding runs out on Friday evening — allowing for any one senator to shut the government down briefly. Sen. Rand Paul (R-Ky.) caused such a shutdown last month in protest over a budget deal.

Paul would not rule out doing everything he can to stop the spending bill if he views it as poorly as he did a budget bill in February.

“I will oppose the bill. I have to make a decision about whether or I will accept a time agreement,” Paul told reporters on Tuesday.

Senate leaders are already entertaining a short-term spending bill in preparation for any antics by Paul.

"We're going to be here into the weekend, perhaps. But I think there could be some measures taken to keep the lights on. But we'll get it done," said Senate Majority Whip John Cornyn (R-Texas). "Anything can happen around here."

Congressional leaders had hoped to file the bill, which would fund the government through the end of September, on Monday night with a House vote on Wednesday. But Congress is bogged down over policy provisions that various congressional factions are trying to attach to the must-pass bill. Many lawmakers view the legislation as their last chance to get their priorities signed into law before the midterm elections.

“Negotiations continue between the four leaders. A few sticking points remain, but we are very close," said Senate Minority Leader Chuck Schumer (D-N.Y.). "I think it will be a fair compromise."

Lawmakers and aides estimated there were as many as 20 provisions still being debated. One of the most controversial is $900 million in funding for the Gateway tunnel project in New York, a key priority of Schumer and New York-area Republicans and Democrats.

Gateway supporters are trying to include language that would allow the project to apply for competitive grant money and prevent the Trump administration from squashing the project. Trump has told Republicans he will veto a bill that funds the project specifically. Schumer and GOP leaders were still battling over the provision as of Tuesday afternoon, and the New Yorker said the tunnel is of national significance despite Trump's complaints.

The White House remains unmoved, however.

"The secretary of transportation has explained if you put that much money in one project it's going to crimp projects across the country she needs to fund. It's also a project that a majority of House Republicans... voted against," Short said. "The president has made his wishes well known so I think we're going to be fine."

Another sticking point: immigration. Talks to protect young immigrants facing deportation fell apart over the weekend, but congressional Democrats spent Monday and Tuesday pushing to freeze hiring of immigration enforcement officials in return for providing Trump more than $1 billion in funding on his border wall.

Democrats and Republicans are likely to agree on about $1.6 billion in border funding that would help finance some fencing and security and avoid directly funding the large concrete wall that Trump wants, according to a Democratic aide.

Republicans are seeking to fix an error in the new tax law that lowers tax bills for farmers that sell grain to cooperatives at the expense of other companies. Though Senate Democrats and some Senate Republicans are willing to rewrite the provision in exchange for a boost in Low-Income Housing Tax Credits in the spending bill, Ryan has resisted, according to people in both parties. Ryan allies say that just because he rejected an offer from Schumer to fix the so-called "grain glitch," it doesn't mean the issue is dead altogether.

Congressional Democrats also pushed provisions to protect special counsel Robert Mueller but have been rebuffed by GOP leaders. An attempt to shore up Obamacare's insurance markets is also stalled in a battle over abortion.

Lawmakers believe neither of those provisions will be in the omnibus.

A Tuesday morning school shooting in Maryland, however, may have thrown another wild card into the mix: GOP leaders are pressing to include popular legislation that would improve the National Instant Criminal Background Check System for firearms purchases.

"We remain hopeful that Fix NICS is in the omni," Short said of the proposal to improve the FBI's background check system.

But Democrats want a broader gun debate and note that the provision is a modest way to simply bolster existing gun laws. Meanwhile, conservatives believe it would make it more difficult for some veterans to buy a gun, which could keep that provision out as well.

"There are still some key questions. There's a NICS question, there's an Internet sales tax question, there's [an Obamacare] question. There's a Gateway project financing question," said Rep. Jim Jordan (R-Ohio), a conservative leader. "It looks like a lot of those things aren't gonna be in it, which is a good step, but it still spends way too much money."

The Wall Street Journal

https://www.wsj.com/articles/trump-to-ramp-up-trade-restraints-on-china-1521593091

Trump to Ramp Up Trade Restraints on China

By: Bob Davis, 3/20/18

The White House is preparing to crack down on what it says are improper Chinese trade practices by making it significantly more difficult for Chinese firms to acquire advanced U.S. technology or invest in American companies, individuals involved in the planning said.

The administration plans to release on Thursday a package of proposed punitive measures aimed at China that include tariffs on imports worth at least $30 billion.

But the tariffs won't be imposed immediately. Rather, U.S. industry will be given an opportunity to comment on which products should be subject to the duties. As part of the package, the White House will announce possible investment restrictions by Chinese firms in the U.S. and will direct the Treasury Department to outline rules governing investment from China.

Final details of the plan, including the amount of imports to be hit by tariffs, remain in flux, those involved with the discussions said. While the rough amount and rationale for the tariffs are expected to be disclosed on Thursday, the final decisions will come once U.S. industry has had its say, they said.

A White House spokeswoman declined to comment.

The effort stems from a monthslong investigation by the administration into Chinese intellectual property practices that found the damage to U.S. companies from forced technology transfer is $30 billion annually.

The administration has warned Beijing that it risked tariffs if it didn't significantly liberalize its market and eliminate practices that disadvantage foreign firms.

While the administration's plans to put tariffs on China have received most of the attention, it is considering other significant penalties, especially those aimed at state-owned Chinese firms. It plans to argue that Chinese state-owned firms buy U.S. technology not for commercial purposes, but to apply for military use and otherwise gain an edge in the race for global technological dominance.

The administration believes that Beijing, in requiring U.S. companies to form joint ventures to do business in China, then pressures them to transfer important technology to their Chinese partners. The U.S. also contends Beijing improperly subsidizes Chinese companies looking to overtake U.S. rivals in such advanced technologies as semiconductors, artificial intelligence and robotics.

Chinese officials have said that they are improving their protection of intellectual property and liberalizing their economy. They also complain that the U.S. hasn't given them a specific list of demands that they need to meet to head off tariffs.

The country's responses to challenges from President Donald Trump loomed large as China's leaders closed out an annual political gathering on Tuesday.

Premier Li Keqiang, the titular No. 2 leader, struck a conciliatory tone on trade with the U.S. At a news briefing in Beijing's Great Hall of the People, Mr. Li said "there are no winners" in a trade war between the world's two largest economies, and appealed for calm.

People involved in the planning say the Trump administration is looking at making reciprocity the core of U.S. investment relations with China, meaning that the U.S. would impose restrictions on Chinese investment similar to those that U.S. firms face in China. That could mean that the U.S. would insist that Chinese firms form joint ventures before doing business in the U.S., unless China dropped those restrictions.

The U.S. has already made it more difficult for Chinese companies to invest in the U.S. by blocking Chinese bids to purchase U.S. semiconductor firms. That is done by an interagency review of foreign acquisitions by the Committee on Foreign Investment in the U.S. Congress is looking to broaden CFIUS reviews of acquisitions so they include joint ventures too.

The expansion would include reviews of technology transfers to foreigners and could apply to joint ventures both outside and within the U.S. But CFIUS looks solely at national security concerns. The administration wants to address economic harm as well, according to these people.

Any imposition of tariffs, without going first to the World Trade Organization, is sure to prompt a chorus of criticism not just from Beijing but from U.S. industry, which has opposed tariffs as counterproductive. The WTO adjudicates trade cases and has the power to authorize tariffs in cases where a losing party doesn't change its practices. The administration is also considering bringing a case against Chinese trade practices that are covered by the WTO.

Oregon Sen. Ron Wyden, the senior Democrat on the Senate Finance Committee, said he opposes the broad imposition of tariffs. "American producers who haven't gotten a fair shake in the past aren't going to get that back by just have tariffs slapped on imports indiscriminately," he said.

Tariffs are bound to cause China to retaliate, said Clement Leung, Hong Kong's representative in the U.S. Chinese officials "cannot show any weakness" at a time when the country's leader, Xi Jinping, has just been confirmed for his second term, Mr. Leung said. Hong Kong, a trading center that operates somewhat independently from the rest of China, would be hurt by limits on trade.

Whatever the political blowback, Harvard law professor Mark Wu, a trade expert, says that the White House has authority to impose tariffs under section 301 of the Trade Act of 1974.

"In situations where the U.S. Trade Representative deems unfair trade practices to fall outside the scope of a WTO-covered agreement, then the statute permits the executive branch to take action directly without first seeking recourse through WTO dispute settlement" procedures, he said.

Frustration with Chinese trade practices has been building among both the governments and private sectors of the U.S., Japan and Europe. One reason the U.S. is considering a separate WTO case is to try to recruit allies to pressure China. But any move to impose tariffs could allow Beijing to portray itself as a victim. Coalition-building has become more complicated in the wake of a separate U.S. action to levy tariffs on steel and aluminum imports from allied nations.

For instance, finance ministers and central bankers from the Group of 20 countries, meeting in Buenos Aires on Tuesday, failed to reach any new agreement on shared principles when it comes to trade policies, as the split between the U.S. and other major economies deepened over the U.S.'s tariff policies.

The administration is considering recommendations from two other reports that would impose draconian investment restrictions on China. The U.S.-China Economic and Security Review Commission, a Congressional panel that takes a hard line on China, last year urged the administration to prohibit "the acquisition of U.S. assets by Chinese state-owned or state-controlled entities, including sovereign wealth funds."

A report for the Pentagon by its Defense Innovation Unit Experimental, which examines technology issues, has recommended that the Pentagon pursue a policy of "deterring Chinese technology transfer" by broadening CFIUS's mandate and strengthening export controls on technology to China.

China Investment Corp., Chinese sovereign-wealth fund which could get hit by sanctions, is putting together a fund targeting as much as $5 billion with Goldman Sachs Group Inc., aimed at investing in U.S. manufacturing and other sectors. CIC hopes the fund would pass muster with U.S. regulators, say those people familiar with the plans.

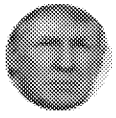
It is unclear how far the administration will go in pursuing these ideas. Blocking the acquisition of all purchases by Chinese state firms, for instance, would mean that Chinese state-owned airlines couldn't buy Boeing jets. Toughening export controls on, say, semiconductor production machinery could cede the market to Japanese vendors.

The administration's actions on China come on the heels of plans to levy tariffs on steel and aluminum imports. Japan, Korea and the European Union are scrambling to get exemptions from those levies, which are set to go into effect on Friday.

Donald J. Trump @realDonaldTrump · 21h

Our Nation was founded by farmers. Our independence was won by farmers. And our continent was tamed by farmers. Our farmers always lead the way -- we are PROUD of them, and we are DELIVERING for them! #NationalAgricultureDay

28K 28K 115K



Donald J. Trump @realDonaldTrump · 2h

AUSTIN BOMBING SUSPECT IS DEAD. Great job by law enforcement and all concerned!

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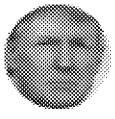

Donald J. Trump @realDonaldTrump · 2h

Department of Justice should have urged the Supreme Court to at least hear the Drivers License case on illegal immigrants in Arizona. I agree with @LouDobbs. Should have sought review.

3.6K 4.5K 18K

Donald J. Trump @realDonaldTrump · 2h

...there was no probable cause for believing that there was any crime, collusion or otherwise, or obstruction of justice!" So stated by Harvard Law Professor Alan Dershowitz.

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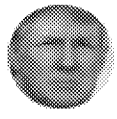

Donald J. Trump @realDonaldTrump · 1h

"Special Council is told to find crimes, whether a crime exists or not. I was opposed to the selection of Mueller to be Special Council. I am still opposed to it. I think President Trump was right when he said there never should have been a Special Council appointed because.....

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Message

From: Daniell, Kelsi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD867173479344B3BDA202B3004FF830-DANIELL, KE]
Sent: 5/25/2018 1:40:36 PM
To: Abboud, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6f5af791a1842f1adcc088cbf9ed3ce-Abboud, Mic]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Bodine, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2cc6086fcc44c3be6b5d32b262d983-Bodine, Sus]; Cory, Preston (Katherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd80b15f6d04a3ba11fc8ca3c85bc50-Cory, Kathe]; Ferguson, Lincoln [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08cd7f82606244de96b61b96681c46de-Ferguson, L]; Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]; Frye, Tony (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58c08abdfc1b4129a10456b78e6fc2e1-Frye, Rober]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Hanson, Paige (Catherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95adc1b2ac3b40ab9dc591801d594df8-Hanson, Cat]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Kelly, Albert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08576e43795149e5a3f9669726dd044c-Kelly, Albe]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; McMurray, Forrest [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=344246fb2cb643bfab4f92fe016566e2-McMurray, F]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]; Rodrick, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6515dbe46dae466da53c8a3aa3be8cc2-Rodrick, Ch]; Ross, David P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=119cd8b52dd14305a84863124ad6d8a6-Ross, David]; Shimmin, Kaitlyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=becb3f33f9a14acd8112d898cc7853c6-Shimmin, Ka]; Wehrum, Bill [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: EPA News Highlights 5.25.18

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EPA Morning News Highlights 05.25.18

NWI Times: EPA Meeting about New Lead Cleanup Around Federated Metals Site Draws Large Crowd Seeking Answers

Dozens of Hammond and Whiting residents gathered Wednesday to hear what action the U.S. Environmental Protection Agency plans to take to identify and remove possible lead contamination in the soil on their properties near the long-shuttered Federated Metals site. The public meeting at the Whiting Family YMCA was the first to provide information about the soil sampling study area, which includes a mix of industrial, commercial and residential properties as well as vacant lots, community centers, playgrounds, parks, churches and schools.

Chemical Watch: Pruitt Pledges EPA Action on Legacy of PFASs

US EPA Administrator Scott Pruitt has pledged to address possible health hazards posed by perfluoroalkyl and polyfluoroalkyl substances (PFASs). But the agency's approach will apparently focus on contamination by the legacy chemicals PFOA and PFOS. Meanwhile, thousands of PFASs could remain in active commerce, attendees heard at a recent agency summit. Speaking before state representatives, federal agencies, trade groups and NGOs at the 22 May meeting in Washington, DC, Mr Pruitt announced plans to take such actions on legacy PFASs as developing a maximum contaminant level (MCL) for drinking water and enabling cleanup efforts.

The Hill: EPA Grapples with Potential Health Threat in Drinking Water

Environmental Protection Agency (EPA) chief Scott Pruitt is starting to grapple with a class of chemicals used in manufacturing that has been found in drinking water in recent years. Pruitt convened a summit this week with state officials, industry representatives, environmental advocates and others to discuss the presence of per- and polyfluoroalkyl substances (PFAS) in the water supply. He labeled the issue a “national priority” and promised certain steps toward potentially regulating the chemicals' presence in water.

The Record News: Hoosick Falls Mayor Rob Allen Meets EPA Administrator Scott Pruitt, Talks PFOA

Mayor Rob Allen met face-to-face with Environmental Protection Agency Administrator Scott Pruitt earlier this week to discuss the village’s tainted water supply. Allen met with Pruitt in Washington D.C. when he attended the National Leadership Summit on PFAS.

Ag Net West: USDA-EPA Discuss Year-Round E15

U.S. Department of Agriculture (USDA) and Environmental Protection Agency (EPA) officials met to discuss ways to increase ethanol usage and to address refiner concerns about volatility in the market for biofuel credits. An Agri-Pulse report says the meeting followed months of discussions at the White House on the issue. It also follows months of concerns over the way EPA Administrator Scott Pruitt is overseeing the program. The ethanol industry is pressing the EPA to finally move forward with issuing a vapor pressure waiver that will allow E15 to be sold all year.

National Morning News Highlights 05.25.18

Fox News: Trump Welcomes ‘Productive’ Statement from North Korea, Says Dems ‘Rooting Against’ Talks

President Trump kept the diplomacy door open with North Korea on Friday, welcoming the regime's latest "productive" statement following the administration's decision to cancel the highly anticipated summit with Kim Jong Un. Trump nixed the summit, which was slated for June 12 in Singapore, following threats from North Korea. But hours after the U.S. pulled out of the meeting, North Korea issued a statement suggesting the regime was open to talks.

Politico: Trump's Next Economic Threat: Surging Gas Prices

President Donald Trump is hoping a wave of tax-cut-fueled economic euphoria will boost his approval ratings and his party's political fortunes this fall. A sharp spike in gas prices could slam the brakes on all of that. As Americans head out for traditional Memorial Day weekend road trips, they'll confront gas prices of nearly $3 a gallon, the highest since 2014 and a 25 percent spike since last year.

TRUMP TWEETS

NWI Times

http://www.nwitimes.com/news/local/lake/epa-meeting-about-new-lead-cleanup-around-federated-metals-site/article_87bca833-555a-5687-a26d-1dd3485d0186.html

EPA Meeting about New Lead Cleanup Around Federated Metals Site Draws Large Crowd Seeking Answers

By: LuAnn Franklin, 05/24/18

Dozens of Hammond and Whiting residents gathered Wednesday to hear what action the U.S. Environmental Protection Agency plans to take to identify and remove possible lead contamination in the soil on their properties near the long-shuttered Federated Metals site.

The public meeting at the Whiting Family YMCA was the first to provide information about the soil sampling study area, which includes a mix of industrial, commercial and residential properties as well as vacant lots, community centers, playgrounds, parks, churches and schools.

Andrew Maguire, EPA on-scene coordinator, went through the history of the Hammond plant at 2230 Indianapolis Blvd. from 1937 to its closing in 1987, and how EPA teams, acting under the EPA's Resource Conservation & Recovery Act, consolidated waste there from 2003 to 2006. In September 2016, that program referred the surrounding area to the Superfund program, because soil sampling indicated pollution from smokestacks had spread beyond the Federated Metals site.

The study area is bounded by the alley between 119th Street and Fischrupp Avenue to the north, extending to Acthison on the west and White Oak Avenue to the east. The southern border is located between George Lake Trail and East Lakeview Street.

Soil sampling on some properties found lead above the EPA's designed level, Maguire said. Of the 51 properties sampled, 31 were found to have levels at the surface exceeding 400 parts per million, or ppm. Of those, 10 properties showed lead levels equal to or exceeding 1,200 ppm.

Removing contaminated soil, replacing it with clean soil and restoring the yard begins next week on properties where "sensitive populations" reside, he said. "For this project, sensitive population is defined as pregnant women and children under (age) 7."

The EPA also will evaluate removing soil in properties where children in the household have an elevated blood lead level, Maguire said.

All the work will be done at no cost to the property owners. Repairs of any damage done to a home's foundation during the project will be the EPA's responsibility, he said.

"The EPA is actively seeking properties to sample," he said. "We've sampled extensively outside the zone. That line is not set in stone. It is a work in progress."

Residents signed agreements to allow EPA officials and contractors to enter their property, including a tour of basements in homes.

Asked why all the soil in the area isn't being replaced, Maguire said it costs $50,000 to remediate each property.

"There is no responsible party," he said. "Unfortunately Federated Metals went bankrupt."

Chemical Watch

https://chemicalwatch.com/67167/pruitt-pledges-epa-action-on-legacy-pfass

Pruitt Pledges EPA Action on Legacy PFASs

05/24/18

US EPA Administrator Scott Pruitt has pledged to address possible health hazards posed by perfluoroalkyl and polyfluoroalkyl substances (PFASs). But the agency's approach will apparently focus on contamination by the legacy chemicals PFOA and PFOS.

Meanwhile, thousands of PFASs could remain in active commerce, attendees heard at a recent agency summit. Speaking before state representatives, federal agencies, trade groups and NGOs at the 22 May meeting in Washington, DC, Mr Pruitt announced plans to take such actions on legacy PFASs as developing a maximum contaminant level (MCL) for drinking water and enabling cleanup efforts.

Absent from the proposed plan, however, was an approach for assessing the thousands of PFASs used in such consumer products as food packaging, firefighting foams, building materials and textiles.

Industry groups hold that there is no evidence newer "short-chain" PFASs carry the same risks as their "long-chain" predecessors. Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), which are not regulated, have been phased out under a stewardship programme and are no longer manufactured in the US.

Speaking at the summit, Jessica Bowman, executive director of American Chemistry Council subsidiary the FluoroCouncil, said regulators "should recognise the differences between various PFAS chemistries".

"Not all PFAS require risk-based regulation," Ms Bowman said.

Disagreement

But some NGOs and state officials are unconvinced on the safety of short-chain PFASs and would like to see them regulated as a class.

"There is a direct disagreement that short-chain products are known to be any safer," Erik Olson, senior director for health and food at the National Resources Defense Council, told Chemical Watch. He was the only NGO representative invited to speak at the summit.

"I have yet to see any information that says these chemicals are safer to drink in your water," said Brandon Kernen of the New Hampshire Department of Environmental Services. "There [are] a lot more questions than answers."

Mr Olson recommends that the EPA halt approval of new PFASs and issue significant new use rules (Snurs) limiting uses of those now in commerce. And he said the Food and Drug Administration (FDA) should revoke approval of the 19 PFASs allowed as food contact substances.

Jeff Morris, director of the EPA's Office of Pollution Prevention and Toxics (OPPT), said PFASs will be considered as a possible class of substances to be targeted as the agency prioritises chemicals for risk evaluation under TSCA.

Manufacturers have sought approval for 900 PFASs in the past 12 years, almost all before TSCA was amended in 2016, said Mr Morris. He did not say how many were approved, but he said the EPA has data from some 900 studies on approximately 200 PFASs.

EPA approach

The EPA laid out the following "concrete steps" to address PFASs:

- evaluate the need for a nationwide maximum contaminant level (MCL) in drinking water for PFOA and PFOS;
- publish groundwater cleanup recommendations for PFOA and PFOS by autumn;
- consider naming some PFASs hazardous substances under the Superfund program, establishing liability for cleaning them up;
- develop toxicity values by this summer for PFBS (perfluorobutane sulfonate) and GenX, a PFOA alternative used in producing Teflon; and
- produce a national PFAS management plan by this autumn.

The ACC said it supports "consideration of MCLs for PFOS, PFOA and other legacy PFAS", as well as regulation barring their import.

The Hill

http://thehill.com/policy/energy-environment/389297-epa-grapples-with-potential-health-threat-in-drinking-water

EPA Grapples with Potential Health Threat in Drinking Water

By: Timothy Cama, 05/28/18

Environmental Protection Agency (EPA) chief Scott Pruitt is starting to grapple with a class of chemicals used in manufacturing that has been found in drinking water in recent years.

Pruitt convened a summit this week with state officials, industry representatives, environmental advocates and others to discuss the presence of per- and polyfluoroalkyl substances (PFAS) in the water supply. He labeled the issue a "national priority" and promised certain steps toward potentially regulating the chemicals' presence in water.

Among other steps, Pruitt said EPA would formally consider whether to set national limits on the drinking water concentration of two of the thousands of chemicals in the family: perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

The chemical industry even endorsed the actions, though cautioned that the EPA has to use "sound science" as it moves forward.

But some in Congress, along with environmental and public health advocates, are skeptical that Pruitt will take strong action on PFAS. They point to the Trump administration's deregulatory bent and an email uncovered last week in which a White House aide said an as-yet-unreleased federal study on the chemicals could be a "public relations nightmare."

"At this point, it really just seems like a public show, with no action to really to back it up," said David Andrews, a senior scientist at the Environmental Working Group.

Pruitt's actions on PFAS were also overshadowed by an uproar over EPA barring journalists from much of the summit and allegations that a security guard shoved a reporter out of the building when she tried to cover it.

The man-made chemicals have been used to make products like Teflon, Scotchgard and firefighting products. Companies have been using them for decades.

But only recently have the health risks from PFAS garnered attention. The risks are under scrutiny in part due to the Flint, Mich., water crisis, which spurred a nationwide focus on water contamination that has uncovered water issues at military bases and manufacturing facilities in New York, New Hampshire, Michigan, North Carolina, among other places.

Consumption of at least some of the compounds has been linked to cancer, thyroid disease, immune system problems and other ailments.

Pruitt organized the PFAS summit earlier this year in response to growing calls from lawmakers and states for EPA to take actions like increasing research and exploring regulation.

"This is a national priority that we need to focus on as a country," Pruitt said at the event. "There are concerns across the country about these chemicals because of their persistence, their durability, getting into the environment and impacting communities in an adverse way."

Pruitt made four pledges on behalf of EPA. He said the agency would evaluate whether to set maximum PFOS levels for drinking water, develop recommendations for cleaning the chemicals out of groundwater, consider whether to designate some of them as "hazardous substances" for environmental cleanup purposes and do research on toxicity levels for some of the compounds.

The American Chemistry Council, which represents chemical companies, endorsed Pruitt's approach.

"I think we were overall pretty encouraged. It's fairly consistent with the sort of things that we're looking for in terms of next steps we want EPA to take in this area," said Jessica Bowman, the group's director for fluor-chemistry.

The industry wants to ensure, however, that newer PFAS compounds are not swept up in EPA's action. It argues that legacy chemicals like PFAS and PFAO — neither of which is produced domestically anymore — are the main issue, and newer chemicals are more advanced and less harmful.

"We want to make sure that EPA does take into consideration that there is a significant variation in the substances that all fall within this class of chemistry, and they don't all require risk-based regulation," Bowman said, adding that she believes Pruitt will endorse that view.

But environmental advocates and many lawmakers distrust Pruitt to handle the issue. They say he is unlikely to order the right scientific studies or go far enough to limit acceptable chemical levels in water.

"I'm very concerned about Pruitt's leadership on this issue," said Rep. Brendan Boyle (D-Pa.).

Boyle said he's particularly worried about the revelation last week that an unknown White House aide predicted a "public relations disaster" from a federal health study about the substances. The email was uncovered by a Freedom of Information Act request filed by the Union of Concerned Scientists and first reported by Politico.

Numerous lawmakers are demanding that the Health and Human Services Department's Agency for Toxic Substances and Disease Registry release the research referenced in the email.

Patrick Breysse, that agency's head, said at the EPA summit that he and his staff were "working aggressively" to get the study out.

Sen. Shelley Moore Capito (R-W.Va.) has also put pressure on the EPA over PFAS.

Asked if she's pleased with how EPA is handling the issue, she said, "I'm not totally pleased, no, but I want to find out what kind of levels are acceptable and remediate the problems."

As for whether she has confidence in Pruitt's handling, she said, "I think time will tell, honestly."

It has proven difficult for the EPA to designate a new chemical for filtering under the Safe Drinking Water Act. Since the act was updated in 1996, only one new chemical has been designated for potential regulation, and the EPA still hasn't moved to regulate it.

But the bigger issue, in environmentalists view, is Pruitt's desire to avoid regulation and cater to industry.

"Reading the tea leaves, it's pretty clear that they are following the chemical industry's lead on this," said Erik Olson, director of the health program at the Natural Resources Defense Council.

"We feel that we certainly can't trust EPA to set a health-protective standard for these chemicals."

Pruitt controversial science "transparency" proposal would also make it difficult for the EPA to publish a strong regulation, green advocates say.

The proposal, among other changes, would require that any scientific findings the EPA uses for regulating be based on data that is available to the public and reproducible.

Epidemiological studies, like those examining the effects of contaminants, often rely on personal data that researchers agree to keep private, and they can't be reproduced since they only happen once.

That would make it difficult for the EPA to use some of the most consequential studies on PFAS, advocates say.

"You throw out all evidence that these chemicals are already impacting human health," Andrews said, pointing to research from the major PFOA spill in West Virginia in 2014 as an example.

"The implications could be enormous in terms of ignoring the significant amounts of scientific data that these chemic

The Record News

http://www.troyrecord.com/article/TR/20180524/NEWS/180529891

Hoosick Falls Mayor Rob Allen Meets EPA Administrator Scott Pruitt, Talks PFOA

By: Keith Whitcomb, 05/25/18

Mayor Rob Allen met face-to-face with Environmental Protection Agency Administrator Scott Pruitt earlier this week to discuss the village's tainted water supply.

Allen met with Pruitt in Washington D.C. when he attended the National Leadership Summit on PFAS.

PFAS (Per- and Polyfluoroalkyl Substances) is the name for the group of chemicals that includes PFOA (perfluorooctanoic acid), which a few years ago was discovered in the village's water supply. It was also found in certain residential wells in nearby North Bennington, Vt., and other places. It's a byproduct of making teflon, which factories in the area at one time manufactured. Studies have suggested long-term exposure can lead to health problems. Similar chemicals are involved in foam used by fire departments on especially heavy fires.

Hoosick Falls has since acquired a filtration system, but is seeking a new water supply.

Allen said he asked Pruitt several questions and made a number of comments. Among them, he and others would like to see the EPA set safe, enforceable maximum contaminant levels (MCL) for PFOA and related chemicals.

He also brought up with Pruitt an article published by Politico about emails allegedly showing that a study set to be released by the federal Health and Human Services' Agency for Toxic Substances and Disease Registry was blocked by White House aids and people within the EPA. The study would have said that safe levels for PFAS are quite lower than what the EPA currently recommends.

Allen said that Pruitt told him he didn't know about the study until the Politico report, and that as EPA administrator he wouldn't have the authority to hold or release the study.

The Politico report is especially frustrating to hear for anyone in a community dealing with a PFAS chemical, said Allen. It was nice to see the EPA is talking about these issues, Allen said, but the reality is that any action the EPA would be likely to move forward with can take years. Setting a MCL, for example, can take as long as a decade. Allen said someone at the summit brought up the fact that the EPA has not set an enforceable MCL for a man-made chemical since 1995.

"Our community is used to hearing words," Allen said. "We want action."

Right now, the village is still negotiating with the companies the state has deemed responsible for the PFOA, St. Gobain and Honeywell. It's also researching new water sources. Candidates include the aquifer under the current polluted one, and the Tomhannock Reservoir which is used by the City of Troy. Allen said there are challenges and concerns with each option.

Ag Net West

http://agnetwest.com/usda-epa-discuss-year-round-e15/

USDA-EPA Discuss Year-Round E15

05/25/18

U.S. Department of Agriculture (USDA) and Environmental Protection Agency (EPA) officials met to discuss ways to increase ethanol usage and to address refiner concerns about volatility in the market for biofuel credits.

An Agri-Pulse report says the meeting followed months of discussions at the White House on the issue. It also follows months of concerns over the way EPA Administrator Scott Pruitt is overseeing the program.

The ethanol industry is pressing the EPA to finally move forward with issuing a vapor pressure waiver that will allow E15 to be sold all year.

Growth Energy CEO Emily Skor says President Trump promised to protect the statutory targets under the RFS. "We support Secretary Perdue's efforts to ensure the EPA upholds the commitment to rural families," Skor says, "and there's no reason to delay or attach unrelated gimmicks to benefit a few refinery owners."

The meeting comes as Marathon, the nation's second-largest refining company, is seeking a waiver from the RFS blending requirements. Iowa Senator Chuck Grassley says the Marathon request shows that the "embarrassing loophole," as he calls the RFS waiver authority, needs to be fixed.

Fox News

http://www.foxnews.com/politics/2018/05/25/trump-welcomes-productive-statement-from-north-korea-says-dems-rooting-against-talks.html

Trump Welcomes 'Productive' Statement from North Korea, Says Dems 'Rooting Against' Talks

By: Brooke Singman, 05/25/18

President Trump kept the diplomacy door open with North Korea on Friday, welcoming the regime's latest "productive" statement following the administration's decision to cancel the highly anticipated summit with Kim Jong Un.

Trump nixed the summit, which was slated for June 12 in Singapore, following threats from North Korea. But hours after the U.S. pulled out of the meeting, North Korea issued a statement suggesting the regime was open to talks.

"Very good news to receive the warm and productive statement from North Korea. We will soon see where it will lead, hopefully to long and enduring prosperity and peace. Only time (and talent) will tell!" Trump tweeted on Friday morning.

A top North Korean official had issued a statement Thursday evening expressing the regime's "willingness" to sit down for a summit with the U.S.

"We express our willingness to sit down face-to-face with the U.S. and resolve issues anytime and in any format," North Korean Vice Foreign Minister Kim Kye-gwan said, according to Yonhap News outlet, which cited the Korean Central News Agency (KCNA.)

The official also said that Trump's move to call off the summit highlighted the tensions between the two countries, further emphasizing the need for a meeting. The official added that Kim had been preparing for the summit.

"Despite all of this, the U.S.' unilateral decision to scrap the talks causes us to reconsider whether all of the efforts and the path we have taken is really the right one or not," the official said according to Yonhap. "Our commitment to doing our best for the sake of peace and stability for the world and the Korean Peninsula remains unchanged, and we are open-minded in giving time and opportunity to the U.S."

But on Friday, with the door left open for potential U.S.-North Korea talks, Trump suggested it was the Democrats who were against "negotiations" with the rogue regime.

"Democrats are so obviously rooting against us in our negotiations with North Korea. Just like they are coming to the defense of MS 13 thugs, saying that they are individuals & must be nurtured, or asking to end your big Tax Cuts & raise your taxes instead. Dems have lost touch!" Trump tweeted Friday.

Following Trump's letter to Kim on Thursday suggesting to hold the meeting would have been "inappropriate," House Democratic Leader Nancy Pelosi, D-Calif., blasted the president, suggesting Kim had "won."

Pelosi described the letter from Trump to Kim as a "Valentine."

"He's the big winner and when he got this letter from the president saying 'okay nevermind,' he must be having a giggle fit, right now, in North Korea," Pelosi said on Capitol Hill Thursday.

Also on Friday, the president tweeted about the reported FBI informant who had communicated with members of his campaign in 2016.

"The Democrats are now alluding to the concept that having an informant placed in an opposing party's campaign is different than having a Spy, as illegal as that may be. But what about an 'informant' who is paid a fortune and who 'sets up' way earlier than the Russia Hoax?" Trump tweeted.

Moments later he added: "Can anyone even imagine having Spies placed in a competing campaign, by the people and party in absolute power, for the sole purpose of political advantage and gain? And to think that the party in question, even with the expenditure of far more money, LOST!"

After a high-level Justice Department briefing held Thursday on the Russia case, Democratic lawmakers maintained there was no evidence to support claims of a spy in the Trump campaign.

Politico

https://www.politico.com/story/2018/05/25/trumps-gas-prices-midterms-570916

Trump's Next Economic Threat: Surging Gas Prices

By: Ben White, 05/25/18

President Donald Trump is hoping a wave of tax-cut-fueled economic euphoria will boost his approval ratings and his party's political fortunes this fall. A sharp spike in gas prices could slam the brakes on all of that.

As Americans head out for traditional Memorial Day weekend road trips, they'll confront gas prices of nearly $3 a gallon, the highest since 2014 and a 25 percent spike since last year.

The increased cost of fuel is already wiping out a big chunk of the benefit Americans received from the GOP tax cuts. And things could get worse as summer approaches following the administration's standoff with Iran and a move by oil-producing nations to tighten supplies.

The result: The economic and political benefits Trump and the GOP hoped to reap from cutting tax rates could be swamped by higher pump prices that Americans face every time they hit the road.

"If you look at the benefits of what households are getting from lower rates, roughly one-third of that is wiped out if these higher gas prices are sustained," said Ellen Zentner, chief U.S. economist at Morgan Stanley. "And when we drive down the street, every block we see glaring signs about how much gas costs that day and it's all over the media. The tax cuts were a one-off. It's a one-time level shift in your paycheck that you are not reminded of every day."

The economic impact of higher gas prices is already stark.

Morgan Stanley estimated that if prices remain at current levels, they would cost U.S. households an additional $38 billion this year. Using Joint Committee on Taxation data, it estimated the tax-cut bill would reduce individual taxes by about $128 billion in 2018. And it gets even worse for Trump.

The increase in gas prices is felt most heavily by lower-income Americans — especially in the South where people drive the most — who received the smallest share of the tax-cut benefits. So the increase could hit Trump's blue-collar Southern base the hardest while potentially eroding confidence in the economy and tamping down consumer spending, which accounts for 70 percent of economic output.

So far, consumer spending remains fairly strong as higher wages and lower taxes encourage people to open their wallets. But the first clear impact of higher gas prices emerged in the latest retail sales figures, which showed a 0.3 percent decline in spending at restaurants and bars. Typically, the first area households cut back when feeling pinched is going out to eat. Spending on travel, tourism and apparel, among other categories, could also wind up declining if fuel prices keep rising.

"Gas prices will reduce the benefits of the tax cut by at least one-third, but I think the impact may actually be much larger than that because the bulk of the tax cuts go to high-income households who aren't going to spend much of it," said Mark Zandi, chief economist at Moody's Analytics. "Gas prices mean less today than they did 20 years ago, but they still mean a lot, especially to those folks living on the margins in lower and lower-middle income groups."

When prices fell in 2014 and 2015, they hit the profits of oil giants but left everyone else with more money to spend, helping lift everything from dining out to home sales — and contributing to a boost in overall gross domestic product.

The reverse may now also be true. Higher gas prices will lead to stronger profits for oil and gas companies, but less spending on everything else and potentially higher inflation.

If prices continue to rise, consumers will feel the pinch not just at the pump but in what they pay to heat their homes and for virtually any product that is delivered to their home or the store in cars and trucks.

"The price of oil and inflation are positively — and highly — correlated," wrote Scott Anderson, chief economist at Bank of the West, in a recent note to clients. "In other words, as oil prices increase or decrease, inflation moves in the same direction."

A spike in inflation could push the Federal Reserve to add another interest rate hike this year, further pushing up the cost of borrowing on everything from credit cards to home purchases. Mortgage rates are already rising, and a further increase could reduce home purchases and all the household formation spending that goes along with them.

None of the negative impacts from higher gas prices are guaranteed.

Many analysts view the price spikes as temporary, noting that a decline in political uncertainty in the Middle East could push prices lower. The U.S. is also far less dependent on imported oil than it was during the oil shock of the late 1970s. And Americans spend less now on gas given alternative energy sources and more efficient cars.

But such a sharp spike in prices still has real economic and psychological impacts that could easily blow away any benefits from a tax-cut bill Americans already have mixed feelings about.

A study released this week by the Federal Reserve Bank of New York showed that only 37 percent of households believe they will be better off a year from now because of the tax cuts, while 47 percent expect no change and 16 percent think they will be worse off.

Higher gas prices, meanwhile, act as an immediate tax on consumers and make people feel poorer.

“There’s still a positive impact from the tax cut, but it tells a little different story when the tax cuts are seen against the backdrop of higher gas prices,” Zentner said. “It changes the narrative a little bit.”

Trump Tweets

Donald J. Trump @realDonaldTrump · 1h

Very good news to receive the warm and productive statement from North Korea. We will soon see where it will lead, hopefully to long and enduring prosperity and peace. Only time (and talent) will tell!

6.4K 9.7K 34K

Donald J. Trump @realDonaldTrump · 2h

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8.3K 9.9K 34K

Donald J. Trump @realDonaldTrump · 2h

"Everyone knows there was a Spy, and in fact the people who were involved in the Spying are admitting that there was a Spy...Widespread Spying involving multiple people." Mollie Hemingway, The Federalist Senior Editor But the corrupt Mainstream Media hates this monster story!

6.7K 7.7K 26K

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4.7K 6.1K 21K

Donald J. Trump @realDonaldTrump · 2h

I will be making the Commencment Address today at the United States Naval Academy in Annapolis, Maryland. Look forward to being with some of the greatest people on earth!

4.7K 5.8K 30K

EPA Morning News Highlights 05.25.18

NWI Times: EPA Meeting about New Lead Cleanup Around Federated Metals Site Draws Large Crowd Seeking Answers

Dozens of Hammond and Whiting residents gathered Wednesday to hear what action the U.S. Environmental Protection Agency plans to take to identify and remove possible lead contamination in the soil on their properties near the long-shuttered Federated Metals site. The public meeting at the Whiting Family YMCA was the first to provide information about the soil sampling study area, which includes a mix of industrial, commercial and residential properties as well as vacant lots, community centers, playgrounds, parks, churches and schools.

Chemical Watch: Pruitt Pledges EPA Action on Legacy of PFASs

US EPA Administrator Scott Pruitt has pledged to address possible health hazards posed by perfluoroalkyl and polyfluoroalkyl substances (PFASs). But the agency's approach will apparently focus on contamination by the legacy chemicals PFOA and PFOS. Meanwhile, thousands of PFASs could remain in active commerce, attendees heard at a recent agency summit. Speaking before state representatives, federal agencies, trade groups and NGOs at the 22 May meeting in Washington, DC, Mr Pruitt announced plans to take such actions on legacy PFASs as developing a maximum contaminant level (MCL) for drinking water and enabling cleanup efforts.

The Hill: EPA Grapples with Potential Health Threat in Drinking Water

Environmental Protection Agency (EPA) chief Scott Pruitt is starting to grapple with a class of chemicals used in manufacturing that has been found in drinking water in recent years. Pruitt convened a summit this week with state officials, industry representatives, environmental advocates and others to discuss the presence of per- and polyfluoroalkyl substances (PFAS) in the water supply. He labeled the issue a "national priority" and promised certain steps toward potentially regulating the chemicals' presence in water.

The Record News: Hoosick Falls Mayor Rob Allen Meets EPA Administrator Scott Pruitt, Talks PFOA

Mayor Rob Allen met face-to-face with Environmental Protection Agency Administrator Scott Pruitt earlier this week to discuss the village's tainted water supply. Allen met with Pruitt in Washington D.C. when he attended the National Leadership Summit on PFAS.

Ag Net West: USDA-EPA Discuss Year-Round E15

U.S. Department of Agriculture (USDA) and Environmental Protection Agency (EPA) officials met to discuss ways to increase ethanol usage and to address refiner concerns about volatility in the market for biofuel credits. An Agri-Pulse report says the meeting followed months of discussions at the White House on the issue. It also follows months of concerns over the way EPA Administrator Scott Pruitt is overseeing the program. The ethanol industry is pressing the EPA to finally move forward with issuing a vapor pressure waiver that will allow E15 to be sold all year.

National Morning News Highlights 05.25.18

Fox News: Trump Welcomes 'Productive' Statement from North Korea, Says Dems 'Rooting Against' Talks

President Trump kept the diplomacy door open with North Korea on Friday, welcoming the regime's latest "productive" statement following the administration's decision to cancel the highly anticipated summit with Kim Jong Un. Trump nixed the summit, which was slated for June 12 in Singapore, following threats from North Korea. But hours after the U.S. pulled out of the meeting, North Korea issued a statement suggesting the regime was open to talks.

Politico: Trump's Next Economic Threat: Surging Gas Prices

President Donald Trump is hoping a wave of tax-cut-fueled economic euphoria will boost his approval ratings and his party's political fortunes this fall. A sharp spike in gas prices could slam the brakes on all of that. As Americans head out for traditional Memorial Day weekend road trips, they'll confront gas prices of nearly $3 a gallon, the highest since 2014 and a 25 percent spike since last year.

NWI Times

http://www.nwitimes.com/news/local/lake/epa-meeting-about-new-lead-cleanup-around-federated-metals-site/article_87bca833-555a-5687-a26d-1dd3485d0186.html

EPA Meeting about New Lead Cleanup Around Federated Metals Site Draws Large Crowd Seeking Answers

By: LuAnn Franklin, 05/24/18

Dozens of Hammond and Whiting residents gathered Wednesday to hear what action the U.S. Environmental Protection Agency plans to take to identify and remove possible lead contamination in the soil on their properties near the long-shuttered Federated Metals site.

The public meeting at the Whiting Family YMCA was the first to provide information about the soil sampling study area, which includes a mix of industrial, commercial and residential properties as well as vacant lots, community centers, playgrounds, parks, churches and schools.

Andrew Maguire, EPA on-scene coordinator, went through the history of the Hammond plant at 2230 Indianapolis Blvd. from 1937 to its closing in 1987, and how EPA teams, acting under the EPA's Resource Conservation & Recovery Act, consolidated waste there from 2003 to 2006. In September 2016, that program referred the surrounding area to the Superfund program, because soil sampling indicated pollution from smokestacks had spread beyond the Federated Metals site.

The study area is bounded by the alley between 119th Street and Fischrupp Avenue to the north, extending to Acthison on the west and White Oak Avenue to the east. The southern border is located between George Lake Trail and East Lakeview Street.

Soil sampling on some properties found lead above the EPA's designed level, Maguire said. Of the 51 properties sampled, 31 were found to have levels at the surface exceeding 400 parts per million, or ppm. Of those, 10 properties showed lead levels equal to or exceeding 1,200 ppm.

Removing contaminated soil, replacing it with clean soil and restoring the yard begins next week on properties where "sensitive populations" reside, he said. "For this project, sensitive population is defined as pregnant women and children under (age) 7."

The EPA also will evaluate removing soil in properties where children in the household have an elevated blood lead level, Maguire said.

All the work will be done at no cost to the property owners. Repairs of any damage done to a home's foundation during the project will be the EPA's responsibility, he said.

"The EPA is actively seeking properties to sample," he said. "We've sampled extensively outside the zone. That line is not set in stone. It is a work in progress."

Residents signed agreements to allow EPA officials and contractors to enter their property, including a tour of basements in homes.

Asked why all the soil in the area isn't being replaced, Maguire said it costs $50,000 to remediate each property.

"There is no responsible party," he said. "Unfortunately Federated Metals went bankrupt."

Chemical Watch

https://chemicalwatch.com/67167/pruitt-pledges-epa-action-on-legacy-pfass

Pruitt Pledges EPA Action on Legacy PFASs

05/24/18

US EPA Administrator Scott Pruitt has pledged to address possible health hazards posed by perfluoroalkyl and polyfluoroalkyl substances (PFASs). But the agency's approach will apparently focus on contamination by the legacy chemicals PFOA and PFOS.

Meanwhile, thousands of PFASs could remain in active commerce, attendees heard at a recent agency summit. Speaking before state representatives, federal agencies, trade groups and NGOs at the 22 May meeting in Washington, DC, Mr Pruitt announced plans to take such actions on legacy PFASs as developing a maximum contaminant level (MCL) for drinking water and enabling cleanup efforts.

Absent from the proposed plan, however, was an approach for assessing the thousands of PFASs used in such consumer products as food packaging, firefighting foams, building materials and textiles.

Industry groups hold that there is no evidence newer "short-chain" PFASs carry the same risks as their "long-chain" predecessors. Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), which are not regulated, have been phased out under a stewardship programme and are no longer manufactured in the US.

Speaking at the summit, Jessica Bowman, executive director of American Chemistry Council subsidiary the FluoroCouncil, said regulators "should recognise the differences between various PFAS chemistries".

"Not all PFAS require risk-based regulation," Ms Bowman said.

Disagreement

But some NGOs and state officials are unconvinced on the safety of short-chain PFASs and would like to see them regulated as a class.

"There is a direct disagreement that short-chain products are known to be any safer," Erik Olson, senior director for health and food at the National Resources Defense Council, told Chemical Watch. He was the only NGO representative invited to speak at the summit.

"I have yet to see any information that says these chemicals are safer to drink in your water," said Brandon Kernen of the New Hampshire Department of Environmental Services. "There [are] a lot more questions than answers."

Mr Olson recommends that the EPA halt approval of new PFASs and issue significant new use rules (Snurs) limiting uses of those now in commerce. And he said the Food and Drug Administration (FDA) should revoke approval of the 19 PFASs allowed as food contact substances.

Jeff Morris, director of the EPA's Office of Pollution Prevention and Toxics (OPPT), said PFASs will be considered as a possible class of substances to be targeted as the agency prioritises chemicals for risk evaluation under TSCA. Manufacturers have sought approval for 900 PFASs in the past 12 years, almost all before TSCA was amended in 2016, said Mr Morris. He did not say how many were approved, but he said the EPA has data from some 900 studies on approximately 200 PFASs.

EPA approach

The EPA laid out the following "concrete steps" to address PFASs:

- evaluate the need for a nationwide maximum contaminant level (MCL) in drinking water for PFOA and PFOS;
- publish groundwater cleanup recommendations for PFOA and PFOS by autumn;
- consider naming some PFASs hazardous substances under the Superfund program, establishing liability for cleaning them up;
- develop toxicity values by this summer for PFBS (perfluorobutane sulfonate) and GenX, a PFOA alternative used in producing Teflon; and
- produce a national PFAS management plan by this autumn.

The ACC said it supports "consideration of MCLs for PFOS, PFOA and other legacy PFAS", as well as regulation barring their import.

The Hill

http://thehill.com/policy/energy-environment/389297-epa-grapples-with-potential-health-threat-in-drinking-water

EPA Grapples with Potential Health Threat in Drinking Water

By: Timothy Cama, 05/28/18

Environmental Protection Agency (EPA) chief Scott Pruitt is starting to grapple with a class of chemicals used in manufacturing that has been found in drinking water in recent years.

Pruitt convened a summit this week with state officials, industry representatives, environmental advocates and others to discuss the presence of per- and polyfluoroalkyl substances (PFAS) in the water supply. He labeled the issue a "national priority" and promised certain steps toward potentially regulating the chemicals' presence in water.

Among other steps, Pruitt said EPA would formally consider whether to set national limits on the drinking water concentration of two of the thousands of chemicals in the family: perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

The chemical industry even endorsed the actions, though cautioned that the EPA has to use "sound science" as it moves forward.

But some in Congress, along with environmental and public health advocates, are skeptical that Pruitt will take strong action on PFAS. They point to the Trump administration's deregulatory bent and an email uncovered last week in which a White House aide said an as-yet-unreleased federal study on the chemicals could be a "public relations nightmare."

"At this point, it really just seems like a public show, with no action to really to back it up," said David Andrews, a senior scientist at the Environmental Working Group.

Pruitt's actions on PFAS were also overshadowed by an uproar over EPA barring journalists from much of the summit and allegations that a security guard shoved a reporter out of the building when she tried to cover it.

The man-made chemicals have been used to make products like Teflon, Scotchgard and firefighting products. Companies have been using them for decades.

But only recently have the health risks from PFAS garnered attention. The risks are under scrutiny in part due to the Flint, Mich., water crisis, which spurred a nationwide focus on water contamination that has uncovered water issues at military bases and manufacturing facilities in New York, New Hampshire, Michigan, North Carolina, among other places.

Consumption of at least some of the compounds has been linked to cancer, thyroid disease, immune system problems and other ailments.

Pruitt organized the PFAS summit earlier this year in response to growing calls from lawmakers and states for EPA to take actions like increasing research and exploring regulation.

"This is a national priority that we need to focus on as a country," Pruitt said at the event. "There are concerns across the country about these chemicals because of their persistence, their durability, getting into the environment and impacting communities in an adverse way."

Pruitt made four pledges on behalf of EPA. He said the agency would evaluate whether to set maximum PFOS levels for drinking water, develop recommendations for cleaning the chemicals out of groundwater, consider whether to designate some of them as "hazardous substances" for environmental cleanup purposes and do research on toxicity levels for some of the compounds.

The American Chemistry Council, which represents chemical companies, endorsed Pruitt's approach.

"I think we were overall pretty encouraged. It's fairly consistent with the sort of things that we're looking for in terms of next steps we want EPA to take in this area," said Jessica Bowman, the group's director for fluor-chemistry.

The industry wants to ensure, however, that newer PFAS compounds are not swept up in EPA's action. It argues that legacy chemicals like PFAS and PFAO — neither of which is produced domestically anymore — are the main issue, and newer chemicals are more advanced and less harmful.

"We want to make sure that EPA does take into consideration that there is a significant variation in the substances that all fall within this class of chemistry, and they don't all require risk-based regulation," Bowman said, adding that she believes Pruitt will endorse that view.

But environmental advocates and many lawmakers distrust Pruitt to handle the issue. They say he is unlikely to order the right scientific studies or go far enough to limit acceptable chemical levels in water.

"I'm very concerned about Pruitt's leadership on this issue," said Rep. Brendan Boyle (D-Pa.).

Boyle said he's particularly worried about the revelation last week that an unknown White House aide predicted a "public relations disaster" from a federal health study about the substances. The email was uncovered by a Freedom of Information Act request filed by the Union of Concerned Scientists and first reported by Politico.

Numerous lawmakers are demanding that the Health and Human Services Department's Agency for Toxic Substances and Disease Registry release the research referenced in the email.

Patrick Breysse, that agency's head, said at the EPA summit that he and his staff were "working aggressively" to get the study out.

Sen. Shelley Moore Capito (R-W.Va.) has also put pressure on the EPA over PFAS.

Asked if she's pleased with how EPA is handling the issue, she said, "I'm not totally pleased, no, but I want to find out what kind of levels are acceptable and remediate the problems."

As for whether she has confidence in Pruitt's handling, she said, "I think time will tell, honestly."

It has proven difficult for the EPA to designate a new chemical for filtering under the Safe Drinking Water Act. Since the act was updated in 1996, only one new chemical has been designated for potential regulation, and the EPA still hasn't moved to regulate it.

But the bigger issue, in environmentalists view, is Pruitt's desire to avoid regulation and cater to industry.

"Reading the tea leaves, it's pretty clear that they are following the chemical industry's lead on this," said Erik Olson, director of the health program at the Natural Resources Defense Council.

"We feel that we certainly can't trust EPA to set a health-protective standard for these chemicals."

Pruitt controversial science "transparency" proposal would also make it difficult for the EPA to publish a strong regulation, green advocates say.

The proposal, among other changes, would require that any scientific findings the EPA uses for regulating be based on data that is available to the public and reproducible.

Epidemiological studies, like those examining the effects of contaminants, often rely on personal data that researchers agree to keep private, and they can't be reproduced since they only happen once.

That would make it difficult for the EPA to use some of the most consequential studies on PFAS, advocates say.

"You throw out all evidence that these chemicals are already impacting human health," Andrews said, pointing to research from the major PFOA spill in West Virginia in 2014 as an example.

"The implications could be enormous in terms of ignoring the significant amounts of scientific data that these chemic

The Record News

http://www.troyrecord.com/article/TR/20180524/NEWS/180529891

Hoosick Falls Mayor Rob Allen Meets EPA Administrator Scott Pruitt, Talks PFOA

By: Keith Whitcomb, 05/25/18

Mayor Rob Allen met face-to-face with Environmental Protection Agency Administrator Scott Pruitt earlier this week to discuss the village's tainted water supply.

Allen met with Pruitt in Washington D.C. when he attended the National Leadership Summit on PFAS.

PFAS (Per- and Polyfluoroalkyl Substances) is the name for the group of chemicals that includes PFOA (perfluorooctanoic acid), which a few years ago was discovered in the village's water supply. It was also found in certain residential wells in nearby North Bennington, Vt., and other places. It's a byproduct of making teflon, which factories in the area at one time manufactured. Studies have suggested long-term exposure can lead to health problems. Similar chemicals are involved in foam used by fire departments on especially heavy fires.

Hoosick Falls has since acquired a filtration system, but is seeking a new water supply.

Allen said he asked Pruitt several questions and made a number of comments. Among them, he and others would like to see the EPA set safe, enforceable maximum contaminant levels (MCL) for PFOA and related chemicals.

He also brought up with Pruitt an article published by Politico about emails allegedly showing that a study set to be released by the federal Health and Human Services' Agency for Toxic Substances and Disease Registry was blocked by White House aids and people within the EPA. The study would have said that safe levels for PFAS are quite lower than what the EPA currently recommends.

Allen said that Pruitt told him he didn't know about the study until the Politico report, and that as EPA administrator he wouldn't have the authority to hold or release the study.

The Politico report is especially frustrating to hear for anyone in a community dealing with a PFAS chemical, said Allen. It was nice to see the EPA is talking about these issues, Allen said, but the reality is that any action the EPA would be likely to move forward with can take years. Setting a MCL, for example, can take as long as a decade. Allen said someone at the summit brought up the fact that the EPA has not set an enforceable MCL for a man-made chemical since 1995.

"Our community is used to hearing words," Allen said. "We want action."

Right now, the village is still negotiating with the companies the state has deemed responsible for the PFOA, St. Gobain and Honeywell. It's also researching new water sources. Candidates include the aquifer under the current polluted one, and the Tomhannock Reservoir which is used by the City of Troy. Allen said there are challenges and concerns with each option.

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The ethanol industry is pressing the EPA to finally move forward with issuing a vapor pressure waiver that will allow E15 to be sold all year.

Growth Energy CEO Emily Skor says President Trump promised to protect the statutory targets under the RFS. "We support Secretary Perdue's efforts to ensure the EPA upholds the commitment to rural families," Skor says, "and there's no reason to delay or attach unrelated gimmicks to benefit a few refinery owners."

The meeting comes as Marathon, the nation's second-largest refining company, is seeking a waiver from the RFS blending requirements. Iowa Senator Chuck Grassley says the Marathon request shows that the "embarrassing loophole," as he calls the RFS waiver authority, needs to be fixed.

Fox News

http://www.foxnews.com/politics/2018/05/25/trump-welcomes-productive-statement-from-north-korea-says-dems-rooting-against-talks.html

Trump Welcomes 'Productive' Statement from North Korea, Says Dems 'Rooting Against' Talks

By: Brooke Singman, 05/25/18

President Trump kept the diplomacy door open with North Korea on Friday, welcoming the regime's latest "productive" statement following the administration's decision to cancel the highly anticipated summit with Kim Jong Un.

Trump nixed the summit, which was slated for June 12 in Singapore, following threats from North Korea. But hours after the U.S. pulled out of the meeting, North Korea issued a statement suggesting the regime was open to talks.

"Very good news to receive the warm and productive statement from North Korea. We will soon see where it will lead, hopefully to long and enduring prosperity and peace. Only time (and talent) will tell!" Trump tweeted on Friday morning.

A top North Korean official had issued a statement Thursday evening expressing the regime's "willingness" to sit down for a summit with the U.S.

"We express our willingness to sit down face-to-face with the U.S. and resolve issues anytime and in any format," North Korean Vice Foreign Minister Kim Kye-gwan said, according to Yonhap News outlet, which cited the Korean Central News Agency (KCNA.)

The official also said that Trump's move to call off the summit highlighted the tensions between the two countries, further emphasizing the need for a meeting. The official added that Kim had been preparing for the summit.

"Despite all of this, the U.S.' unilateral decision to scrap the talks causes us to reconsider whether all of the efforts and the path we have taken is really the right one or not," the official said according to Yonhap. "Our commitment to doing our best for the sake of peace and stability for the world and the Korean Peninsula remains unchanged, and we are open-minded in giving time and opportunity to the U.S."

But on Friday, with the door left open for potential U.S.-North Korea talks, Trump suggested it was the Democrats who were against "negotiations" with the rogue regime.

"Democrats are so obviously rooting against us in our negotiations with North Korea. Just like they are coming to the defense of MS 13 thugs, saying that they are individuals & must be nurtured, or asking to end your big Tax Cuts & raise your taxes instead. Dems have lost touch!" Trump tweeted Friday.

Following Trump's letter to Kim on Thursday suggesting to hold the meeting would have been "inappropriate," House Democratic Leader Nancy Pelosi, D-Calif., blasted the president, suggesting Kim had "won."

Pelosi described the letter from Trump to Kim as a "Valentine."

"He's the big winner and when he got this letter from the president saying 'okay nevermind,' he must be having a giggle fit, right now, in North Korea," Pelosi said on Capitol Hill Thursday.

Also on Friday, the president tweeted about the reported FBI informant who had communicated with members of his campaign in 2016.

"The Democrats are now alluding to the concept that having an informant placed in an opposing party's campaign is different than having a Spy, as illegal as that may be. But what about an 'informant' who is paid a fortune and who 'sets up' way earlier than the Russia Hoax?" Trump tweeted.

Moments later he added: "Can anyone even imagine having Spies placed in a competing campaign, by the people and party in absolute power, for the sole purpose of political advantage and gain? And to think that the party in question, even with the expenditure of far more money, LOST!"

After a high-level Justice Department briefing held Thursday on the Russia case, Democratic lawmakers maintained there was no evidence to support claims of a spy in the Trump campaign.

Politico

https://www.politico.com/story/2018/05/25/trumps-gas-prices-midterms-570916

Trump's Next Economic Threat: Surging Gas Prices

By: Ben White, 05/25/18

President Donald Trump is hoping a wave of tax-cut-fueled economic euphoria will boost his approval ratings and his party's political fortunes this fall. A sharp spike in gas prices could slam the brakes on all of that.

As Americans head out for traditional Memorial Day weekend road trips, they'll confront gas prices of nearly $3 a gallon, the highest since 2014 and a 25 percent spike since last year.

The increased cost of fuel is already wiping out a big chunk of the benefit Americans received from the GOP tax cuts. And things could get worse as summer approaches following the administration's standoff with Iran and a move by oil-producing nations to tighten supplies.

The result: The economic and political benefits Trump and the GOP hoped to reap from cutting tax rates could be swamped by higher pump prices that Americans face every time they hit the road.

"If you look at the benefits of what households are getting from lower rates, roughly one-third of that is wiped out if these higher gas prices are sustained," said Ellen Zentner, chief U.S. economist at Morgan Stanley. "And when we drive down the street, every block we see glaring signs about how much gas costs that day and it's all over the media. The tax cuts were a one-off. It's a one-time level shift in your paycheck that you are not reminded of every day."

The economic impact of higher gas prices is already stark.

Morgan Stanley estimated that if prices remain at current levels, they would cost U.S. households an additional $38 billion this year. Using Joint Committee on Taxation data, it estimated the tax-cut bill would reduce individual taxes by about $128 billion in 2018. And it gets even worse for Trump.

The increase in gas prices is felt most heavily by lower-income Americans — especially in the South where people drive the most — who received the smallest share of the tax-cut benefits. So the increase could hit Trump's blue-collar Southern base the hardest while potentially eroding confidence in the economy and tamping down consumer spending, which accounts for 70 percent of economic output.

So far, consumer spending remains fairly strong as higher wages and lower taxes encourage people to open their wallets. But the first clear impact of higher gas prices emerged in the latest retail sales figures, which showed a 0.3 percent decline in spending at restaurants and bars. Typically, the first area households cut back when feeling pinched is going out to eat. Spending on travel, tourism and apparel, among other categories, could also wind up declining if fuel prices keep rising.

"Gas prices will reduce the benefits of the tax cut by at least one-third, but I think the impact may actually be much larger than that because the bulk of the tax cuts go to high-income households who aren't going to spend much of it," said Mark Zandi, chief economist at Moody's Analytics. "Gas prices mean less today than they did 20 years ago, but they still mean a lot, especially to those folks living on the margins in lower and lower-middle income groups."

When prices fell in 2014 and 2015, they hit the profits of oil giants but left everyone else with more money to spend, helping lift everything from dining out to home sales — and contributing to a boost in overall gross domestic product.

The reverse may now also be true. Higher gas prices will lead to stronger profits for oil and gas companies, but less spending on everything else and potentially higher inflation.

If prices continue to rise, consumers will feel the pinch not just at the pump but in what they pay to heat their homes and for virtually any product that is delivered to their home or the store in cars and trucks.

"The price of oil and inflation are positively — and highly — correlated," wrote Scott Anderson, chief economist at Bank of the West, in a recent note to clients. "In other words, as oil prices increase or decrease, inflation moves in the same direction."

A spike in inflation could push the Federal Reserve to add another interest rate hike this year, further pushing up the cost of borrowing on everything from credit cards to home purchases. Mortgage rates are already rising, and a further increase could reduce home purchases and all the household formation spending that goes along with them.

None of the negative impacts from higher gas prices are guaranteed.

Many analysts view the price spikes as temporary, noting that a decline in political uncertainty in the Middle East could push prices lower. The U.S. is also far less dependent on imported oil than it was during the oil shock of the late 1970s. And Americans spend less now on gas given alternative energy sources and more efficient cars.

But such a sharp spike in prices still has real economic and psychological impacts that could easily blow away any benefits from a tax-cut bill Americans already have mixed feelings about.

A study released this week by the Federal Reserve Bank of New York showed that only 37 percent of households believe they will be better off a year from now because of the tax cuts, while 47 percent expect no change and 16 percent think they will be worse off.

Higher gas prices, meanwhile, act as an immediate tax on consumers and make people feel poorer.

"There's still a positive impact from the tax cut, but it tells a little different story when the tax cuts are seen against the backdrop of higher gas prices," Zentner said. "It changes the narrative a little bit."

Trump Tweets

Donald J. Trump @realDonaldTrump · 1h

Very good news to receive the warm and productive statement from North Korea. We will soon see where it will lead, hopefully to long and enduring prosperity and peace. Only time (and talent) will tell!

6.4K 9.7K 34K

Donald J. Trump @realDonaldTrump · 2h

Democrats are so obviously rooting against us in our negotiations with North Korea. Just like they are coming to the defense of MS 13 thugs, saying that they are individuals & must be nurtured, or asking to end your big Tax Cuts & raise your taxes instead. Dems have lost touch!

8.3K 9.9K 34K

Donald J. Trump @realDonaldTrump · 2h

"Everyone knows there was a Spy, and in fact the people who were involved in the Spying are admitting that there was a Spy...Widespread Spying involving multiple people." Mollie Hemingway, The Federalist Senior Editor But the corrupt Mainstream Media hates this monster story!

6.7K 7.7K 26K

Donald J. Trump @realDonaldTrump · 2h

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6.7K 7.7K 26K

Donald J. Trump @realDonaldTrump · 2h

Can anyone even imagine having Spies placed in a competing campaign, by the people and party in absolute power, for the sole purpose of political advantage and gain? And to think that the party in question, even with the expenditure of far more money, LOST!

8.8K 8.0K 30K

Donald J. Trump @realDonaldTrump · 2h

The Democrats are now alluding to the the concept that having an Informant placed in an opposing party's campaign is different than having a Spy, as illegal as that may be. But what about an "Informant" who is paid a fortune and who "sets up" way earlier than the Russian Hoax?

4.7K 6.1K 21K

Donald J. Trump @realDonaldTrump · 2h

I will be making the Commencment Address today at the United States Naval Academy in Annapolis, Maryland. Look forward to being with some of the greatest people on earth!

4.7K 5.8K 30K

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 4/24/2018 5:26:22 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]
Subject: FW: Strengthening Transparency in Regulatory Science
Attachments: Data Access Draft_ signature 4 24.docx

For your records, attached is the final word document that is being printed for signature.
Thanks,
Brittany

From: Nickerson, William
Sent: Tuesday, April 24, 2018 1:24 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Strengthening Transparency in Regulatory Science

The signature version

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-XXXX-XX]

RIN 2080-AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

DATES: Comments must be received on or before **[insert date 30 days after date of publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA-2018-0259, at *https:// www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a

written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/ commenting-epa-dockets.*

FOR FURTHER INFORMATION, CONTACT: Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564-0221; email address: *staff_osa@epa.gov*.

SUPPLEMENTARY INFORMATION:

Submitting CBI. Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address using U.S Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA–HQ–OA-2018-0259, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. For other methods of delivery, see https://www.epa.gov/dockets/where-send-comments-epa-dockets.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that

includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information

A. Does this action apply to me?

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

B. What action is the agency taking?

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

C. What is the agency's authority for taking this action?

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048;

Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

II. Background

The best available science must serve as the foundation of EPA's regulatory actions.[1] Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in enhancing the public's ability to understand and meaningfully participate in the regulatory process.[2] In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure=that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models

[1] See Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

[2] See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.[3] This proposed rule is also consistent with Executive Orders 13777[4] and 13783,[5] and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*[6] (the Guidelines) and OMB *Memorandum 13-13: Open Data Policy – Managing Information as an Asset.*[7] It builds upon prior EPA actions[8] in response to government-wide data access and sharing policies, as well as the experience of other

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[3] EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA*, 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

[4] Exec. Order No. 13777, 82 Fed. Reg. 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

[5] Exec. Order No. 13783, 82 Fed. Reg. 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

[6] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

[7] *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* (https://project-open-data.cio.gov/policy-memo/). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

[8] Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency; ,

federal agencies in this space.[9] In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.[10] These policies are informed by the policies recently adopted by some major scientific journals,[11] spurred in some part by the "replication crisis." [12]

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: specifically, the dose response data and models that underlie what we are calling "pivotal regulatory science." "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory

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[9] For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the US Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (https://www.census.gov/fsrdc).

[10] These include policies and recommendations from: the Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data*, *Expanding Access to Research Data*, and *Access to Research Data in the 21st Century*; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

[11] For example, see related policies from the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*.

[12] See: https://www.nature.com/articles/s41562-016-0021; http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full

science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying "pivotal regulatory science") is available to the public for validation[13] in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis. Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA's regulatory science should be consistent with the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*.[14] Robust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-

[13] EPA has not consistently followed previous EPA policy (e.g, EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.
[14] https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf

linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: a broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines[15] (which apply to "third party" information - e.g., non-government scientific research – if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of

[15] February 22, 2002 (67 F.R 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information

the Federal government.[16] Nothing in the proposed rule compels the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.[17] The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach."[18] More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy[19] have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,[20] to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.[21] EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective

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[16] See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

[17] https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

[18] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

[19] https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.

[20] For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature.

[21] For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc.

and may also include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.[22]

Implementation of this proposed rule will be consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be "significant regulatory actions" pursuant to E.O. 12866. The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

III. Request for Comment

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other

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[22]These recommendations are consistent with those of Lutter and Zorn (2016). https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re

policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above. EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate. Although the proposed regulatory text would impose requirements specifically on final regulations determined to be "significant regulatory actions" under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under EO 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant

final regulatory actions under EO 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of "*pivotal regulatory science*," and "*dose response data and models*" and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future

significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

IV. Statutory and Executive Orders Reviews

A. *Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies[23] This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy,

[23] https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to EO 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: "Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. …" They concluded that "an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[24]

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel."

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

[24] https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 30

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements

Dated: _____.

_____

E. Scott Pruitt,

Administrator

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

PART 30—Transparency in Regulatory Decisionmaking

1. Add part 30 to read as follows:

PART 30—Transparency in Regulatory Decisionmaking

Sec.

Authority: Clean Air Act §§ 103, 301(a), 42 U.S.C. §§ 7403, 7601(a); Clean Water Act §§ 104, 501, 33 U.S.C. §§ 1254, 1361; Safe Drinking Water Act §§ 1442, 1450(a)(1), 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act §§ 2002(a)(1), 7009, 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) §§ 115, 311, 42 U.S.C. §§ 9616, 9660; Emergency Planning and Community Right-To-Know Act § 328, 42 U.S.C. § 11048; Federal Insecticide, Fungicide, and Rodenticide Act §§ 25(a)(1), 136r(a), 7 U.S.C. §§ 136r(a), 136w; and Toxic Substances Control Act, as amended, § 10, 15 U.S.C. § 2609.

§30.1 What is the purpose of this subpart?

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

§30.2 What definitions apply to this subpart?

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

Dose response data and models means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions

typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

Regulatory decisions mean final regulations determined to be "significant regulatory actions" by the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory science means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

Research data means "research data" as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

§30.3 How do the provisions of this subpart apply?

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of

this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

§30.4 What requirements apply to EPA's use of studies in taking final action?

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

§30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered "publicly available in a manner sufficient for independent validation" when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

(a) Data (where necessary, data would be made available subject to access and use restrictions).

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

§30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default

assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

§30.7 What role does independent peer review in this section?

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

§30.8 How is EPA to account for cost under this subpart?

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

§30.9 May the EPA Administrator grant exemptions to this subpart?

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or

(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

§30.10 What other requirements apply under this subpart?

EPA shall implement the provisions of this section consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in P.L. 89-487, and other applicable federal laws.

Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

Message

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To: Askinazi, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0f11a6972234134ae9b2f59a4a26709-Askinazi, V]; Barkas, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=808724835d8a457fb0c5333e62b34291-Barkas, Jessica]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]; Blair, Susanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c869b985f3d43db982c18aaabd826bd-Blair, Susa]; Blunck, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=827cd31fd0484c319e5a2e7511f65461-Blunck, Christopher]; Brown, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da0a099605514dbeb3ebab7aaf253de6-Brown, Sam]; Buster, Pamela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0d03c8a52440b7a95343287b8928c5-PBuster]; Canavan, Sheila [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5453ba7f3d4582a0eff06ed80a5e79-Canavan, Sheila]; Caraballo, Mario [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e9d657e48042fea4bb7c68f78a023c-Caraballo, Mario]; Carroll, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882c7705ed3f4d50aba9a7870f9eb6cc-MCarr03]; Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Christian, Myrta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=207ad12497b04bcf8e80a0024b35a18a-MChris02]; Corado, Ana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb9257919594061b763f306c2f8be60-ACorado]; Davies, Clive [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eca39ab66ea413993d7355fd46b1008-Davies, Clive]; DeDora, Caroline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e587cd3b59b46f59a369df26390fd9f-Newton, Caroline]; Devito, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be78622515bd451e96e948786357fb45-SDevito]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Drewes, Scott [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1107458a6d814a61ab24b605aff2c7ba-Drewes, Scott]; Dunton, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ffa0e71e87448cc9fd86ba1379ea93a-Dunton, Cheryl]; Ebzery, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5729928cba7e4025bbdcd3504c791095-JEbzery]; Edelstein, Rebecca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9549e6e2f43e4a3c88cc3bea8f7220f5-Rebecca L Edelstein]; Edmonds, Marc [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed31dcc62754411aae5e1be96ed01f1d-MEdmonds]; Eglsaer, Kristie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5365adea6f9a4f3397bdc735dafe4c32-Friesenhahn, Kristie]; Elwood, Holly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc14ca33efe94036a4b406c9951eb70a-HElwood]; Faeth, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12af792b39cc4b4fa8089976f3f8859f-lfaeth]; Farquharson, Chenise [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=6b240335cb7b41d79edb4ef922386a23-Farquharson, Chenise]; Fehrenbacher, Cathy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369151285d0143bba4f6fb3f9991e583-CFehrenb]; Feustel, Ingrid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Feustel, Ingrid]; Frank, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ede4e3e063144b1da75b5ef2b4d1f800-Dfrank03]; Gibson, Hugh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e63bc90e77f4cfe8a7636cd926faf94-Hgibson]; Gimlin, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=060960590fc242daa65c8532e11da375-Pgimlin]; Gorder, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36f179fec0d1415881a7ca9d924d2f22-CGORDER]; Gordon, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbaa06ff76ce4f1fb9c75df41c350372-Gordon, Brittney]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Gray, Shawna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfa1bf931d974750a8db6345742c5a6c-Gray, Shawna]; Groeneveld, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cea7bd5d8ba4a8cb97852f4695d8e28-Groeneveld, Thomas]; Guthrie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=921669a0369f4172b7b71f7d4dddb7df-Guthrie, Christina]; Helfgott, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=552774baf1154c2b8f0b55d9d4f152c8-Daniel A. Helfgott]; Henry, Tala [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bfc0a617a4a43baa8856541c70622be-THENRY02]; Kapust, Edna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbc694a771064c54a3554f5cd8344baf-EKapust]; Kemme, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b458e296e4f4cf9aa843ba8da7c5bfc-Kemme, Sara]; Koch, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5e11973f9c0476ea9784f4b0a932373-EKOCH]; Krasnic, Toni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f94b31db1dba47189537584f7f0aaacc-tkrasnic]; Lavoie, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ac7844f12646c095e4e9093a941623-Lavoie, Emma]; Leczynski, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f368cd532514486f94339a3433894029-bleczyns]; Lee, Mari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7fa44d3c03fa45da9d33603ea6cbe7ec-Lee, Mari]; Lee, Virginia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=956f7f6c1c91456bbef1e6ade5423766-VLee]; Leopard, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c7e250715234083a7a99796d2543127-Leopard, Matthew]; Liva, Aakruti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39285a08436f46e5b8a284c1b5975a15-Shah, Aakruti]; Lobar, Bryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0299fc8f8c344582bc873a6c26e952fb-Blobar]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Menasche, Claudia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76305791bbca4d5ab562de082a59f6ed-Menasche, C]; Morris, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55c34872e6ea40cab78be910aec63321-Morris, Jeff]; Moss, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57d0ffce93a041db8f353bf0e1a7bdf3-KMoss]; Mottley, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33a000296a364b0dad31fb9aaa34605d-Mottley, Tanya]; Moyer, Adam

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pentagon's Use of Paint Stripper Unclear as EPA Moves to Curb Toxic

By Pat Rizzuto and Sam Pearson

Posted May 17, 2018, 6:37 PM

A White House office is working with the Defense Department and the EPA to decide how the military and its contractors could continue to use a paint stripper the agency now plans to restrict, EPA Administrator Scott Pruitt told Congress.

INSIDEEPA.COM ARTICLES

EPA Again Finds Formaldehyde Poses Leukemia Risks But Stalls Study

After years of additional study and scientific review, EPA has again found that formaldehyde poses leukemia and other cancer risks, though Democratic senators say the draft finding has prompted Trump EPA appointees to block release of the assessment and they are urging Administrator Scott Pruitt to quickly release it.

Democrats Take Rare Step Of Using CRA To Kill Trump Rule, Despite Critique

Democrats are taking the rare step of using the Congressional Review Act (CRA), the law that eases Congress' ability to repeal EPA and other agencies' rules, to block a Trump administration rule rolling back Obama-era 'net neutrality' mandates, despite criticism from environmentalists that it legitimizes use of a poorly-written law that Republicans and industry have long-used as a deregulatory tool and which they are seeking to repeal.

GREENWIRE ARTICLES

Who's donating to Pruitt's defense? Time will tell

Kevin Bogardus, E&E News reporter Published: Thursday, May 17, 2018

EPA Administrator Scott Pruitt yesterday arrived at the Dirksen Senate Office Building to testify before a Senate Appropriations subcommittee on his agency's fiscal 2019 budget proposal. Tom Williams/CQ Roll Call/Associated Press

You may wait a long time to see who is contributing to EPA Administrator Scott Pruitt's legal defense fund.

Like other federal officials, the EPA chief is required to report gifts, like travel and tickets to events, he has received on his public financial disclosure report. That also includes contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website.

But those reports are filed just once a year. If Pruitt's legal defense fund was created this year, he will report contributions as gifts on his financial disclosure report covering the 2018 calendar year. That report isn't required to be filed until May 2019 at the earliest.

https://www.eenews.net/greenwire/2018/05/17/stories/1060082001

Emails: EPA all ears as industry pitched 'secret science'

Maxine Joselow, E&E News reporter

Published: Thursday, May 17, 2018

EPA headquarters in Washington. @EPAScottPruitt/Twitter

Industry groups pitched EPA a proposal last spring that closely resembled what became Administrator Scott Pruitt's "secret science" plan, according to emails released this week under Freedom of Information Act litigation.

The National Association of Manufacturers offered detailed suggestions on EPA's handling of scientific studies last May to the agency's regulatory reform task force, which was soliciting suggestions on rules and rulemaking.

"A common complaint among manufacturers in recent years has been a process at the EPA for evaluating science that is not transparent and minimizes third party stakeholder input," wrote Ross Eisenberg, NAM's vice president of energy and resources policy.

https://www.eenews.net/greenwire/2018/05/17/stories/1060081997

Chemicals could be making workers sick at coffee roasters

Published: Thursday, May 17, 2018

A Centers for Disease Control and Prevention investigation suggests chemicals in the air at coffee roasting operations could present a widespread health threat to employees.

A small group of CDC researchers spent the last two years investigating tiny coffee shops and large roasters around the country.

Their early results, based on 11 site reports, indicate that employees across the $74 billion industry could be experiencing health effects from the fumes given off in the roasting process.

https://www.eenews.net/greenwire/2018/05/17/stories/1060081989

CHEMICAL WATCH ARTICLES

US Osha seeks input on UN GHS conference

18 May 2018 / GHS, United States

The US Occupational Safety and Health Administration (Osha) will host a public meeting to discuss proposals in preparation for the 35th session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS).

At the 12 June meeting, Osha, along with the US Interagency GHS Coordinating Group, will provide updates on GHS-related interests. And it will consider comments submitted during the meeting when developing governmental positions for the UN session.

It will also give an update on the Regulatory Cooperation Council (RCC), the *Federal Register* notice says.

The meeting will take place at the Department of Transportation headquarters in Washington, DC. The UN meeting will be held between 4 and 6 July in Geneva.

Further Information:

- Notice

US EPA eyes proposal on costs and benefits of rules

18 May 2018 / United States

The US EPA is working on a proposal to address how it weighs costs and benefits in its regulations.

According to its website, the White House's Office of Management and Budget (OMB) is conducting a standard interagency review of the proposal, "Increasing consistency and transparency in considering costs and benefits in the rulemaking process". Its status is listed as "prerule stage".

An EPA spokesperson told Chemical Watch the agency does not comment on the substance of actions under formal interagency review. But the spokesperson said the agency is "seeking to provide consistency and certainty in the way EPA calculates costs and benefits of its regulations."

The OMB website reflects three stakeholder meetings on the proposal. These were requested by

- the American Petroleum Institute (API);
- the National Association of Manufacturers (NAM); and
- the American Forest and Paper Association (AF&PA).

The American Chemistry Council (ACC) attended two of these.

Consideration of the proposal comes as the EPA takes comment on a controversial proposed rule aimed at increasing the transparency of the science it uses to underpin its regulatory decisions.

Related Articles

- US EPA science policy to 'change agency culture' on data
- US EPA formally issues 'science transparency' proposal

Further Information:

- OMB review

OTHER ARTICLES

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WSOC Charlotte

Products like leave-in conditioner, hot oil treatments, root simulators **and** relaxers, commonly used by black girls **and** women, may also contain harmful ...

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Globalnews.ca

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Sanders joins effort to release report on toxic substances

Vermont Biz

Vermont Business Magazine US Senator Bernie Sanders (I-Vermont) joined an effort with 10 other senators calling on EPA Administrator Scott Pruitt ...

Editorial: Toxic stalling tactics - The Intelligencer

PFOS study deemed 'public relations nightmare' - Times Herald-Record

Pallone Accuses White House of Trying to Suppress Report on PFCs in Drinking Water - NJ Spotlight

20 natural cleaning hacks to replace harmful chemicals

Treehugger

We are so afraid of the perceived dangers of dirt and germs that all around our homes we spray and sprinkle **toxic chemicals** that likely do more harm ...

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 5/8/2018 2:41:18 PM
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Subject: News Clips (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Oil and Coal Executives Clamored for EPA Chief, Records Show

By Jennifer A. Dlouhy and Eric Roston

Posted May 8, 2018, 8:20 AM

The pleas began almost as soon as Scott Pruitt became Environmental Protection Agency administrator: requests from oil executives, coal miners, and energy lobbyists desperate to nab time with the newly confirmed regulator.

Walmart Backs States' Effort to Centralize Chemical Reporting

By Pat Rizzuto

Posted May 8, 2018, 7:48 AM

Walmart is working with a group to make it easier for companies to comply with state laws requiring businesses to report chemicals in children's products.

Eight States Urge EPA to Halt Draft Rule Limiting Science Use

By Katherine Tam

Posted May 7, 2018, 3:57 PM

A group of eight attorneys general are urging EPA Administrator Scott Pruitt to consult with the National Academy of Sciences before proceeding with a draft science "transparency" rule.

INSIDEEPA.COM ARTICLES

Pruitt's Science Plan Faces Host Of Legal Hurdles; Some Doubt Promulgation

Administrator Scott Pruitt's plan requiring EPA to use only publicly available information to justify its regulatory decisions faces a host of legal hurdles, industry officials and environmentalists say, including vague or undefined terminology, statutory mandates likely at odds with the rule and potential violations of administrative law.

EPA Appears Unlikely To Quickly Set PFAS Standard, Despite DOD Calls

EPA appears unlikely to quickly develop and adopt an enforceable drinking water standard for any perfluorinated chemicals as some lawmakers, states and others are seeking, despite calls from the Defense Department (DOD), which may be responsible for hundreds of contaminated water supplies, for a consistent national standard to preempt a patchwork of state limits.

Critics Doubt EPA Plan To Redact Confidential Data In Transparency Rule

Critics of EPA Administrator Scott Pruitt's proposal to require only publicly available research to justify regulatory decisions say agency plans to protect confidential information, such as personal data or trade secret studies, by redacting it are not adequate, will result in a host of adverse effects and will undermine agency decisionmaking.

EPA's Defense Of TSCA Rules Marks Key Legal Test After Early Court Losses

The Trump administration's upcoming defense of EPA rules implementing the recently revised toxics law will mark one of the first substantive tests for how well new regulations will withstand legal scrutiny after the agency suffered a series of early court losses as they sought to defend other regulatory delays and officials are scrambling to correct perceived flaws in several draft rules.

EPA Rule Deadline Tracking System May Help Avoid 'Sue-And-Settle' Rules

EPA is creating a system to track all its statutory rulemaking deadlines to support its goal of meeting every binding deadline by 2022, a goal that could help the agency avoid "sue and settle" agreements imposing new deadlines for agency action but one that EPA's Chief of Operations Henry Darwin acknowledges is a "heavy lift."

ACC Lauds Draft EPA Transparency Rule's Focus On Dose-Response

The American Chemistry Council (ACC) is lauding EPA's recently proposed rule on science transparency, arguing it "gets it right" with its bid to move away from the agency's long-time strict, default linear dose-response approach, even as the group suggests the proposal may not adequately protect trade secrets that its members submit for chemical approvals.

Tozzi Backs Bolstering Existing Data Laws Over EPA 'Secret Science' Rule

Former White House Office of Management & Budget (OMB) regulatory review chief Jim Tozzi is opposing EPA Administrator Scott Pruitt's proposed "secret science" rule to bar use of data in decisions if it is not publicly available, countering that a more effective way to improve transparency would be to bolster two existing data laws.

Expecting EPA Hurdles, NRDC Makes Case For Suit On 'New' Chemicals Plan

Anticipating procedural challenges from EPA, environmentalists are making the case that an appellate court should consider the merits of their litigation challenging the agency's framework for reviewing new chemicals, charging the policy has the effect of a legislative rule, was issued without following proper rulemaking procedure, and should be vacated.

Environmentalists Seek To Boost Ethics Claim In TSCA Rules Challenge

Environmentalists challenging EPA's rules for prioritizing and reviewing existing chemicals are seeking to include additional documents in the administrative record on Nancy Beck, the top political appointee in EPA's toxics office, in an effort to bolster their claim that the former chemical industry lobbyist has a conflict of interest and inappropriately revised the rules.

Environmentalists Seek More Time For EPA Science Rule Comments

Environmentalists are urging EPA to extend by 60 days its deadline for public comments on Administrator Scott Pruitt's controversial proposed rule requiring use of only public information in regulatory decisions, saying the 30 days EPA has offered is not adequate to address a rule of such magnitude.

California Adopts First Green Chemistry Priority Product, 2018-20 Work Plan

California toxics department officials have adopted the first regulatory listing of a priority product under its landmark Safer Consumer Products (SCP) green chemistry program, triggering the next phase in which manufacturers must determine whether they must conduct new chemical analyses to change their products' formulation to make them less hazardous.

GREENWIRE ARTICLES

Agency employees, Jeff Bezos up for government 'Oscars'

Nick Sobczyk, E&E News reporter

Published: Monday, May 7, 2018

Employees from EPA and the departments of Energy and the Interior are in the running for distinguished civil service awards.

The Partnership for Public Service yesterday announced 27 finalists for its Samuel J. Heyman Service to America Medals, known as the "Sammies" for short.

The group will be honored at a ceremony tomorrow to commemorate Public Service Recognition Week, and seven winners will be crowned at an Oct. 2 gala in Washington.

"Amid the political headlines, it's easy to overlook our nation's career public servants who perform the essential day-to-day work of government," said Max Stier, president and CEO of the Partnership for Public Service, in a statement. "That's why the Service to America Medals are so important — they showcase the many remarkable men and women who assist their fellow Americans with passion to maintain the safety, health and prosperity of the nation."

https://www.eenews.net/greenwire/2018/05/07/stories/1060081005

Newspapers find dangers in Philadelphia schools

Published: Monday, May 7, 2018

Schools in Philadelphia contain environmental hazards like lead paint chips that endanger students, according to an investigation by *The Philadelphia Inquirer* and the *Philadelphia Daily News*.

Dean Pagan, 6, was hospitalized last November with severe lead poisoning after eating paint chips that fell from the ceiling of his first-grade classroom.

"When you send your child to school, you think he's going to be safe and you don't have to worry," said Dean's father, David Pagan.

According to Dean's parents, he lost the ability to do simple math.

https://www.eenews.net/greenwire/2018/05/07/stories/1060080985

OTHER ARTICLES

Health Advocates Kick Off Week of Action Urging Lowe's and EPA to Ban Toxic Paint Strippers

Safer Chemicals, Healthy Families (press release) (blog)

Nationwide actions urge ban on toxic methylene chloride after four ... a pending ban on the use of these **toxic chemicals** in paint stripper products:.

Yikes! Toxic Chemicals Discovered in Black Hair Care Products

Eurweb.com

Some of these products have **toxic chemicals** that are linked to lymphoma, asthma, reproductive disorders and birth defects along with other ...

Iowa widow battles dealer after it crashes her new car, initially won't replace it

WFMYNews2.com

What many call “new car smell” can be **toxic chemicals** used in car manufacturing. Especially when a car is new, or in warm weather, those chemicals ...

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 4/25/2018 3:20:27 PM
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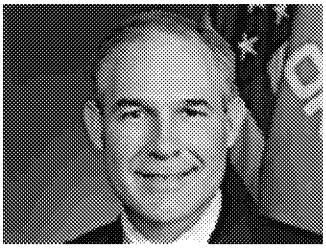
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt Seeks to Constrict EPA Use of Scientific Studies for Rules

EPA Administrator Scott Pruitt wants to make a lasting change to the way the agency uses science to make policy, a move environmental groups say will sharply limit the public health studies the EPA can rely on.

Pruitt Must Address 'Drip, Drip' of Allegations, a GOP Leader Says



The Senate's third-ranking Republican said April 24 that Scott Pruitt has to address ethics questions, which he suggested are making it difficult for the EPA chief to do his job.

INSIDEEPA.COM ARTICLES

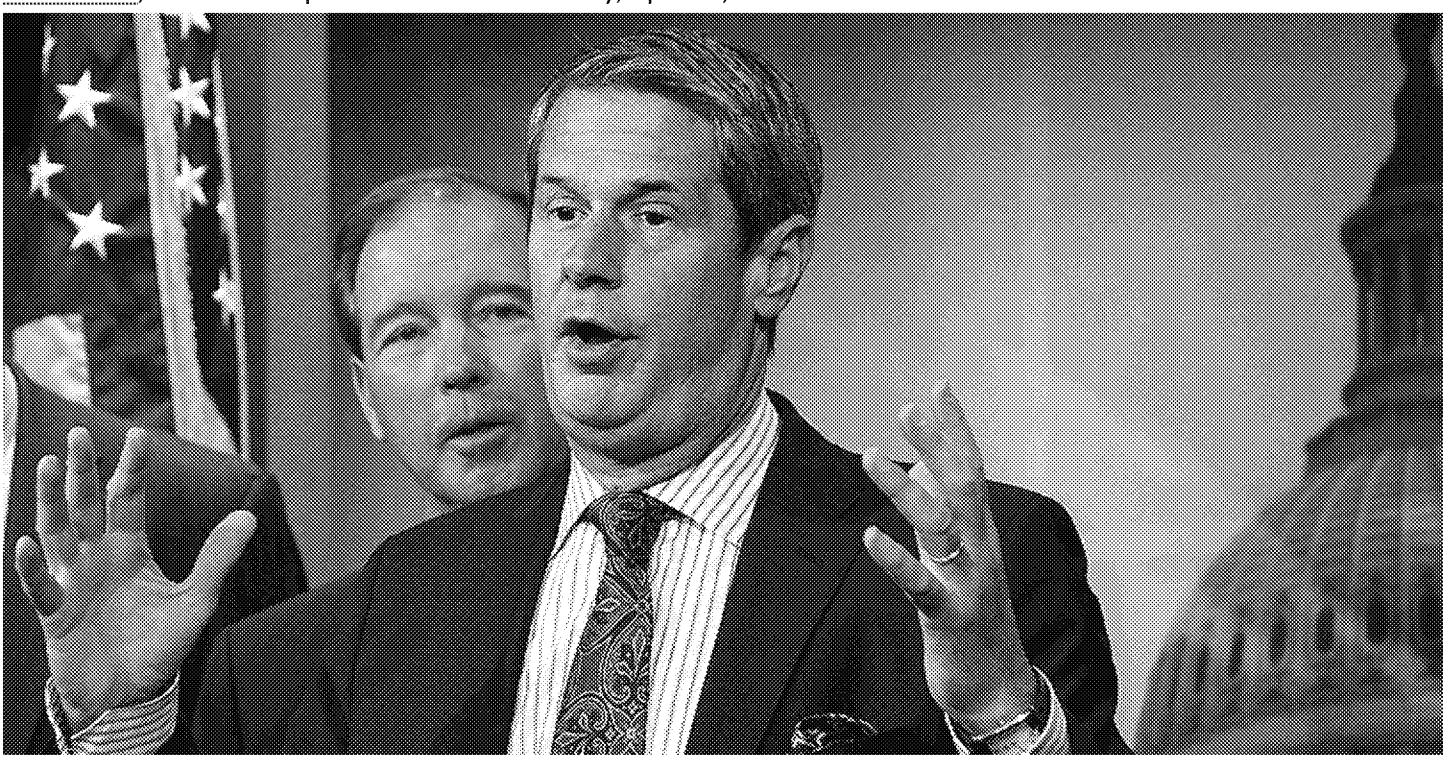
Facing Legal Hurdles, EPA's 'Secret Science' Plan Punts On Key Issues

EPA Administrator Scott Pruitt has signed a long-promised plan barring the agency's use of any information in decision-making that is not publicly available, but the proposed rule punts on a host of tricky legal and implementation issues, including statutory mandates to use the best available science and how to address confidential trade secrets and medically protected data.

GREENWIRE ARTICLES

Rollout of Lautenberg law divides senators who championed it

Corbin Hiar, E&E News reporter Published: Tuesday, April 24, 2018



Sen. Tom Udall (D-N.M.) and then-Sen. David Vitter (R-La.) speak during a news conference on chemical safety reform in 2015. Manuel Balce Ceneta/Associated Press

A conservative and a liberal stood side by side in June 2016 as President Obama signed into law the senators' hard-fought compromise legislation to overhaul the nation's bedrock chemical safety law for the first time in its 40-year history.

Today, Louisiana's David Vitter is out of Congress, lobbying for the chemical industry that long supported him, and Sen. Tom Udall (D-N.M.), who remains in office, is battling his former legislative partner over the implementation of the Toxic Substances Control Act reform they championed.

Their quick retreat from common ground to familiar opposition positions is an indication to policy experts that the TSCA reform deal was an extraordinary agreement that would be impossible to make today — and one which is now being viewed very differently by the lawmakers who pushed to enshrine it in law.

https://www.eenews.net/greenwire/2018/04/24/stories/1060079925

Agency merges teams, launches FOIA office

Kevin Bogardus, E&E News reporter

Published: Tuesday, April 24, 2018

EPA headquarters in Washington. Claudine Hellmuth/E&E News

EPA has created a new national office to help handle its Freedom of Information Act requests.

General counsel Matt Leopold said in an internal email obtained by E&E News that the agency will bring together two teams of EPA staffers from different programs who manage the public records requests and house them in one place in EPA's legal office.

"I am pleased to announce the creation of a new National Freedom of Information Act (FOIA) Office at EPA," Leopold told EPA employees in the email sent yesterday. "The FOIA Office brings together the FOIA program staff from the Office

of Environmental Information and the staff from the FOIA Expert Assistance Team from the Office of General Counsel (OGC) into OGC."

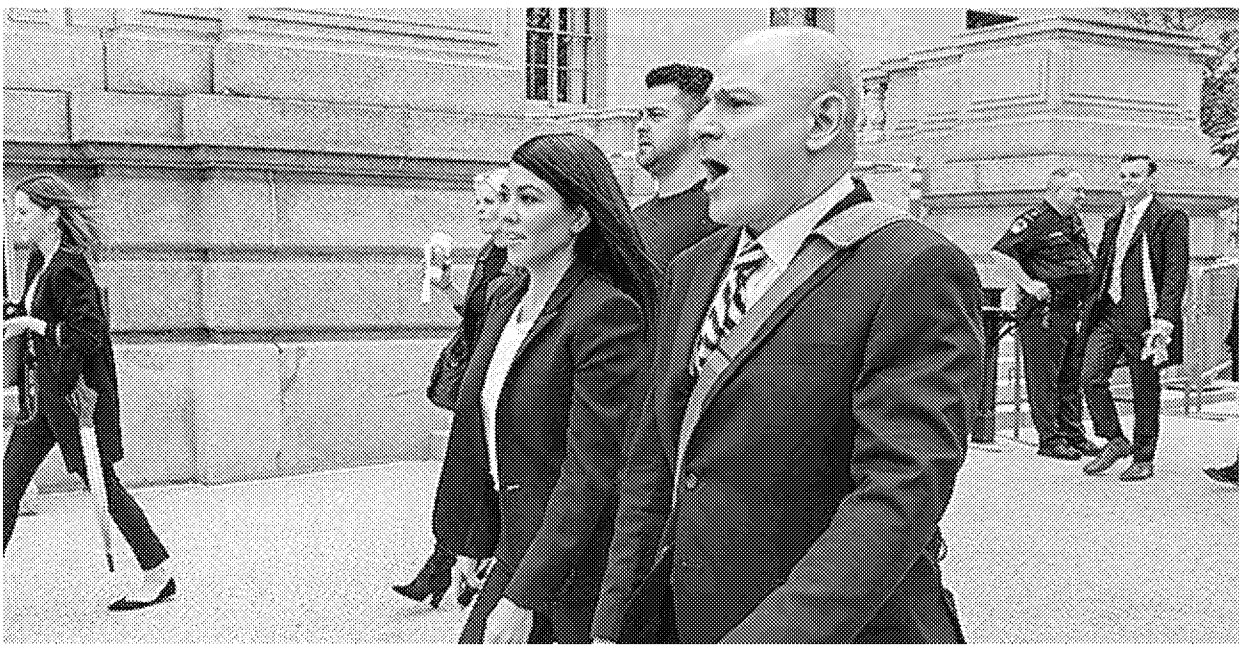
Leopold also said EPA's General Law Office in OGC will continue to handle FOIA litigation for the agency as well as provide legal counseling and response to appeals. In addition, Neil Bigioni, deputy regional counsel in EPA's Region 3 office in Philadelphia, will be the new FOIA office's acting director until the position is filled permanently.

https://www.eenews.net/greenwire/2018/04/24/stories/1060079945

Cosmetics safety bill gets Kardashian backing

Corbin Hiar, E&E News reporter

Published: Tuesday, April 24, 2018



Reality TV star Kourtney Kardashian (center) is on Capitol Hill today to advocate for overhauling the nation's cosmetic safety law. Corbin Hiar/E&E News

A bipartisan cosmetics safety bill is getting a boost from a reality television star who is both an avid consumer and purveyor of personal care products.

Kourtney Kardashian, the eldest sister in the hit show "Keeping Up with the Kardashians," arrived fashionably late to a morning briefing for Capitol Hill staffers and reporters set up by the Environmental Working Group.

The 38-year-old mother of three argued that the "Personal Care Products Safety Act," S. 1113, from Sens. Dianne Feinstein (D-Calif.) and Susan Collins (R-Maine), is necessary so that consumers can feel confident the products they and their families are using don't contain potentially harmful chemicals.

https://www.eenews.net/greenwire/2018/04/24/stories/1060079949

CHEMICAL WATCH ARTICLES

US EPA, Health Canada and Echa collaborate on testing alternatives

Case studies will boost regulatory acceptance of NAMs, authorities hope

24 April 2018 / Alternative approaches to testing, Canada, Europe, United States

Scientists from regulatory agencies across the world will soon publish the first results from a series of joint case studies, set up to increase the use of new approach methodologies (NAMs) for chemical prioritisation, screening and quantitative risk assessment.

The US EPA, Health Canada and Echa are coordinating an initiative called Accelerating the Pace of Chemical Risk Assessment (APCRA). Through meetings and workshops, the group has identified some key barriers to accepting NAMs for regulatory decision making. These include the current practice of benchmarking new tests against lab animal studies as well as a general lack of understanding and confidence in applying NAMs.

The initiative began with a meeting hosted by the EPA in September 2016, followed by a workshop last year. Its aim is to "enhance collaboration across international organisations with an emphasis on learning by doing", explains Rusty Thomas from the EPA, Tara Barton-Maclaren from Health Canada and Mike Rasenberg from Echa, co-authors of a recent APCRA paper in *Chemical Research in Toxicology*.

"Through case studies, the collaborators are engaging in two-way dialogues to exchange information about how these NAMs can be applied to various decisions. As these case studies progress, training and communication through webinars, workshops and meetings will occur as well as expanding case studies to other applications with more collaborators," they add.

APCRA has developed six case studies, on:

- risk evaluation;
- chemical categorisation; and
- exposure evaluation

A first risk evaluation case study looks into using bioactivity as a conservative estimate of no– and low effect levels in animal studies. The project compares the point of departure on dose-response curves, corresponding to the no- or low effect level, from NAMs and animal studies for several hundred chemicals. It will be published in a scientific journal in the next few months.

A second case study takes a "prospective" approach, generating NAM data for a number of substances. "Traditional" animal tests will then be carried out on a subset of the chemicals to help analyse the results and improve the NAMs

approach. It is a collaboration between Echa, the EPA, the US National Toxicology Programme, Health Canada, the European Commission's Joint Research Centre, and Singapore's A*Star programme.

Meanwhile, one of the chemical categorisation case studies involves a systematic literature review of per- and polyfluoroalkyl substances, followed by NAMs analysis; another attempts to integrate NAM profiles for categorisation.

For exposure, the group has chosen to focus on computational exposure science and *in silico* approaches.

Future case studies will need to explore new ways of describing hazard in ways that fit with the information that NAMs provide, such as looking at whether bioactivity in a certain pathway can predict adverse effects, according to the journal article.

They should also examine new ways of describing risk, "being protective without the requirement of being predictive", add the authors.

Further Information:

- 2016 APCRA article in Chem Res Tox
- APCRA 2017 workshop discussion

NGOs urge member states to support REACH nano amendments

Calls to back restrictions on phthalates and CMRs, ahead of REACH Committee meeting

24 April 2018 / Alternatives assessment & substitution, CMRs, Europe, Nanomaterials, Phthalates, REACH, Textiles & apparel

A group of NGOs has written to EU member states, urging them to support proposals to amend REACH annexes for nanomaterials and to restrict carcinogenic, mutagenic and reprotoxic (CMR) substances in textiles.

In the letter, which has been sent ahead of a REACH Committee meeting on 25-26 April, the group also asks members to vote in favour of the European Commission's proposal for a restriction on four phthalates.

The group of seven NGOs includes:

- the European Environmental Bureau (EEB);
- ClientEarth;
- the Center for International Environmental Law (Ciel); and
- the Health and Environment Alliance (HEAL).

After several years of delays, the Commission proposed changes to REACH annexes to address substances in nanoforms last year.

These include the addition of a new section to Annex IX, which calls for further testing if specific additional particle properties "significantly influence the hazard or the exposure to those nanoforms".

The NGOs say its placing there is "contrary to the spirit of REACH" and defeats the purpose of adapting the annexes for nanomaterials.

The provision should be inserted in Annex VI, they say, as this would make REACH more "future proof" at no extra cost for registrants. Annex VI details the information needed for the submission of a registration dossier and evaluation.

Textiles CMR restriction

The NGOs say the restriction on CMRs in textiles should cover all that are category 1A and 1B substances with a harmonised classification. It should not be "just those 40 plus substances for which the European Commission was able to find evidence of use in the textiles sector".

Additionally, consumer organisations Beuc and Anec provided comments ahead of the meeting, calling for a "systematic, comprehensive approach" on the restriction.

The proposal should be amended, they say, to ensure:

- better protection of small children;
- regular updates to the list of restricted substances and applicable concentration limits; and
- the addition of disposable textile within the scope of the restriction.

Phthalates restriction proposal

Regarding the intention to restrict four phthalates – bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) – the NGOs say member states should reject an exemption on exports to non-EU countries.

This is to avoid "completely unacceptable double standards", they add.

The group has also called on member states to reject exemptions for outdoor, industrial and agriculture uses, as well as for spare parts for the automotive and aerospace sectors.

And they say they "firmly oppose" a proposal to defer the restriction on automotive and aerospace articles for 60 months.

Related Articles

- EU Commission plans to restrict phthalates under RoHS2
- EU Commission consults on REACH annex revision for nanomaterials
- REACH annex nano revision 'not future proof'
- Commission clarifies scope of proposed CMR in textiles restriction
- EU Commission plans to restrict phthalates under RoHS2

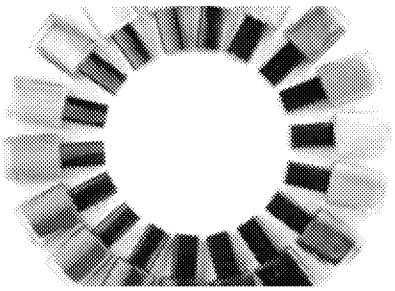
Further Information:

- NGOs' letter
- Commission's draft Regulation amending REACH annexes to include nanomaterials
- Beuc and Anec comments

California launches healthy nail salon certification programme

Guidelines bar products containing tolulene, DBP, formaldehyde, MMA monomer

25 April 2018 / Personal care, United States, Voluntary action



California's Department of Toxic Substances Control (DTSC) has issued guidelines for local governments that choose to establish healthy nail salon programmes.

The initiative, mandated by the state legislature in 2016, aims to reduce exposure to toxic chemicals for employees and customers.

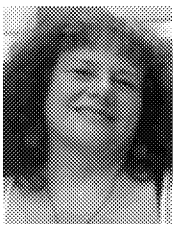
The department estimates that California has 48,000 nail salons. Of these, about 200 have been designated as 'healthy' in five jurisdictions that already have a similar programme: Alameda, San Mateo and Santa Clara counties; the city of Santa Monica; and the city and county of San Francisco.

In order to be certified as a healthy nail salon, a business must:

- choose polishes and related products that do not contain dibutyl phthalate (DBP), toluene, formaldehyde, or liquid methyl methacrylate (MMA) monomer;
- avoid using nail polish thinners, if possible, and use none that contain toluene or methyl ethyl ketone (MEK);
- choose polish removers that do not contain ethyl acetate or butyl acetate;
- obtain safety data sheets (SDSs) for all products used;
- have employees use disposable gloves and evaluate whether respirator masks are needed to prevent exposure to dust;
- follow approved practices for handling, storing and disposing of toxic substances, as well as approved sanitation practices; and
- provide at least basic ventilation.

To receive a 'gold' certification, salons must also have air conditioning and/or a job-specific ventilation system; employ protective goggles; use environmentally friendly cleaning products; provide ergonomic seating and lighting; and train employees on healthy work practices.

The DTSC is separately considering naming nail salon products as a 'priority product' under the Safer Consumer Products (SCP) programme.



Julie Miller

Reporter

Related Articles

- California seeks input on safer consumer products priorities

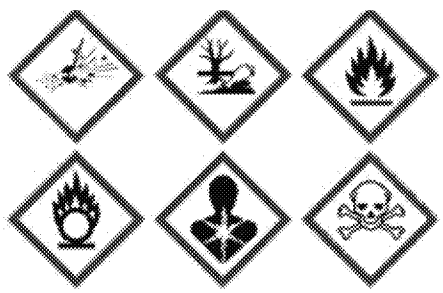
Further Information:

- Nail salon guidelines

Majority of EU online chemical mixtures ads lack hazard warnings

Echa enforcement project leads to hundreds of fines for CLP breaches

25 April 2018 / Classification, labelling and packaging Regulation, Enforcement, Europe, Substances of concern



A major Echa Enforcement Forum project that checked more than 1,300 online adverts for hazardous chemical mixtures across the EU has found over 82% were non-compliant under the CLP Regulation.

Of the 1,083 non-compliant internet adverts, 903 did not mention the type or types of hazard indicated on the product label, the agency said. And only 220 – 16.7% of inspected online adverts – had the correct information on hazard.

Nearly all of the inspected websites – 95.9% – belonged to professional suppliers.

Checks were carried out on the following product types:

- household, e.g. cleaning products (37.7%);

- construction, e.g. paints, coatings, adhesives (16.7%);
- motor, e.g. cleaning agents, coatings, lubricants (14%);
- hobby, e.g. glues, paints, solvents (11.9%);
- garden, e.g. plant protection agents, biocides (9.3%); and
- others (10.4%).

The Forum embarked on the project in 2016 with an objective to focus on the compliance of online sales with Article 48(2) of CLP. This states that an advert must mention hazards indicated on the label if the mixture can be purchased without seeing this.

National enforcement authorities from 15 European countries took part in the pilot project. Its scope also included compliance with the requirement under Article 17(2) that hazard warnings are written in the official language of the member state.

Outcomes

Desktop inspections were carried out between January and August last year, with most taking place in Germany (508), followed by the Czech Republic (361), Echa said in a report.

Inspectors issued 280 fines, 124 verbal advice and 460 written advice statements. In four cases, enforcement authorities undertook a criminal complaint or referred the case to the public prosecutor's office.

For 321 cases, follow-up activities continued after the operational phase of the project finished on 31 August last year. In 223 cases, information was forwarded to another enforcement authority in the same member state for further action.

Recommendations

Echa issued a set of recommendations, based on the findings of the project, as well as feedback from the questionnaires completed by national authorities.

Industry and trade associations could develop "common strategies" to clarify what is a lawful sale on the internet, Echa said. A collection of "positive examples" could also be compiled by industry and distributed to associations to pass to the companies concerned.

In recommendations to the European Commission, the agency called for "specification of the wording of Article 48 (2)" to avoid undefined legal concepts. The Commission should also consider developing a guideline for online retailers to facilitate their implementation of Article 48 (2), it said.

Enforcement authorities should continue to perform inspections and Forum members that did not participate in the project should consider conducting their own, the agency added.

Additionally, given the high rate of non-compliance detected, the Forum could include the topic in a future REACH-En-Force (Ref) project.

The Forum's Ref-6 project is currently underway to check whether the classification and labelling (C&L) of a mixture corresponds to the information presented in the safety data sheet (SDS).

Related Articles

- Echa Forum progresses project on internet sales of chemicals
- EU enforcement project targeting C&L of mixtures underway

Further Information:

- Report
- Press release

Canada clears 59 inorganic, organometallic substances from further assessment

Included in earlier assessments and management plans

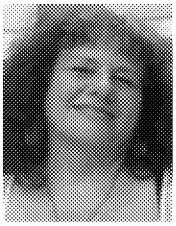
25 April 2018 / Canada, Environmental Protection Act, Inorganics, Metals

The Canadian government has listed 59 inorganic and organometallic substances it considers have been addressed in other assessment activities and will, therefore, not undergo further evaluation at this time under the Canadian Environmental Protection Act (Cepa).

The 20 April list includes:

- an arsenic-containing substance (10H-phenoxarsine, 10,10'-oxybis-) that was included in the assessment of "arsenic and its compounds";
- a cadmium-containing substance (hexanoic acid, 2-ethyl-, cadmium salt), included in the assessment of cadmium compounds;
- 11 substances that were included in the assessment of chromium compounds;
- two fluoride compounds addressed in the assessment of inorganic fluorides;
- four substances that were included in the assessment of nickel compounds;
- 26 ammonia compounds, addressed in the assessment of "ammonia in the aquatic environment";
- four uranium-containing substances, addressed in the assessment of "releases of radionuclides from nuclear facilities" and drinking water guidelines for uranium;
- two substances covered by Health Canada's risk assessment strategy for mercury and its compounds and the drinking water guidelines for mercury; and
- eight lead-containing substances considered to have been addressed by Health Canada's *Final human health state of the science report on lead* and risk management strategy on lead.

Environment and Climate Change Canada will accept public comment for 60 days.



Julie Miller

Reporter

Further Information:

- Approach notice

Swedish chemicals agency withdraws report on ecolabelling

25 April 2018 / Labelling, Sweden

The Swedish Chemicals Agency, Kemi, says it has found errors in its study, *Mapping of dangerous substances in ecolabelling systems*, and has suspended publication. The agency discovered "certain ambiguities" and incorrect references to rules, it says. A corrected version will be published as soon as the changes are made.

The study, looking at the role of ecolabelling in chemical restriction, was published in March.

Related Articles

- Sweden study looks at ecolabelling role in chemical restrictions

Further Information:

- Kemi press release (in Swedish)

OTHER ARTICLES

Sleepy time: Some nap mats at Seattle child-care centers contain toxic chemicals

Seattle Times

“This study shows that, clearly, we can reduce kids' exposures to these **chemicals** linked to serious health problems simply by taking them out of the **products**,” said Erika Schreder, science director of the Seattle-based advocacy group **Toxic**-free Future **and** a co-author of the paper published Tuesday in ...

California Department of Toxic Substances Control

East County Magazine

April 23, 2018 (Sacramento) -- The California Department of **Toxic Substances** Control (DTSC) this week issued guidelines to help local government agencies in California voluntarily establish and implement a program to make salons healthier for nail care workers, who are exposed to **toxic chemicals** in

EPA practices are hindering transparency and public confidence in TSCA's new chemicals program

Environmental Defense Fund (blog)

This is our final post in a series spurred by our review of 69 public files for new chemicals we received from EPA's Docket Center. For most of these chemicals, EPA made a determination that they are "not likely to present unreasonable risk" under the **Toxic Substances** Control Act (TSCA), which ...

Scott Pruitt Threatens Reproductive and Environmental Justice for Women

Center For American Progress

Administrator Pruitt is failing to lead the agency's response to Flint as well as other **toxic chemical** cases. Instead, he is eliminating important grant programs, such as the Lead Risk Reduction Program, which educates Americans about how to reduce exposure to lead in their homes and also certifies and ...

Message

From: Tanner, Barbara [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85D9A3F12DFA4B4ABAAE51BC4723EDDB-TANNER, BARBARA]
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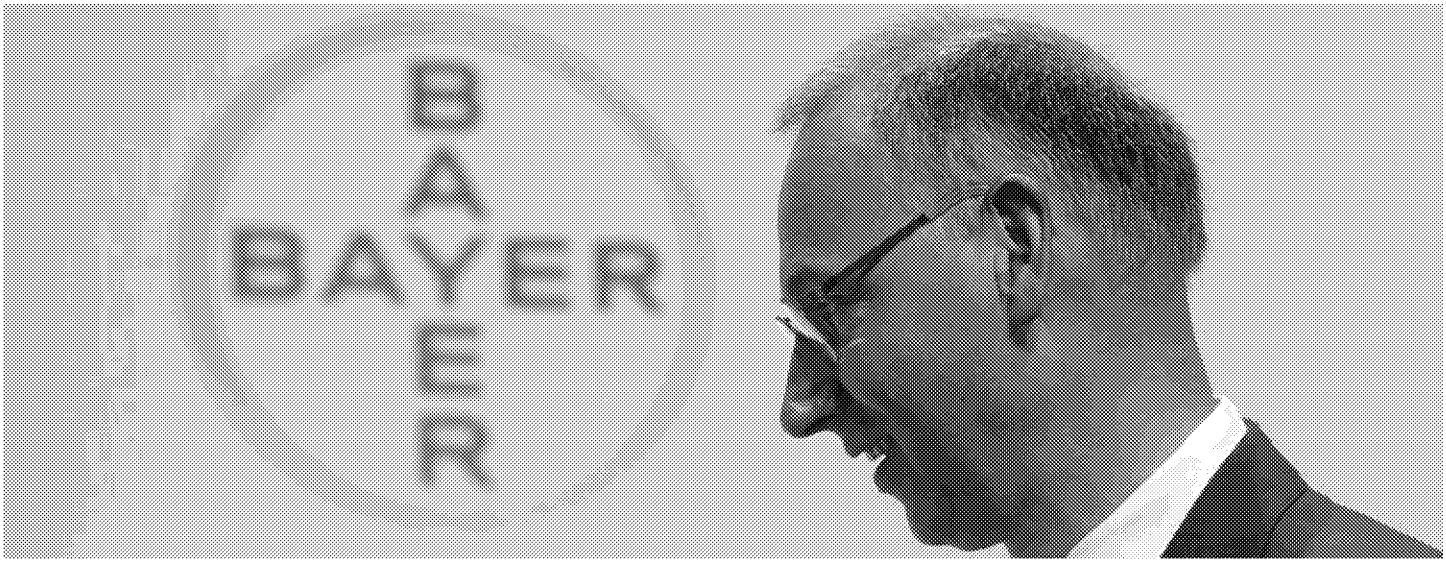


Werner Baumann, chief executive of Bayer AG, tries to allay investors fears after a $289 million jury award involving its popular pesticide Roundup.
Photographer: Krisztian Bocsi/Bloomberg via Getty Images
News

Bayer CEO Tries to Calm Nerves After $289 Million Roundup Award

Posted Aug. 23, 2018, 7:41 AM

- Bayer plans to appeal the jury award
- Company could face up to $5 billion in costs linked to glyphosate cases

Bayer AG Chief Executive Officer Werner Baumann sought to soothe investors' worries after a $289 million jury award over the controversial weed-killer Roundup, saying the $66 billion purchase of Monsanto Co. still makes sense.

There is "no reason to break out in nervousness" in the aftermath of the Aug. 10 verdict, Baumann told Germany's Handelsblatt newspaper in his first interview since the jury's decision.

"The fact is that absolutely nothing has changed about the compelling logic of the Monsanto takeover, about the potential for value creation for our shareholders, about the attractiveness of the agriculture market and about the goals we have communicated."

The California court awarded a school groundskeeper the damages over claims that exposure to Roundup caused his non-Hodgkin's lymphoma. The trial was the first over allegations that the herbicide causes cancer. Bayer has said it will appeal, and U.S. jury awards against companies are often overturned or reduced. But the German company could still face as much as $5 billion in costs linked to cases over glyphosate, the main ingredient in Roundup, analysts at Sanford C. Bernstein & Co. estimate.

The verdict—the first of what may be thousands of cases—shocked observers both inside and outside Bayer, erasing $16 billion from the company's market value in a week. Baumann has contended that facts should rule over emotion in the debate over whether Roundup causes cancer.

https://news.bloombergenvironment.com/environment-and-energy/bayer-ceo-tries-to-calm-nerves-after-289-million-roundup-award

Chemical Groups Cite Duty Relief Bill at China Hearing

By Len Bracken
Posted Aug. 22, 2018, 6:36 PM

Congress is likely to suspend duties on upwards of one thousand chemicals, two industry representatives said Aug. 22 at a hearing reviewing China-specific tariffs.

Pruitt's Cameo in Beef Industry Video OK, Watchdog Says (1)

By Sylvia Carignan
Posted Aug. 22, 2018, 4:04 PM Updated Aug. 22, 2018, 4:55 PM

Former EPA Administrator Scott Pruitt's appearance in a beef industry association video didn't violate lobbying, publicity, or propaganda regulations, according to a government watchdog.

INSIDEEPA.COM ARTICLES

Wheeler Sees Need For EPA Staff Succession Plans But Major Union Wary

Acting EPA Administrator Andrew Wheeler in a recent meeting with Region 5 employees signaled he agrees with their concerns about declining personnel levels and the need to plan for hiring younger people to replace a slew of retiring staffers, though a major EPA union remains wary that his deregulatory agenda will deter new hires.

CHEMICAL WATCH ARTICLES

TSCA problem formulations set 'improper precedents', say former EPA staff

'Questionable exclusions and loopholes' scrutinised in risk evaluations

22 August 2018 / TSCA, United States

Former US EPA staff members have cautioned that the approach to TSCA 'problem formulations' sets "improper precedents for future chemical risk evaluations" under the recently reformed law.

The comments from the Environmental Protection Network – an EPA alumni group formed last year to provide a "defense against efforts to undermine" the agency's mission – came in response to a consultation on TSCA problem formulations. These further refine the scope of the first ten risk evaluations that the EPA is conducting following the update of the law in 2016.

In line with comments raised by consumer advocacy groups, the EPN's concerns centred on the EPA's decision to exclude certain conditions of use from its evaluations. The group says this runs counter to its mandate to consider risks resulting from all intended, known and reasonably foreseen uses of a chemical.

And, because all ten chemicals addressed in the problem formulations have chronic toxic effects, "a comprehensive aggregate assessment of all co-occurring exposures is critical, since excluding even one pathway will underestimate cancer and non-cancer effects."

Public health professionals group AHPA said in comments that by not considering all uses, the EPA is likely to conclude the total exposure level to a substance is lower than it is. And it may therefore "determine incorrectly" that the substance does not present an unreasonable risk – a decision they say is "unlawful and lacks scientific credibility".

A coalition of NGOs lead by Safer Chemicals, Healthy Families agreed in its response that the EPA is "on a path to produce evaluations that ignore important exposure pathways and at-risk populations, disregard evidence of adverse effects and reach misleading and incomplete conclusions that understate risks and weaken public health protection."

It has called on the agency to put the risk evaluations on hold in order to "rethink how they are being conducted, and [to] initiate them in accordance with the law and principles of sound science".

Excluded uses questioned

Comments from an array of groups have focused on the "questionable exclusions and loopholes" in the problem formulations.

Among those omitted, the Environmental Defense Fund said, are exposures:

- that could potentially be covered by another EPA-administered statute;
- resulting from past conditions of use that could reasonably recur;
- from accidents; and
- resulting from imperfect compliance with existing regulations.

The EPA "cannot ignore ongoing, real-world exposures" such as these, the NGO said.

The SCHF coalition cautioned that by excluding discontinued uses, industry could cease production of a specific use to prevent its inclusion in the risk evaluation, and then re-enter the marketplace without restriction or a risk determination. But if the agency were to evaluate those abandoned uses, it would have the authority to permanently

ban or restrict them under section 6(a) of TSCA, "providing certainty to the marketplace and long-term public health protection".

The coalition added that it "appears that EPA will examine each source of exposure in isolation and will not consider either the combined effect of multiple exposures or the contribution of environmental releases to overall exposure and risk". This, it said, is in violation of the law's mandate to evaluate a chemical in its totality.

And it cited a "minimal effort" to identify data gaps and assess how they will impact conclusions. It has called on the EPA to use its authorities to require testing to address these.

Industry generally supportive

The American Chemistry Council said in its comments that it "generally supports the approach taken to addressing conditions of use" in the first ten problem formulations.

Focusing on those uses that "raise the greatest potential for risk ... allows EPA to be efficient, while still addressing the highest priority conditions of use", it said.

The trade group, however, has called for the development of a framework that "articulates its process for deciding when conditions of use are in or out of scope".

This would "streamline future efforts, provide greater understanding of EPA's decisions, increase transparency and reproducibility and enable industry to identify the types of information that may be most helpful" to develop and/or share with EPA, it said.

The problem formulations consultation closed on 16 August. The EPA must finalise its risk evaluations by December 2019.

Note: Your access to this subscriber-only article is through a corporate subscription

Kelly Franklin
North America editor

Related Articles

- EPA issues TSCA 'problem formulation' documents
- EPA names first ten chemicals for new TSCA evaluations
- EPA 'narrowing' scope of first ten TSCA risk evaluations

Further Information:

- Risk evaluations and docket links

EU committee gives Opinion on safety of sunscreen ingredient

23 August 2018 / Europe, Personal care, Substances of concern

The EU's Scientific Committee on Consumer Safety (SCCS) concluded that the use of phenylene bisdiphenyltriazine – S86 – is safe as a UV-filter in sunscreen products at a concentration of up to 5%.

Because of the insoluble nature of S86 and as no data were provided on safety via inhalation exposure, the SCCS said it considers its use safe only in dermally applied products and not in products that would lead to inhalation exposure.

It added that S86 may contain impurities (NMP and hydrazine), which are classified as category 1B carcinogenic, mutagenic and reprotoxic (CMR) chemicals and identified in the EU as SVHCs.

Therefore, the SCCS recommended the level of NMP and hydrazine be kept to trace levels. Potential effects of the substance on the environment were not assessed by committee.

Further Information:

- Opinion on the safety of cosmetic ingredient S86

Echa round-up

23 August 2018 / Classification, labelling and packaging Regulation, Europe, REACH

Norwegian intention to identify an SVHC

Norway has submitted its intention for identification of perfluorobutane sulfonic acid (PFBS), its salts and related substances as an SVHC. It is expected to submit the proposal in March next year.

New public consultations on testing proposals

Echa has started 19 new public consultations on testing proposals. The deadline to comment these is 24 September. There are currently 30 public consultations open on testing proposals.

CLH consultation

The agency is consulting on a harmonised classification and labelling proposal for 7-oxa-3-oxiranylbicyclo[4.1.0]heptane.

The Netherlands is proposing a future entry in Annex VI of the CLP Regulation for carcinogenicity 1B, reproductive toxicity 1B, acute toxicity 3 and 4. The substance has an existing classification.

The deadline for comments is 19 October.

The substance is mainly used a chemical intermediate and as a reactive diluent in epoxy resins.

CLH intentions

Echa has received new intentions to harmonise the classification and labelling of:

- dimethomorph (ISO);
- 1,3-bis(isocyanatomethyl)benzene;
- 1,3-bis(1-isocyanato-1-methylethyl)benzene;
- 2,4,6-triisopropyl-m-phenylene diisocyanate;
- 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate; and
- 1,5-naphthylene diisocyanate.

Do you need to notify trichloroethylene uses?

Echa has advised companies on their notification obligations in relation to uses authorised this month for the substance trichloroethylene.

The Commission granted authorisation for five uses to the company Blue Cube Germany Assets on 10 August.

If this company supplies the substance directly or indirectly, the authorisation numbers should be included in their extended safety data sheet (e-SDS) and on the labels.

Conditions of authorisation must be complied with as described in the eSDS. Within three months of first delivery of the substance, Echa must be notified and provided with occupational exposure data. A written declaration as described in the decision, if relevant, is also required.

The agency sends this information to the authorisation holder, who uses it in preparing review reports for extending the authorisation period.

As the first exposure measurements are due by 3 February 2019, the agency needs the information as soon as possible, it says. The review report is due by 21 April 2019.

Lead in gunshot Opinion available

The final Opinion of the Committees for Risk Assessment (Rac) and Socio-economic Analysis (Seac) to restrict lead in gunshot used on wetlands is available on the agency's website.

Updated publications

Echa has updated its factsheet on information on chemicals and its leaflet 'Chemical safety and your business'.

They are both available in 23 EU languages.

Further Information:

- Registry of current SVHC intentions

- Current testing proposals
- Consultation
- Registry of intentions
- Notification on authorised uses
- Lead in gunshot Opinion
- Information on chemicals
- Chemical safety and your business

EU CLP poison centres notification deadline 'impossible' to meet

Cefic concern over IT delays and Commission's 2020 cut-off

23 August 2018 / Accidents, emergency response & poison centres, Classification, labelling and packaging Regulation, Europe

Delays and unresolved issues mean it will be "impossible" for the European Commission to deliver the IT tools needed for the 1 January 2020 deadline for harmonised information relating to emergency health response (poison centres), Cefic says.

The deadline falls under Annex VIII of the classification, labelling and packaging (CLP) Regulation. It will require importers and downstream users to notify national appointed bodies if they are placing hazardous substances on the market specifically for consumer use by this date.

Trade associations and member states have been commenting on the requirements at recent meetings of the competent authorities for REACH and CLP (Caracal).

In a paper published after the 12 June meeting, Cefic said that with 18 months to go, the Commission would be unable to "deliver results for a quality workability study" and solve "highly important issues".

The workability study was launched shortly after the Cefic paper. It will address stakeholder concerns over the practicalities of new requirements on the submission of information. The year-long exercise will focus on industries with complex material inputs and supply chains and propose solutions to the problems raised.

Interim results will be discussed in the study steering group and stakeholder advisory group at the start of 2019, as well as at Caracal meetings.

Cefic said it anticipates the study will "demonstrate the need [for] amending the text of the annex to make it workable". It added that progress on an Echa notification portal has been "slow" and the decision to develop an agency database is "still open".

The trade body also said that the time allowed for building the poison centres notification (PCN) format and the "delays the pilot projects have suffered make the proposed dates unrealistic for such a complex project".

Industry, it said, will need to dedicate "considerable resources" to comply with Annex VIII and therefore it "cannot accept" the use of "overcomplicated" tools.

"Cefic considers it will be impossible for companies to prepare for compliance with this amount of uncertainty remaining over basic features."

The notification deadline for companies marketing substances for professional use is 1 January 2021, and for industrial use 2024.

Member states

Meanwhile, member states are considering the possibility of hosting their own database in case Echa does not have a centralised one in place, Cefic said.

They are also preparing to include national requirements. "The exercise of harmonisation will be completely futile if this happens," it said. Cefic has asked the Commission to convey this message to member states to "ensure alignment".

However, Cefic added that it accepts parallel national submission systems "if when no additional information is required the PCN format can be used and when submissions through the central portal are also accepted".

In its paper, Poland's competent authority said it expects the Commission to adopt the draft of its Decision "as soon as possible" so it is ready for a vote in the Echa Management Board meeting on 20-21 September.

It added that although a "keen supporter" of the EU central system, it is concerned about future financing. It would like the Commission to provide certainty, via a legal instrument, that member states would be free from additional Echa fee requirements.

A spokesperson for the European Commission told Chemical Watch that some of the tools, such as the Unique Formula Identifier (UFI) generator and a first version of the notification format, have already been released via Echa's website. "The first version of the notification portal should also be released in 2019 and further developed over time with additional features and search capacities."

Luke Buxton

Europe desk editor

Related Articles

- EU Commission publishes CLP poison centres amendment
- Commission launches EU poison centre workability study

Further Information:

- Cefic paper
- Poland paper

US NGOs: 'Science transparency' policy contravenes TSCA

Groups urge EPA to withdraw 'unlawful' proposal

23 August 2018 / Confidentiality & right-to-know, TSCA, United States

Environmental and consumer advocacy groups say that the US EPA's proposed 'science transparency' rule is in direct contravention to TSCA mandates, and are urging the agency to withdraw the "unlawful" proposal.

The latest opposition has come in a consultation on the agency's controversial proposed rule, 'Strengthening transparency in regulatory science'. This seeks to ensure that science underpinning regulatory decisions is available for public validations.

Nearly half a million individuals and organisations have weighed in on the rule, with the majority reiterating concerns that the proposal could require the agency to discard legitimate science. But recent comments have also highlighted the ways in which the proposal runs counter to EPA's requirements under the recently reformed TSCA law.

TSCA science requirements

As amended by the 2016 Lautenberg Act, TSCA requires the EPA to rely on "best available science" and "reasonably available information". And it must make decisions consistent with the "weight of scientific evidence".

But in comments submitted on behalf of nearly 90 organisations, Earthjustice argued that the proposal "directly contravenes the specific mandate" of TSCA.

TSCA establishes a "comprehensive scheme for how EPA is to consider scientific data", wrote the environmental law nonprofit. "A rule that deliberately excludes this best science cannot be reconciled with these firm Congressional mandates and public health purposes," it added.

The Environmental Protection Network – a group of former EPA employees – commented that although Congress detailed the types of science that EPA should use in TSCA, "availability of sufficient underlying data for the public to 'validate' or 'reproduce' study results is not even among the factors the agency is to consider, much less a determinative factor nullifying all those enumerated".

And the group argued the proposal runs against the requirement for decisions to be based on the "weight of the scientific evidence", as it blocks evidence from the weighting process entirely.

Earthjustice also pointed out that because the proposal only applies to 'significant regulatory actions', EPA could arguably use non-public science to support a determination that a substance does not pose an unreasonable risk – as this would result in no regulatory activity – but not to regulate a harmful one. This, it says, is "arbitrary and capricious and cannot stand".

"In sum, EPA's proposed rule is inconsistent with TSCA's plain text," wrote the Environmental Defense Fund (EDF). "EPA should not adopt the proposed rule because it cannot be reconciled with the agency's duties under TSCA."

Industry view

The American Sustainable Business Council – representing more than a quarter million businesses – agreed with NGO comments that the rule would run counter to TSCA's 'best available science' mandate.

"The more research the EPA considers, the more informed and appropriate their response can be to findings about harmful effects of chemicals," said the business coalition.

But a joint comment from three paving, stone and concrete associations – the NAPA, NSSGA, and NRMCA – said that increased transparency under the rule would help EPA carry out its 'best available science' requirements, particularly with respect to its mandates surrounding "suitability, documentation and consideration of uncertainty and variability."

And the American Chemistry Council said in a public statement that it believes that the approach outlined in the proposed rule is one Congress demonstrated its support of when it modified TSCA's science provisions in the law's 2016 overhaul.

"When it comes to the science, EPA should 'show its work'," said the trade group.

And it suggested in its comments that the EPA's Integrated Risk Information System (IRIS) programme should also be subject to the new policy.

Nonetheless, the ACC said that the rule should be tailored to each environmental law it affects, and "implemented by regulations specific to the objective and scientific disciplines of each statute," including TSCA.

Kelly Franklin
North America editor

Related Articles

- US EPA formally issues 'science transparency' proposal
- Thinktank defends US EPA 'science transparency' proposal
- Groups unite against US EPA 'science transparency' proposal
- Stakeholders square off on codifying science criteria under TSCA

Further Information:

- Docket

San Francisco bans single-use food service ware containing PFAS

Requirements to take effect from 1 January 2020

23 August 2018 / Food contact, PFCs, United States

San Francisco is set to ban the sale or use of single-use food service ware made with perfluoroalkyl and polyfluoroalkyl substances (PFAS).

Earlier this month, the California city's mayor approved Ordinance 201-18, amending existing food service and packaging waste reduction laws.

The updated law will require single-use items used for prepared, takeout and leftover food – such as bowls, plates, trays, cups, lids, straws, utensils and napkins – to be 'fluorinated chemical free'.

It also covers single-use food service ware accessories, such as condiment packets, chopsticks, cup sleeves, napkins, stirrers and toothpicks.

Restaurants, food retailers, vendors, city contractors and city departments will all be subject to the requirements, which come into force on 1 January 2020.

'Unnecessary action'

Jonathan Corley, a spokesperson for the chemical industry trade association, FluoroCouncil said the ban was "unnecessary, contrary to sound science and will provide no further benefits to public health or the environment."

The use of PFAS in food packaging is already thoroughly regulated by the US Food and Drug Administration (FDA), Mr Corley told Chemical Watch, and the agency has determined the chemicals "are safe for their intended use".

They "help protect the quality and integrity of food, extend shelf life and help in the safe transportation and storage of food," he added.

But Gretchen Lee Salter, interim director of the NGO Safer States, praised San Francisco's "forward thinking" on the issue.

"Taking PFAS out of food packaging will not only prevent exposure during the use of the packaging but also after it is disposed, since they have been shown to leak into compost," she told Chemical Watch.

She called on other US cities and states to follow the example.

Pressure on PFAS

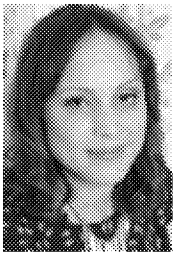
San Francisco's move comes as the use of PFAS in food contact materials (FCMs) faces mounting pressure.

In March, Washington became the first US state to pass a law prohibiting the substances in certain FCMs. The ban takes effect from 1 January 2022, subject to the availability of safer alternatives.
And New York has restricted state agency purchasing of food containers containing them.

The American Academy of Pediatrics named fluorinated chemicals as an "additive of most concern" in a July policy statement calling for increased regulation of food contact materials.

And in March, the industry-backed Food Safety Alliance for Packaging issued a guidance document, urging suppliers to avoid such substances as PFAS when alternatives exist.

Meanwhile, the NGO Mind the Store campaign is speaking with major food retailers to speed their removal from FCMs and will announce its progress in its 'retailer report card' later this year.
Policies like San Francisco's mark the "beginning of the end" for PFAS, said the NGO.



Tammy Lovell
Business reporter

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Message

From: Abboud, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6F5AF791A1842F1ADCC088CBF9ED3CE-ABBOUD, MIC]
Sent: 4/25/2018 3:20:23 PM
To: Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Bennett, Tate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1fa92542f7ca4d01973b18b2f11b9141-Bennett, El]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Bodine, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2cc6086fcc44c3be6b5d32b262d983-Bodine, Sus]; Bowman, Liz [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3d4d94d3e4b4b1f80904056703ebc80-Bowman, Eli]; Cory, Preston (Katherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd80b15f6d04a3ba11fc8ca3c85bc50-Cory, Kathe]; Daniell, Kelsi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd867173479344b3bda202b3004ff830-Daniell, Ke]; Ferguson, Lincoln [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08cd7f82606244de96b61b96681c46de-Ferguson, L]; Ford, Hayley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4748a9029cf74453a20ee8ac9527830c-Ford, Hayle]; Frye, Tony (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58c08abdfc1b4129a10456b78e6fc2e1-Frye, Rober]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Hanson, Paige (Catherine) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95adc1b2ac3b40ab9dc591801d594df8-Hanson, Cat]; Hewitt, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41b19dd598d340bb8032923d902d4bd1-Hewitt, Jam]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]; Kelly, Albert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08576e43795149e5a3f9669726dd044c-Kelly, Albe]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Leopold, Matt [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e5cdf09a3924dada6d322c6794cc4fa-Leopold, Ma]; Letendre, Daisy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b691cccca6264ae09df7054c7f1019cb-Letendre, D]; Lyons, Troy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15e4881c95044ab49c6c35a0f5eef67e-Lyons, Troy]; McMurray, Forrest [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=344246fb2cb643bfab4f92fe016566e2-McMurray, F]; Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]; Rodrick, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6515dbe46dae466da53c8a3aa3be8cc2-Rodrick, Ch]; Ross, David P [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: EPA News Highlights 4.25.18

Attachments: EPA News Highlights 4.25.18.docx

EPA News Highlights 4.25.18

The Detroit News: Va. Tech. Expert, Team Win $2M For Lead Water Research

Federal officials are giving nearly $2 million for research to a team led by the Virginia Tech researcher who uncovered elevated lead levels in Flint's drinking water to research preventing such problems nationwide. Staffers are slated to use the money to create a consumer-based framework to detect and control lead in drinking water, the agency said in a statement. The "community science project" aims to raise awareness while helping "the most vulnerable communities to actively participate in identifying risks and evaluating opportunities to mitigate those risks." "Our team will establish one of the largest citizen-science engineering projects in U.S. history to help individuals and communities deal with our shared responsibility for controlling exposure to lead in drinking water through a combination of low-cost sampling, outreach, direct collaboration and modeling," said a statement by Marc Edwards, the principal investigator on the project at Virginia Polytechnic Institute and State University, where he has long worked.

NBC Bay Area: EPA Fines East Bay Cities, Water Agencies For Allowing Sewage Into Bay

Oakland, Alameda, Berkeley, Albany and two municipal districts in the East Bay have been fined almost $400,000 for allowing untreated sewage to enter the Bay, U.S. Environmental Protection Agency officials said Tuesday. The East Bay Municipal Utility District and the Stege Sanitary District for El Cerrito, Kensington and parts of Richmond were also fined for the violations, which occurred between September 2014 and June 2017. EPA officials said the cities violated the terms of a 2014 Clean Water Act settlement "consent decree" that required upgraded sewer infrastructure to protect local waters. In 2014, the eight cities and agencies paid $1.5 million for past sewage penalties and agreed to upgrade 1,500 miles of infrastructure over 21 years, according to the EPA. EPA officials said the cities and districts have inspected 720 miles of sewer pipe and spent $80 million to upgrade 100 miles of sewers since the settlement.

The Washington Examiner: Scott Pruitt Announces New EPA Rule To Combat 'Secret Science'

Environmental Protection Agency Administrator Scott Pruitt announced a proposed rule Tuesday that would block the agency from using scientific studies that do not make public the raw data used in the research. The embattled EPA administrator was surrounded by conservative allies when he announced the change at agency headquarters, with no media present because the agency did not invite reporters. Pruitt argues the proposed rule, subject to a 30-day comment period, would improve transparency and ensure science used in policymaking can be independently verified. It fits with a policy he implemented last year to boot scientists from key advisory boards to the EPA.

The Hill: Pruitt Signs Proposed Rule To Erase 'Secret Science' From EPA

Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a rule proposal Tuesday aimed at increasing "transparency" in science all while limiting reporter, environmentalist and scientist access to the event. The proposal, signed at EPA headquarters, aims to expose the methodology behind scientific findings and cut back on what Pruitt has deemed "secret science." Speaking in front of a number of well-known climate change skeptics including the Competitive Enterprise Institute's Myron Ebell, Pruitt announced that the new rule would require science to "be transparent, reproducible and able to be analyzed by those in the marketplace." Reporters were not invited to attend

the event, and details surrounding the announcement and rule proposal were kept secret until 30 minutes before the EPA's Twitter account announced it would be live-streamed.

The Wall Street Journal: Trump Faces Pressure To Choose Sides In Fight Between Corn Growers And Oil Refiners
President Donald Trump is caught between two powerful business constituents of the Republican Party as he faces growing pressure to resolve a dispute between the oil industry and the Farm Belt. Oil refineries want out of a costly requirement to blend ethanol into the gasoline they produce. Corn growers say the requirement diversifies the U.S. fuel supply, and insist Mr. Trump fulfill promises to at least hold the ethanol mandate. Both sides have close ties to the GOP and the White House. Tensions between the two industries have been building since well before Mr. Trump became president, the result of a 2005 law that requires refineries to blend about 10% plant-based ethanol into the fuel they produce, or buy credits from rivals to cover their blending obligations. Congress created the mandate in hopes of reducing carbon emissions and weaning the U.S. from foreign crude at a time when oil prices had begun soaring.

National News Highlights 4.25.18

The New York Times: Trump's Travel Ban Faces A Supreme Court Test
The Supreme Court will hear a challenge on Wednesday to President Trump's latest effort to limit travel from countries said to pose a threat to the nation's security. The case, a major test of presidential power, will require the justices to decide whether Mr. Trump's campaign promises to impose a "Muslim ban" were reflected in executive orders that restricted travel from several predominantly Muslims nations. Just a week after he took office, President Trump issued his first travel ban, causing chaos at the nation's airports and starting a cascade of lawsuits and appeals. Fifteen months later, after two revisions of the ban and a sustained losing streak in the lower courts, the Supreme Court took up the case in its last scheduled argument of the term. A decision is expected by late June. The case, Trump v. Hawaii, No. 17-965, concerns Mr. Trump's third and most considered bid to make good on his campaign promise to secure the nation's borders. Challengers to the latest ban, issued as a presidential proclamation in September, said it was tainted by religious animus and not adequately justified by national security concerns.

The Washington Post: Trump Rallies Behind VA Nominee After Suggesting He Drop Out Because Of 'Ugly' Process
The White House rallied around Ronny L. Jackson's nomination to lead the Department of Veterans Affairs late Tuesday as the president's doctor was besieged by accusations that he improperly dispensed drugs, created a hostile workplace and became intoxicated on duty. The administration's decision to fight on in defense of the nomination came hours after President Trump publicly suggested that Jackson should consider pulling out because of the "abuse" he was facing. But by late afternoon, Trump had huddled with Jackson, and White House aides vowed to fight the charges. "I don't want to put a man through a process like this," Trump had said earlier when asked about Jackson's nomination during a joint news conference with French President Emmanuel Macron. "It's too ugly, and it's too disgusting."

TRUMP TWEETS

The Detroit News
https://www.detroitnews.com/story/news/michigan/flint-water-crisis/2018/04/24/va-tech-edwards-epa-grant-flint-water/34221001/
Va. Tech. Expert, Team Win $2M For Lead Water Research
By The Detroit News, 4/24/18

Federal officials are giving nearly $2 million for research to a team led by the Virginia Tech researcher who uncovered elevated lead levels in Flint's drinking water to research preventing such problems nationwide.

Staffers are slated to use the money to create a consumer-based framework to detect and control lead in drinking water, the agency said in a statement. The "community science project" aims to raise awareness while helping "the

most vulnerable communities to actively participate in identifying risks and evaluating opportunities to mitigate those risks."

"Our team will establish one of the largest citizen-science engineering projects in U.S. history to help individuals and communities deal with our shared responsibility for controlling exposure to lead in drinking water through a combination of low-cost sampling, outreach, direct collaboration and modeling," said a statement by Marc Edwards, the principal investigator on the project at Virginia Polytechnic Institute and State University, where he has long worked.

"We will tap a growing 'crowd' of consumers who want to learn how to better protect themselves from lead, and in the process, also create new knowledge to protect others. Whether from wells or municipalities, we all consume water, and we can collectively work to reduce health risks."

The U.S. Environmental Protection Agency is expected to announce the funding Wednesday.

The grant dovetails with federal efforts to tackle lead exposure and comes weeks after Edwards testified in the district court case involving Nick Lyon, the state Health and Human Services director, who is charged with involuntary manslaughter linked to the Flint water crisis.

The Flint water crisis began when the city's water supply was contaminated with lead in April 2014, when a state-appointed emergency manager switched the source of the city's drinking water supply from Lake Huron to the Flint River. When the move was made, the Michigan Department of Environmental Quality did not require adequate corrosion-control chemicals to treat the water, causing lead to leach from joints, pipes and fixtures

Prosecutors have said the switch helped create the conditions for a Legionnaires' outbreak that killed 12 and sickened 79 others.

Edwards, an environmental engineer, tested the water of Flint resident Lee-Anne Walter in 2015 and found elevated lead levels he had not seen in 25 years. He assembled a team of Virginia Tech researchers, took them to Flint to test the water, launched a website and paid $150,000 to complete the work.

He also found documents showing that state leaders knew in the summer of 2015 that there was lead contamination in Flint's water. Edwards testified before Congress in March 2016 about the crisis.

The EPA grant follows the launch of a task force this year to address childhood lead exposure.

"Lead exposure is one of the greatest environmental threats we face as a country, and it's especially dangerous for our children," EPA Administrator Scott Pruitt said. "This research will move us one step closer to advancing our work to eradicate lead in drinking water."

NBC Bay Area

https://www.nbcbayarea.com/news/local/EPA-Fines-East-Bay-Cities-Water-Agencies-For-Allowing-Sewage-Into-Bay-480745591.html

EPA Fines East Bay Cities, Water Agencies For Allowing Sewage Into Bay

By Bay City News, 4/24/18

Oakland, Alameda, Berkeley, Albany and two municipal districts in the East Bay have been fined almost $400,000 for allowing untreated sewage to enter the Bay, U.S. Environmental Protection Agency officials said Tuesday.

The East Bay Municipal Utility District and the Stege Sanitary District for El Cerrito, Kensington and parts of Richmond were also fined for the violations, which occurred between September 2014 and June 2017.

EPA officials said the cities violated the terms of a 2014 Clean Water Act settlement "consent decree" that required upgraded sewer infrastructure to protect local waters.

In 2014, the eight cities and agencies paid $1.5 million for past sewage penalties and agreed to upgrade 1,500 miles of infrastructure over 21 years, according to the EPA.

EPA officials said the cities and districts have inspected 720 miles of sewer pipe and spent $80 million to upgrade 100 miles of sewers since the settlement.

The current violations include sanitary sewer overflows reaching the water, failure to meet limits for chlorine and coliform and failing to repair small defects within a year.

Oakland incurred the highest fines at $226,500, with EBMUD paying the second-highest portion at $134,000.

"We knew heading into the consent decree that we could not eliminate these issues overnight, and we knew some stipulated penalties would be unavoidable," Oakland Public Works spokesman Sean Maher said in an email.

Oakland has reduced sewage spills into the Bay by 16 percent since 2014, and the agency is reaching multiple goals outlined in the decree, like pipe rehabilitation, Maher said.

EBMUD spokeswoman Jenesse Miller said the fines are reasonable and the district is confident that it can improve in the next few years.

Miller said the violations stemmed from numerous issues, but a main cause was a very wet winter that came after a five-year drought.

"We discovered our operators needed better muscle memory, if you will, to manage the sudden and enormous inflow of storm water into our system," Miller said in an email.

The district is organizing more on-site trainings before storms and evaluating standard operating procedures. Miller said the training has paid off and there weren't any violations during the most recent set of late-winter storms.

Trump, Macron Make a Show as Best Buds But Tussle Over Iran
The district will pay the fines with wastewater revenue, which comes from taxpayers, according to Miller.

The Washington Examiner

https://www.washingtonexaminer.com/policy/energy/scott-pruitt-announces-new-epa-rule-to-combat-secret-science

Scott Pruitt Announces New EPA Rule To Combat 'Secret Science'
By Josh Siegel, 4/24/18

Environmental Protection Agency Administrator Scott Pruitt announced a proposed rule Tuesday that would block the agency from using scientific studies that do not make public the raw data used in the research.

The embattled EPA administrator was surrounded by conservative allies when he announced the change at agency headquarters, with no media present because the agency did not invite reporters.

Pruitt argues the proposed rule, subject to a 30-day comment period, would improve transparency and ensure science used in policymaking can be independently verified. It fits with a policy he implemented last year to boot scientists from key advisory boards to the EPA.

"The science that we use is going to be transparent, reproducible and able to be analyzed by those in the marketplace," Pruitt said. "This is the right approach. Today is a red letter today. It's a banner day. It's an agency taking responsibility for how we do our work and respect the process to make sure we can enhance confidence in our decision making."

The proposal is modeled after legislation proposed by House Science Committee Chairman Lamar Smith, R-Texas, who tried to impose a similar requirement through legislation, but it failed to pass. Smith attended Pruitt's announcement, with Sen. Mike Rounds, R-S.D., who authored a mirroring bill in the Senate.

Supporters of the idea said they want to end the use of “secret science” in rulemaking.

"Surely, we can all agree on two things," Smith said. "We need clean air and water, and EPA's regulations should be supported by legitimate and publicly available data. Today’s announcement ensures data will be secret no more."

The proposed rule would have the effect of restricting the science the EPA could use when drafting environmental regulations, which critics say would allow the agency to justify weaker rules because it has less research to work with and can favor information that fits its goals, rather than relying on the best science.

Some scientific research uses personal health information from individuals who participate knowing the details are not to be made public but used to inform policymaking.

“Administrator Pruitt is very clearly trying to exclude and ignore longstanding pollution and medical science that is peer-reviewed, embraced by the National Academy of Sciences among others, and also based on health data that people were promised would be kept confidential,” John Walke, the clean air director of the Natural Resources Defense Council, told the Washington Examiner.

Walke argues the rule would be struck down in court because it is an arbitrary and capricious decision under the Administrative Procedure Act, which governs agency rule-making and requires regulatory decisions to be backed by data.

It also could violate laws that mandate the use of "best available science," including the Toxic Substances Control Act and Safe Drinking Water Act, opponents of the policy said.

“It is arbitrary and illegal for EPA to condition use of science and relevant information on the public availability of confidential health information, confidential business information, computer codes, and the like, rather than the validity and integrity of that science and information,” Walke said. “Moreover, EPA is very likely to tie itself up knots trying, unsuccessfully, to allow confidential information desired by industry, while disallowing health studies based on confidential patient data that would support stronger health safeguards.”

Major studies that have depended on confidential information include a major 1993 study by Harvard University linking air pollution to premature deaths.

Companies can’t reveal proprietary information either, so businesses also could be subject to the policy. That means the EPA could be blocked from considering confidential business information, such as data submitted by auto companies intended to aid in determining fuel-efficiency standards.

“It seems like this will handicap the EPA in making rules based on public health or industry data, and I think we should tread cautiously,” Joseph Majkut, director of climate policy at the Niskanen Center, a free-market think tank, told the Washington Examiner. “Private industry data and public health surveys cannot be as transparent as Pruitt would like to protect their property or the privacy of people in the studies. Insofar as the science behind them is solid, and in the case of Harvard and others it seems to be, then we risk losing valuable sources of information. I'm all for an open and transparent scientific process, but we probably don't want to throw the baby out with the bathwater.”

But the text of the proposed rule says Pruitt may grant exemptions on a case-by-case basis when publishing underlying data is "impracticable."

It lists exposing "confidential business information" as a possible exception, so corporate-funded research could potentially get an opt-out. Information that is "sensitive to national and homeland security" also can be kept private.

Pruitt's announcement of the new rule comes as he is slated to visit Capitol Hill Thursday for the first time since a flood of allegations about his spending, ethics, and hiring practices prompted investigations by Congress, the White House, and the EPA's inspector general.

He is scheduled to testify before a House Energy and Commerce subcommittee in the morning and at a House Appropriations subcommittee in the afternoon.

The EPA administrator, in the lead-up to the hearings, is losing Republican support.

Three key Senate Republicans on Monday called for Pruitt to face more hearings about his recent controversies, including Sen. Jim Inhofe, R-Okla., a reliable Pruitt ally from his home state.

Sen. Lisa Murkowski, R-Alaska, told reporters Tuesday she plans to invite Pruitt to testify next month before the Senate appropriations subcommittee that oversees the EPA's budget.

Smith and Rounds, however, sought to reinforce support that Pruitt maintains from many conservatives.

"I know of no administration official who goes on the offensive, is not intimidated, and does the right thing regardless," Smith said. "We couldn't have a better head of the EPA."

The Hill

http://thehill.com/policy/energy-environment/384636-pruitt-signs-proposed-rule-to-erase-secret-science-from-agency

Pruitt Signs Proposed Rule To Erase 'Secret Science' From EPA

By Miranda Green, 4/24/18

Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a rule proposal Tuesday aimed at increasing "transparency" in science all while limiting reporter, environmentalist and scientist access to the event.

The proposal, signed at EPA headquarters, aims to expose the methodology behind scientific findings and cut back on what Pruitt has deemed "secret science."

Speaking in front of a number of well-known climate change skeptics including the Competitive Enterprise Institute's Myron Ebell, Pruitt announced that the new rule would require science to "be transparent, reproducible and able to be analyzed by those in the marketplace." Reporters were not invited to attend the event, and details surrounding the announcement and rule proposal were kept secret until 30 minutes before the EPA's Twitter account announced it would be live-streamed.

Pruitt said the new ruling shows "an agency taking responsibility for how we do our work, in respecting process ... so that we can enhance confidence in our decision making." He also dubbed the current process which had, until now, allowed science to be peer reviewed rather than open to public scrutiny, "simply wrong headed."

The rule will replicate, through agency action, two bills previously introduced in the House and Senate meant to restrict the kind of science the EPA can use when writing regulations.

The House bill authored by Rep. Lamar Smith (R-Texas), now called the Honest and Open New EPA Science Treatment Act, would mandate all scientific data and findings be made publicly available before they are used to justify agency regulations. Versions of Smith's bill passed the GOP-controlled House three times, but the Senate hasn't taken it up.

Last week, internal documents released by a Freedom of Information Act request by the Union of Concerned Scientists found that EPA political staffers have been working for months in conjunction with Smith and his staff to mimic the bill.

Speaking at the event Tuesday, Smith thanked Pruitt for being a "courageous leader" of the agency and blamed the "liberal media and alarmist environmental groups," for finding negatives in his legislation.

"For too long, EPA has withheld data that has been hidden from the American people," Smith said.

Opponents of the new rule say it would limit the number of available scientific studies that could be used by the agency in its rulemaking, namely by excluding a number of public health studies.

Timed with Pruitt's announcement, seven Democratic Lawmakers sent a letter to Pruitt on Tuesday denouncing the new policy. The letter, led by Sen. Tom Carper (D-Del.), tells Pruitt, "Your proposed new policy likely violates several laws with which EPA must comply as the agency writes rules to protect our air, water and land from harmful pollution."

The lawmakers said Pruitt's new policy likely would run afoul of a number of laws that mandate rulemaking be based on the "best available science ... because it would require EPA to ignore some of the 'best' scientific studies."

"Courts have explained that 'best available science' means that agencies 'should seek out and consider all existing scientific evidence relevant to the decision' and 'cannot ignore existing data,' " the letter read.

The Wall Street Journal

https://www.wsj.com/articles/trump-faces-pressure-to-choose-sides-in-fight-between-corn-growers-and-oil-refiners-1524648602

Trump Faces Pressure To Choose Sides In Fight Between Corn Growers And Oil Refiners

By Tim Puko and Bradley Olson, 4/25/18

President Donald Trump is caught between two powerful business constituents of the Republican Party as he faces growing pressure to resolve a dispute between the oil industry and the Farm Belt.

Oil refineries want out of a costly requirement to blend ethanol into the gasoline they produce. Corn growers say the requirement diversifies the U.S. fuel supply, and insist Mr. Trump fulfill promises to at least hold the ethanol mandate. Both sides have close ties to the GOP and the White House.

Tensions between the two industries have been building since well before Mr. Trump became president, the result of a 2005 law that requires refineries to blend about 10% plant-based ethanol into the fuel they produce, or buy credits from rivals to cover their blending obligations. Congress created the mandate in hopes of reducing carbon emissions and weaning the U.S. from foreign crude at a time when oil prices had begun soaring.

By the time Mr. Trump took office, though, oil and gas supplies had gone from shortage to saturation thanks to the shale-drilling boom. Now, oil refiners—and some Trump advisers—consider a rollback of the 2005 regulation years overdue.

That leaves Mr. Trump stuck between conflicting promises to cut government regulation and to support ethanol mandates. He was one of the few in the Republican presidential primary race to emphasize the mandate in Iowa—the nation's biggest corn-producing state and home to the first nominating contests.

The Trump White House has failed to broker a deal, even after hosting supporters from both sides in the Oval Office. The administration has struggled for months after several proposals for administrative solutions have run into opposition from corn or oil backers.

"I can't see any obvious middle ground," said Sandy Fielden, director of oil and products research at Morningstar. "If there was an easy answer, we'd all be looking at it."

The impasse has refineries taking matters into their own hands, appealing directly to the Environmental Protection Agency for relief in the form of waivers. The agency has stepped up waiver approvals. That has infuriated agricultural interests and put more pressure on the White House to come up with a permanent solution.

The agricultural lobby has been uncomfortable with EPA chief Scott Pruitt, who, before coming to Washington, had called the ethanol mandate "unworkable" and filed a legal brief in 2013 backing a lawsuit challenging it when he was Oklahoma attorney general. Mr. Pruitt landed the EPA role in part because of a recommendation from Carl Icahn, a billionaire adviser to Mr. Trump's transition team and an owner of a small refinery operator that faces around $250 million in costs to comply with the ethanol mandate.

More oil refiners are looking to take advantage of a loophole in the law that has only widened since Mr. Pruitt took over the agency. Small refineries with less than 75,000 barrels a day of capacity—even if owned by a large company—can get a waiver if they prove the mandates are causing "disproportionate economic hardship," according to the EPA website.

To get a waiver, each refinery gets evaluated on its own finances—independent from the health of its parent company. Compliance costs could still be tens of millions of dollars, which alone appears to be enough now to prove economic harm, industry lobbyists said.

For years, the EPA regularly rejected requests from refiners seeking waivers from ethanol requirements. Then this March, the agency agreed to waive millions in obligations for Philadelphia Energy Solutions, a major East Coast refiner that filed for bankruptcy after its costs to comply with the program rose to $231 million in 2016. The EPA then began granting a number of waivers to the small refineries able to demonstrate economic harm, including one owned by Andeavor Corp. , one of the country's largest independent refiners and a company big enough to be part of the S&P 500.

The agency has rejected just one of about 30 applicants so far this year, encouraging more refiners to consider applying for the first time. It has received applications from oil giants Exxon Mobil Corp. and Chevron Corp.

Many now see an EPA waiver as a given. Some are even asking for waivers that would allow them recoup costs from years past. "If you can show economic harm—which is pretty easy to do—you have to consider it," according to one oil-industry lobbyist who has been pushing the Trump administration for a waiver for a client. "People never imagined they would be eligible."

One factor behind the change at EPA is a federal appeals-court decision last year that found the agency had been too restrictive in doling out waivers. Mr. Pruitt has since decided to accept every recommendation on a waiver from the Energy Department—which is responsible for calculations evaluating a refinery's claim of economic harm—and grant full waivers even when the Energy Department recommended only partial waivers. This is opening the floodgates for applications and approvals, analysts and refiners say.

"The criteria used to grant waivers has not changed since previous administrations," EPA spokeswoman Liz Bowman said. "EPA follows a longstanding, established process."

Many in both the refining and farming industries dispute that assertion, and see a significant change in EPA policy. There are 38 plants across the U.S. that could qualify for the exemptions, according to the agency. Based on their capacity, the number of qualifying refineries could make up as much as 10% of the nation's fuel supply, according to a Wall Street Journal analysis. More than half have already received them.

One result of the increase in waivers is a falling price for credits that many refineries need to buy to cover their obligations for ethanol blending. The cost of credits has halved in recent months as traders and companies have grown increasingly confident that the Trump administration will take action to reduce the burden oil refiners face in complying with the law.

Sen. Chuck Grassley, a Republican from Iowa, in a call with reporters Tuesday accused the EPA of abusing the waivers to cap the price of ethanol credits. EPA officials deny undermining the ethanol program.

While Mr. Trump has received support from Mr. Icahn and frequently touts his own backing of the fossil-fuel business, he has to be mindful of Iowa's political clout and Mr. Grassley's in particular. Aside from Iowa's early primary, Mr. Grassley runs the powerful Senate Judiciary Committee, which oversees the confirmation of judges and has launched investigations into matters related to the president's campaign and businesses.

"The president has said to me both publicly and privately many times that he intends, and he is keeping his commitment to ethanol," Mr. Grassley said Tuesday. Mr. Pruitt is "undercutting the president's promises."

The New York Times

https://www.nytimes.com/2018/04/25/us/politics/trump-travel-ban-supreme-court.html

Trump's Travel Ban Faces A Supreme Court Test

By Adam Liptak and Michael Shear, 4/25/18

WASHINGTON — The Supreme Court will hear a challenge on Wednesday to President Trump's latest effort to limit travel from countries said to pose a threat to the nation's security. The case, a major test of presidential power, will require the justices to decide whether Mr. Trump's campaign promises to impose a "Muslim ban" were reflected in executive orders that restricted travel from several predominantly Muslims nations.

Just a week after he took office, President Trump issued his first travel ban, causing chaos at the nation's airports and starting a cascade of lawsuits and appeals. Fifteen months later, after two revisions of the ban and a sustained losing streak in the lower courts, the Supreme Court took up the case in its last scheduled argument of the term. A decision is expected by late June.

The case, Trump v. Hawaii, No. 17-965, concerns Mr. Trump's third and most considered bid to make good on his campaign promise to secure the nation's borders. Challengers to the latest ban, issued as a presidential proclamation in September, said it was tainted by religious animus and not adequately justified by national security concerns.

But the administration said the third order was the product of careful study by several agencies of the security and information-sharing practices of nations around the world. Mr. Trump's lawyers urged the courts to ignore Mr. Trump's statements and Twitter posts and to focus solely on the text of the proclamation and the process that produced it.

Mr. Trump's first travel ban, issued in January 2017, was promptly blocked by courts around the nation. A second version, issued two months later, fared little better, though the Supreme Court allowed part of it go into effect in June when it agreed to hear the Trump administration's appeals from two appeals court losses. But the Supreme Court dismissed those appeals in October after the second ban expired.

The current ban initially restricted travel from eight nations — Iran, Libya, Syria, Yemen, Somalia, Chad, Venezuela and North Korea — six of which were predominantly Muslim. Chad was recently removed from the list.

The restrictions vary in their details, but, for the most part, citizens of the countries are prohibited from immigrating to the United States, and many are barred from working, studying or vacationing here.

In December, in a sign that the Supreme Court may uphold the latest order, the court allowed it to go into effect as the case moved forward. The decision effectively overturned a compromise in place since last June, when the court said travelers with connections to the United States could continue to travel here notwithstanding restrictions in an earlier version of the ban.

Justices Ruth Bader Ginsburg and Sonia Sotomayor dissented from the December ruling.

Hawaii, several individuals and a Muslim group challenged the latest ban's limits on travel from the predominantly Muslim nations; they did not object to the portions concerning North Korea and Venezuela. They prevailed before a

Federal District Court there and before a three-judge panel of the United States Court of Appeals for the Ninth Circuit, in San Francisco.

The appeals court ruled that Mr. Trump had exceeded the authority that Congress had given him over immigration and had violated a part of the immigration laws barring discrimination in the issuance of visas.

In a separate decision that is not directly before the justices, the United States Court of Appeals for the Fourth Circuit, in Richmond, Va., blocked the ban on different grounds, saying it violated the Constitution's prohibition of religious discrimination.

The Supreme Court said it would consider both the statutory and constitutional questions when it agreed to hear the case.

Lawyers for the challengers have said Mr. Trump's own statements provided powerful evidence of anti-Muslim animus. The latest order, they said, was infected by the same flaws as the previous ones.

The Washington Post

https://www.washingtonpost.com/politics/white-house-stands-by-embattled-nominee-to-lead-veterans-affairs/2018/04/24/3013860e-47a6-11e8-9072-f6d4bc32f223_story.html?utm_term=.e17d7add401d

Trump Rallies Behind VA Nominee After Suggesting He Drop Out Because Of 'Ugly' Process

By Josh Dawsey, Seung Min Kim, Lisa Rein and John Wagner, 4/24/18

The White House rallied around Ronny L. Jackson's nomination to lead the Department of Veterans Affairs late Tuesday as the president's doctor was besieged by accusations that he improperly dispensed drugs, created a hostile workplace and became intoxicated on duty.

The administration's decision to fight on in defense of the nomination came hours after President Trump publicly suggested that Jackson should consider pulling out because of the "abuse" he was facing. But by late afternoon, Trump had huddled with Jackson, and White House aides vowed to fight the charges.

"I don't want to put a man through a process like this," Trump had said earlier when asked about Jackson's nomination during a joint news conference with French President Emmanuel Macron. "It's too ugly, and it's too disgusting."

Trump added: "I said to Dr. Jackson, what do you need it for? To be abused by a bunch of politicians? . . . If I was him . . . I wouldn't do it."

Jackson's worsening problems flared into public view Tuesday when lawmakers nixed his confirmation hearing scheduled for Wednesday. The hearing was officially postponed by Sen. Johnny Isakson (Ga.), the Republican chairman of the Veterans' Affairs Committee, and Sen. Jon Tester (Mont.), the ranking Democrat.

Later Tuesday, Tester said during an interview with NPR that the committee had heard complaints from more than 20 current and former military members that Jackson had improperly dispensed drugs, become intoxicated on professional trips and belittled staff members.

"We were told stories where he was repeatedly drunk while on duty, where his main job was to take care of the most powerful man in the world," Tester said. "That's not acceptable."

Tester said concerns about the allegations were "bipartisan in nature," including from Isakson.

A spokeswoman for Isakson said the senator remained undecided about the nomination but continued to harbor serious concerns.

Hours after the president's news conference, more allegations emerged about Jackson, including a 2012 government report that said he exhibited "unprofessional behavior" and should be removed from his post.

"There is a severe and pervasive lack of trust in the leadership that has deteriorated to the point that staff walk on 'eggshells,' " the report found. It described morale under his leadership as in the doldrums and said the office was beset by fighting between Jackson and Jeffrey Kuhlman, President Barack Obama's doctor at the time.

It was another episode where a previously respected figure was lifted to prominence in Trump's orbit — only to have their sheen and reputation tarnished. Jackson had been widely hailed by three presidents and their aides as competent, charming and fiercely protective before Trump stunned Washington last month by picking the doctor to run the country's second-largest federal agency.

Jackson declined to comment on the accusations, and senior aides said he showed no willingness to drop out Tuesday afternoon as he trudged through meetings with senators on Capitol Hill. Privately, he dismissed some of the charges to senior aides, according to administration officials, and said he was being unfairly attacked.

"No, I'm looking forward to the hearing," Jackson said. "I was looking forward to doing it tomorrow, so I'm looking forward to getting it rescheduled and answering all the questions."

White House officials said they were aware of accusations that Jackson dispensed medicine to aides or others, including reporters, without rigorous scrutiny. But several senior officials said the drugs were usually nonnarcotic ones, such as Ambien. They also said that Jackson was never intoxicated or drinking while working in the White House near Trump, but may have had too much to drink on occasion while taking overseas trips.

The White House released several other reports that were laudatory regarding Jackson late Tuesday, including his performance reviews for the past four years.

"Ronny does a great job — genuine enthusiasm, poised under pressure, incredible work ethic and follow through. Ronny continues to inspire confidence with the care he provides to me, my family and my team. Continue to promote ahead of peers," a 2016 note from Obama read.

In a private meeting with Sen. Jerry Moran (R-Kan.) on Capitol Hill, Jackson denied any wrongdoing, according to the senator. During that meeting, the White House doctor also specifically denied ever drinking on duty, according to a spokesman for the senator.

"He does deny that he's done anything wrong in his service to the country and particularly his time at the White House as a physician in the medical unit," Moran said, adding that Jackson "indicated that he knows of nothing that would prohibit him from being qualified, capable and the right person to be secretary of the Department of Veterans Affairs."

Two senior officials said that Jackson's nomination had been handled "disastrously," in the words of one, who spoke on the condition of anonymity, and that it had been overshadowed by fights over secretary of state nominee Mike Pompeo and CIA director nominee Gina Haspel. In the future, one of these people said, more attention will be put on Jackson.

Senior White House officials said Trump was convinced by a coterie of aides, and Jackson, that the accusations were overblown. In the meeting Tuesday afternoon, Jackson offered to withdraw, a senior administration official said, but said he would prefer to push forward. Others present in the meeting included White House Chief of Staff John F. Kelly and press secretary Sarah Huckabee Sanders, an administration official said.

Jackson said the accusations were unfair "and just not true," a senior administration official said, describing the meeting.

Trump later told aides he had already taken a lot of flak for an unorthodox pick — and didn't want to give in.

"The president gave us the full green light to push back hard," the official said.

Jackson's nomination also marked the shattering of another norm in Trump's Washington: VA secretaries have historically been approved unanimously, even sometimes by a voice vote. The president nominated David Shulkin, who had led VA's health system under Obama, in the tradition of having a bipartisan Cabinet. But he soured on Shulkin and removed him after an inspector's general report showed that Shulkin took exorbitantly costly trips and misled others about them.

There was uncertain congressional support for Jackson, a longtime presidential physician with little management experience, even before questions were raised about his conduct.

It was unclear why White House aides had not reviewed the allegations before Jackson was nominated last month. He was picked seemingly on a whim by Trump, who fondly calls him "the Doc" and did not formally interview him before nominating him — and ousting Shulkin — by tweet.

Concerns about Jackson were bipartisan. Senate Majority Leader Mitch McConnell (R-Ky.) remained uncommitted to supporting the nominee, and a number of senior GOP aides on Capitol Hill estimated that his chances of confirmation were slim.

Isakson had called Kelly twice in recent days to express concerns about new information, spokeswoman Amanda Maddox said.

Isakson and Tester wrote to Trump on Tuesday morning, asking the White House to provide all documents related to Jackson's service in the White House medical unit as well as all communications between the Pentagon and the White House military office since 2006 that involve allegations or incidents connected to the physician. The senators also requested information the White House has about any allegations involving Jackson that were never relayed to the Pentagon.

In addition to Jackson's lack of management experience at a large organization, the physician had come under fire for his glowing appraisal of Trump's health after the president had his annual physical in January. Jackson declared that the president might live to the age of 200 with a healthier diet.

Isakson said the confirmation hearing is being delayed because the committee needs "some time to get more information."

"I'm concerned that the press is making up far too many stories that aren't true before we even get a chance to have a meeting," Isakson said after meeting privately with Tester on Tuesday morning. "So I think Mr. Jackson and myself and Senator Tester and everybody in Congress need to take a deep breath."

A leading veterans group said Tuesday that it was important for the Senate to fully vet a nominee to lead the department, which has had seven secretaries since the start of the war in Afghanistan.

"On this critical leadership position at this turbulent time, [the United States] cannot afford a misfire by the White House," said Paul Rieckhoff, the founder of Iraq and Afghanistan Veterans of America. "IAVA members nationwide are calling on the Senate to do its job at this defining time and ensure that any nominee for VA Secretary will live up to this awesome responsibility."

Sen. Patty Murray (D-Wash.), a member of the Veterans' Affairs Committee, said Trump didn't take the time to send over a fully vetted nominee.

"It is sloppy, it is disrespectful to our veterans, and it is wrong," Murray said.

TRUMP TWEETS

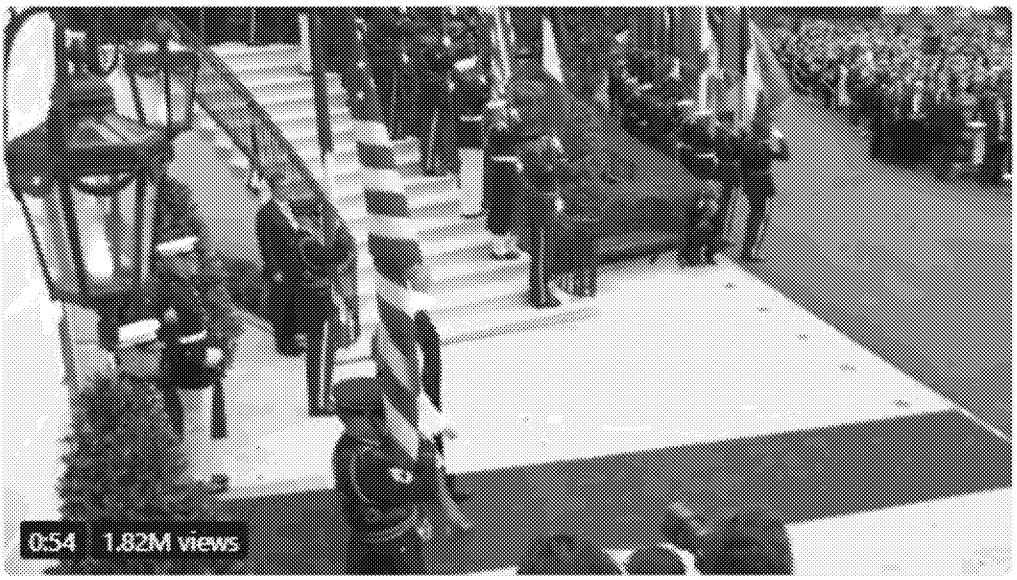
Donald J. Trump @realDonaldTrump · 1h

Congratulations to Republican Debbie Lesko on her big win in the Special Election for Arizona House seat. Debbie will do a Great Job! Press is so silent.

5.6K 6.5K 29K

Donald J. Trump @realDonaldTrump · 17h

Our two great republics are linked together by the timeless bonds of history, culture, and destiny. We are people who cherish our values, protect our civilization, and recognize the image of God in every human soul.



13K 16K 70K

EPA News Highlights 4.25.18

The Detroit News: Va. Tech. Expert, Team Win $2M For Lead Water Research

Federal officials are giving nearly $2 million for research to a team led by the Virginia Tech researcher who uncovered elevated lead levels in Flint's drinking water to research preventing such problems nationwide. Staffers are slated to use the money to create a consumer-based framework to detect and control lead in drinking water, the agency said in a statement. The "community science project" aims to raise awareness while helping "the most vulnerable communities to actively participate in identifying risks and evaluating opportunities to mitigate those risks." "Our team will establish one of the largest citizen-science engineering projects in U.S. history to help individuals and communities deal with our shared responsibility for controlling exposure to lead in drinking water through a combination of low-cost sampling, outreach, direct collaboration and modeling," said a statement by Marc Edwards, the principal investigator on the project at Virginia Polytechnic Institute and State University, where he has long worked.

NBC Bay Area: EPA Fines East Bay Cities, Water Agencies For Allowing Sewage Into Bay

Oakland, Alameda, Berkeley, Albany and two municipal districts in the East Bay have been fined almost $400,000 for allowing untreated sewage to enter the Bay, U.S. Environmental Protection Agency officials said Tuesday. The East Bay Municipal Utility District and the Stege Sanitary District for El Cerrito, Kensington and parts of Richmond were also fined for the violations, which occurred between September 2014 and June 2017. EPA officials said the cities violated the terms of a 2014 Clean Water Act settlement "consent decree" that required upgraded sewer infrastructure to protect local waters. In 2014, the eight cities and agencies paid $1.5 million for past sewage penalties and agreed to upgrade 1,500 miles of infrastructure over 21 years, according to the EPA. EPA officials said the cities and districts have inspected 720 miles of sewer pipe and spent $80 million to upgrade 100 miles of sewers since the settlement.

The Washington Examiner: Scott Pruitt Announces New EPA Rule To Combat 'Secret Science'

Environmental Protection Agency Administrator Scott Pruitt announced a proposed rule Tuesday that would block the agency from using scientific studies that do not make public the raw data used in the research. The embattled EPA administrator was surrounded by conservative allies when he announced the change at agency headquarters, with no media present because the agency did not invite reporters. Pruitt argues the proposed rule, subject to a 30-day comment period, would improve transparency and ensure science used in policymaking can be independently verified. It fits with a policy he implemented last year to boot scientists from key advisory boards to the EPA.

The Hill: Pruitt Signs Proposed Rule To Erase 'Secret Science' From EPA

Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a rule proposal Tuesday aimed at increasing "transparency" in science all while limiting reporter, environmentalist and scientist access to the event. The proposal, signed at EPA headquarters, aims to expose the methodology behind scientific findings and cut back on what Pruitt has deemed "secret science." Speaking in front of a number of well-known climate change skeptics including the Competitive Enterprise Institute's Myron Ebell, Pruitt announced that the new rule would require science to "be transparent, reproducible and able to be analyzed by those in the marketplace." Reporters were not invited to attend the event, and details surrounding the announcement and rule proposal were kept secret until 30 minutes before the EPA's Twitter account announced it would be live-streamed.

The Wall Street Journal: Trump Faces Pressure To Choose Sides In Fight Between Corn Growers And Oil Refiners

President Donald Trump is caught between two powerful business constituents of the Republican Party as he faces growing pressure to resolve a dispute between the oil industry and the Farm Belt. Oil refineries want out of a costly requirement to blend ethanol into the gasoline they produce. Corn growers say the requirement diversifies the U.S. fuel supply, and insist Mr. Trump fulfill promises to at least hold the ethanol mandate. Both sides have close ties to the GOP and the White House. Tensions between the two industries have been building since well before Mr. Trump became president, the result of a 2005 law that requires refineries to blend about 10% plant-based ethanol into the fuel they produce, or buy credits from rivals to cover their blending obligations. Congress created the mandate in hopes of reducing carbon emissions and weaning the U.S. from foreign crude at a time when oil prices had begun soaring.

National News Highlights 4.25.18

The New York Times: Trump's Travel Ban Faces A Supreme Court Test

The Supreme Court will hear a challenge on Wednesday to President Trump's latest effort to limit travel from countries said to pose a threat to the nation's security. The case, a major test of presidential power, will require the justices to decide whether Mr. Trump's campaign promises to impose a "Muslim ban" were reflected in executive orders that restricted travel from several predominantly Muslims nations. Just a week after he took office, President Trump issued his first travel ban, causing chaos at the nation's airports and starting a cascade of lawsuits and appeals. Fifteen months later, after two revisions of the ban and a sustained losing streak in the lower courts, the Supreme Court took up the case in its last scheduled argument of the term. A decision is expected by late June. The case, Trump v. Hawaii, No. 17-965, concerns Mr. Trump's third and most considered bid to make good on his campaign promise to secure the nation's borders. Challengers to the latest ban, issued as a presidential proclamation in September, said it was tainted by religious animus and not adequately justified by national security concerns.

The Washington Post: Trump Rallies Behind VA Nominee After Suggesting He Drop Out Because Of 'Ugly' Process

The White House rallied around Ronny L. Jackson's nomination to lead the Department of Veterans Affairs late Tuesday as the president's doctor was besieged by accusations that he improperly dispensed drugs, created a hostile workplace and became intoxicated on duty. The administration's decision to fight on in defense of the nomination came hours after President Trump publicly suggested that Jackson should consider pulling out because of the "abuse" he was facing. But by late afternoon, Trump had huddled with Jackson, and White House aides vowed to fight the charges. "I don't want to put a man through a process like this," Trump had said earlier when asked about Jackson's nomination during a joint news conference with French President Emmanuel Macron. "It's too ugly, and it's too disgusting."

TRUMP TWEETS

The Detroit News

https://www.detroitnews.com/story/news/michigan/flint-water-crisis/2018/04/24/va-tech-edwards-epa-grant-flint-water/34221001/

Va. Tech. Expert, Team Win $2M For Lead Water Research

By The Detroit News, 4/24/18

Federal officials are giving nearly $2 million for research to a team led by the Virginia Tech researcher who uncovered elevated lead levels in Flint's drinking water to research preventing such problems nationwide.

Staffers are slated to use the money to create a consumer-based framework to detect and control lead in drinking water, the agency said in a statement. The "community science project" aims to raise awareness while helping "the most vulnerable communities to actively participate in identifying risks and evaluating opportunities to mitigate those risks."

"Our team will establish one of the largest citizen-science engineering projects in U.S. history to help individuals and communities deal with our shared responsibility for controlling exposure to lead in drinking water through a combination of low-cost sampling, outreach, direct collaboration and modeling," said a statement by Marc Edwards, the principal investigator on the project at Virginia Polytechnic Institute and State University, where he has long worked.

"We will tap a growing 'crowd' of consumers who want to learn how to better protect themselves from lead, and in the process, also create new knowledge to protect others. Whether from wells or municipalities, we all consume water, and we can collectively work to reduce health risks."

The U.S. Environmental Protection Agency is expected to announce the funding Wednesday.

The grant dovetails with federal efforts to tackle lead exposure and comes weeks after Edwards testified in the district court case involving Nick Lyon, the state Health and Human Services director, who is charged with involuntary manslaughter linked to the Flint water crisis.

The Flint water crisis began when the city's water supply was contaminated with lead in April 2014, when a state-appointed emergency manager switched the source of the city's drinking water supply from Lake Huron to the Flint River. When the move was made, the Michigan Department of Environmental Quality did not require adequate corrosion-control chemicals to treat the water, causing lead to leach from joints, pipes and fixtures

Prosecutors have said the switch helped create the conditions for a Legionnaires' outbreak that killed 12 and sickened 79 others.

Edwards, an environmental engineer, tested the water of Flint resident Lee-Anne Walter in 2015 and found elevated lead levels he had not seen in 25 years. He assembled a team of Virginia Tech researchers, took them to Flint to test the water, launched a website and paid $150,000 to complete the work.

He also found documents showing that state leaders knew in the summer of 2015 that there was lead contamination in Flint's water. Edwards testified before Congress in March 2016 about the crisis.

The EPA grant follows the launch of a task force this year to address childhood lead exposure.

"Lead exposure is one of the greatest environmental threats we face as a country, and it's especially dangerous for our children," EPA Administrator Scott Pruitt said. "This research will move us one step closer to advancing our work to eradicate lead in drinking water."

NBC Bay Area

https://www.nbcbayarea.com/news/local/EPA-Fines-East-Bay-Cities-Water-Agencies-For-Allowing-Sewage-Into-Bay-480745591.html

EPA Fines East Bay Cities, Water Agencies For Allowing Sewage Into Bay

By Bay City News, 4/24/18

Oakland, Alameda, Berkeley, Albany and two municipal districts in the East Bay have been fined almost $400,000 for allowing untreated sewage to enter the Bay, U.S. Environmental Protection Agency officials said Tuesday.

The East Bay Municipal Utility District and the Stege Sanitary District for El Cerrito, Kensington and parts of Richmond were also fined for the violations, which occurred between September 2014 and June 2017.

EPA officials said the cities violated the terms of a 2014 Clean Water Act settlement "consent decree" that required upgraded sewer infrastructure to protect local waters.

In 2014, the eight cities and agencies paid $1.5 million for past sewage penalties and agreed to upgrade 1,500 miles of infrastructure over 21 years, according to the EPA.

EPA officials said the cities and districts have inspected 720 miles of sewer pipe and spent $80 million to upgrade 100 miles of sewers since the settlement.

The current violations include sanitary sewer overflows reaching the water, failure to meet limits for chlorine and coliform and failing to repair small defects within a year.

Oakland incurred the highest fines at $226,500, with EBMUD paying the second-highest portion at $134,000.

"We knew heading into the consent decree that we could not eliminate these issues overnight, and we knew some stipulated penalties would be unavoidable," Oakland Public Works spokesman Sean Maher said in an email.

Oakland has reduced sewage spills into the Bay by 16 percent since 2014, and the agency is reaching multiple goals outlined in the decree, like pipe rehabilitation, Maher said.

EBMUD spokeswoman Jenesse Miller said the fines are reasonable and the district is confident that it can improve in the next few years.

Miller said the violations stemmed from numerous issues, but a main cause was a very wet winter that came after a five-year drought.

"We discovered our operators needed better muscle memory, if you will, to manage the sudden and enormous inflow of storm water into our system," Miller said in an email.

The district is organizing more on-site trainings before storms and evaluating standard operating procedures. Miller said the training has paid off and there weren't any violations during the most recent set of late-winter storms.

Trump, Macron Make a Show as Best Buds But Tussle Over Iran
The district will pay the fines with wastewater revenue, which comes from taxpayers, according to Miller.

The Washington Examiner
https://www.washingtonexaminer.com/policy/energy/scott-pruitt-announces-new-epa-rule-to-combat-secret-science
Scott Pruitt Announces New EPA Rule To Combat 'Secret Science'
By Josh Siegel, 4/24/18

Environmental Protection Agency Administrator Scott Pruitt announced a proposed rule Tuesday that would block the agency from using scientific studies that do not make public the raw data used in the research.

The embattled EPA administrator was surrounded by conservative allies when he announced the change at agency headquarters, with no media present because the agency did not invite reporters.

Pruitt argues the proposed rule, subject to a 30-day comment period, would improve transparency and ensure science used in policymaking can be independently verified. It fits with a policy he implemented last year to boot scientists from key advisory boards to the EPA.

"The science that we use is going to be transparent, reproducible and able to be analyzed by those in the marketplace," Pruitt said. "This is the right approach. Today is a red letter today. It's a banner day. It's an agency taking responsibility for how we do our work and respect the process to make sure we can enhance confidence in our decision making."

The proposal is modeled after legislation proposed by House Science Committee Chairman Lamar Smith, R-Texas, who tried to impose a similar requirement through legislation, but it failed to pass. Smith attended Pruitt's announcement, with Sen. Mike Rounds, R-S.D., who authored a mirroring bill in the Senate.

Supporters of the idea said they want to end the use of “secret science” in rulemaking.

"Surely, we can all agree on two things," Smith said. "We need clean air and water, and EPA's regulations should be supported by legitimate and publicly available data. Today’s announcement ensures data will be secret no more."

The proposed rule would have the effect of restricting the science the EPA could use when drafting environmental regulations, which critics say would allow the agency to justify weaker rules because it has less research to work with and can favor information that fits its goals, rather than relying on the best science.

Some scientific research uses personal health information from individuals who participate knowing the details are not to be made public but used to inform policymaking.

“Administrator Pruitt is very clearly trying to exclude and ignore longstanding pollution and medical science that is peer-reviewed, embraced by the National Academy of Sciences among others, and also based on health data that people were promised would be kept confidential,” John Walke, the clean air director of the Natural Resources Defense Council, told the Washington Examiner.

Walke argues the rule would be struck down in court because it is an arbitrary and capricious decision under the Administrative Procedure Act, which governs agency rule-making and requires regulatory decisions to be backed by data.

It also could violate laws that mandate the use of "best available science," including the Toxic Substances Control Act and Safe Drinking Water Act, opponents of the policy said.

“It is arbitrary and illegal for EPA to condition use of science and relevant information on the public availability of confidential health information, confidential business information, computer codes, and the like, rather than the validity and integrity of that science and information,” Walke said. “Moreover, EPA is very likely to tie itself up knots trying, unsuccessfully, to allow confidential information desired by industry, while disallowing health studies based on confidential patient data that would support stronger health safeguards.”

Major studies that have depended on confidential information include a major 1993 study by Harvard University linking air pollution to premature deaths.

Companies can’t reveal proprietary information either, so businesses also could be subject to the policy. That means the EPA could be blocked from considering confidential business information, such as data submitted by auto companies intended to aid in determining fuel-efficiency standards.

“It seems like this will handicap the EPA in making rules based on public health or industry data, and I think we should tread cautiously,” Joseph Majkut, director of climate policy at the Niskanen Center, a free-market think tank, told the Washington Examiner. “Private industry data and public health surveys cannot be as transparent as Pruitt would like to protect their property or the privacy of people in the studies. Insofar as the science behind them is solid, and in the case of Harvard and others it seems to be, then we risk losing valuable sources of information. I'm all for an open and transparent scientific process, but we probably don't want to throw the baby out with the bathwater.”

But the text of the proposed rule says Pruitt may grant exemptions on a case-by-case basis when publishing underlying data is "impracticable."

It lists exposing "confidential business information" as a possible exception, so corporate-funded research could potentially get an opt-out. Information that is "sensitive to national and homeland security" also can be kept private.

Pruitt’s announcement of the new rule comes as he is slated to visit Capitol Hill Thursday for the first time since a flood of allegations about his spending, ethics, and hiring practices prompted investigations by Congress, the White House, and the EPA’s inspector general.

He is scheduled to testify before a House Energy and Commerce subcommittee in the morning and at a House Appropriations subcommittee in the afternoon.

The EPA administrator, in the lead-up to the hearings, is losing Republican support.

Three key Senate Republicans on Monday called for Pruitt to face more hearings about his recent controversies, including Sen. Jim Inhofe, R-Okla., a reliable Pruitt ally from his home state.

Sen. Lisa Murkowski, R-Alaska, told reporters Tuesday she plans to invite Pruitt to testify next month before the Senate appropriations subcommittee that oversees the EPA's budget.

Smith and Rounds, however, sought to reinforce support that Pruitt maintains from many conservatives.

"I know of no administration official who goes on the offensive, is not intimidated, and does the right thing regardless," Smith said. "We couldn't have a better head of the EPA."

The Hill

http://thehill.com/policy/energy-environment/384636-pruitt-signs-proposed-rule-to-erase-secret-science-from-agency

Pruitt Signs Proposed Rule To Erase 'Secret Science' From EPA

By Miranda Green, 4/24/18

Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a rule proposal Tuesday aimed at increasing "transparency" in science all while limiting reporter, environmentalist and scientist access to the event.

The proposal, signed at EPA headquarters, aims to expose the methodology behind scientific findings and cut back on what Pruitt has deemed "secret science."

Speaking in front of a number of well-known climate change skeptics including the Competitive Enterprise Institute's Myron Ebell, Pruitt announced that the new rule would require science to "be transparent, reproducible and able to be analyzed by those in the marketplace." Reporters were not invited to attend the event, and details surrounding the announcement and rule proposal were kept secret until 30 minutes before the EPA's Twitter account announced it would be live-streamed.

Pruitt said the new ruling shows "an agency taking responsibility for how we do our work, in respecting process … so that we can enhance confidence in our decision making." He also dubbed the current process which had, until now, allowed science to be peer reviewed rather than open to public scrutiny, "simply wrong headed."

The rule will replicate, through agency action, two bills previously introduced in the House and Senate meant to restrict the kind of science the EPA can use when writing regulations.

The House bill authored by Rep. Lamar Smith (R-Texas), now called the Honest and Open New EPA Science Treatment Act, would mandate all scientific data and findings be made publicly available before they are used to justify agency regulations. Versions of Smith's bill passed the GOP-controlled House three times, but the Senate hasn't taken it up.

Last week, internal documents released by a Freedom of Information Act request by the Union of Concerned Scientists found that EPA political staffers have been working for months in conjunction with Smith and his staff to mimic the bill.

Speaking at the event Tuesday, Smith thanked Pruitt for being a "courageous leader" of the agency and blamed the "liberal media and alarmist environmental groups," for finding negatives in his legislation.

"For too long, EPA has withheld data that has been hidden from the American people," Smith said.

Opponents of the new rule say it would limit the number of available scientific studies that could be used by the agency in its rulemaking, namely by excluding a number of public health studies.

Timed with Pruitt's announcement, seven Democratic Lawmakers sent a letter to Pruitt on Tuesday denouncing the new policy. The letter, led by Sen. Tom Carper (D-Del.), tells Pruitt, "Your proposed new policy likely violates several laws with which EPA must comply as the agency writes rules to protect our air, water and land from harmful pollution."

The lawmakers said Pruitt's new policy likely would run afoul of a number of laws that mandate rulemaking be based on the "best available science … because it would require EPA to ignore some of the 'best' scientific studies."

"Courts have explained that 'best available science' means that agencies 'should seek out and consider all existing scientific evidence relevant to the decision' and 'cannot ignore existing data,' " the letter read.

The Wall Street Journal

https://www.wsj.com/articles/trump-faces-pressure-to-choose-sides-in-fight-between-corn-growers-and-oil-refiners-1524648602

Trump Faces Pressure To Choose Sides In Fight Between Corn Growers And Oil Refiners

By Tim Puko and Bradley Olson, 4/25/18

President Donald Trump is caught between two powerful business constituents of the Republican Party as he faces growing pressure to resolve a dispute between the oil industry and the Farm Belt.

Oil refineries want out of a costly requirement to blend ethanol into the gasoline they produce. Corn growers say the requirement diversifies the U.S. fuel supply, and insist Mr. Trump fulfill promises to at least hold the ethanol mandate. Both sides have close ties to the GOP and the White House.

Tensions between the two industries have been building since well before Mr. Trump became president, the result of a 2005 law that requires refineries to blend about 10% plant-based ethanol into the fuel they produce, or buy credits from rivals to cover their blending obligations. Congress created the mandate in hopes of reducing carbon emissions and weaning the U.S. from foreign crude at a time when oil prices had begun soaring.

By the time Mr. Trump took office, though, oil and gas supplies had gone from shortage to saturation thanks to the shale-drilling boom. Now, oil refiners—and some Trump advisers—consider a rollback of the 2005 regulation years overdue.

That leaves Mr. Trump stuck between conflicting promises to cut government regulation and to support ethanol mandates. He was one of the few in the Republican presidential primary race to emphasize the mandate in Iowa—the nation's biggest corn-producing state and home to the first nominating contests.

The Trump White House has failed to broker a deal, even after hosting supporters from both sides in the Oval Office. The administration has struggled for months after several proposals for administrative solutions have run into opposition from corn or oil backers.

"I can't see any obvious middle ground," said Sandy Fielden, director of oil and products research at Morningstar. "If there was an easy answer, we'd all be looking at it."

The impasse has refineries taking matters into their own hands, appealing directly to the Environmental Protection Agency for relief in the form of waivers. The agency has stepped up waiver approvals. That has infuriated agricultural interests and put more pressure on the White House to come up with a permanent solution.

The agricultural lobby has been uncomfortable with EPA chief Scott Pruitt, who, before coming to Washington, had called the ethanol mandate "unworkable" and filed a legal brief in 2013 backing a lawsuit challenging it when he was Oklahoma attorney general. Mr. Pruitt landed the EPA role in part because of a recommendation from Carl Icahn, a billionaire adviser to Mr. Trump's transition team and an owner of a small refinery operator that faces around $250 million in costs to comply with the ethanol mandate.

More oil refiners are looking to take advantage of a loophole in the law that has only widened since Mr. Pruitt took over the agency. Small refineries with less than 75,000 barrels a day of capacity—even if owned by a large company—can get a waiver if they prove the mandates are causing "disproportionate economic hardship," according to the EPA website.

To get a waiver, each refinery gets evaluated on its own finances—independent from the health of its parent company. Compliance costs could still be tens of millions of dollars, which alone appears to be enough now to prove economic harm, industry lobbyists said.

For years, the EPA regularly rejected requests from refiners seeking waivers from ethanol requirements. Then this March, the agency agreed to waive millions in obligations for Philadelphia Energy Solutions, a major East Coast refiner that filed for bankruptcy after its costs to comply with the program rose to $231 million in 2016. The EPA then began granting a number of waivers to the small refineries able to demonstrate economic harm, including one owned by Andeavor Corp. , one of the country's largest independent refiners and a company big enough to be part of the S&P 500.

The agency has rejected just one of about 30 applicants so far this year, encouraging more refiners to consider applying for the first time. It has received applications from oil giants Exxon Mobil Corp. and Chevron Corp.

Many now see an EPA waiver as a given. Some are even asking for waivers that would allow them recoup costs from years past. "If you can show economic harm—which is pretty easy to do—you have to consider it," according to one oil-industry lobbyist who has been pushing the Trump administration for a waiver for a client. "People never imagined they would be eligible."

One factor behind the change at EPA is a federal appeals-court decision last year that found the agency had been too restrictive in doling out waivers. Mr. Pruitt has since decided to accept every recommendation on a waiver from the Energy Department—which is responsible for calculations evaluating a refinery's claim of economic harm—and grant full waivers even when the Energy Department recommended only partial waivers. This is opening the floodgates for applications and approvals, analysts and refiners say.

"The criteria used to grant waivers has not changed since previous administrations," EPA spokeswoman Liz Bowman said. "EPA follows a longstanding, established process."

Many in both the refining and farming industries dispute that assertion, and see a significant change in EPA policy. There are 38 plants across the U.S. that could qualify for the exemptions, according to the agency. Based on their capacity, the number of qualifying refineries could make up as much as 10% of the nation's fuel supply, according to a Wall Street Journal analysis. More than half have already received them.

One result of the increase in waivers is a falling price for credits that many refineries need to buy to cover their obligations for ethanol blending. The cost of credits has halved in recent months as traders and companies have grown increasingly confident that the Trump administration will take action to reduce the burden oil refiners face in complying with the law.

Sen. Chuck Grassley, a Republican from Iowa, in a call with reporters Tuesday accused the EPA of abusing the waivers to cap the price of ethanol credits. EPA officials deny undermining the ethanol program.

While Mr. Trump has received support from Mr. Icahn and frequently touts his own backing of the fossil-fuel business, he has to be mindful of Iowa's political clout and Mr. Grassley's in particular. Aside from Iowa's early primary, Mr. Grassley runs the powerful Senate Judiciary Committee, which oversees the confirmation of judges and has launched investigations into matters related to the president's campaign and businesses.

"The president has said to me both publicly and privately many times that he intends, and he is keeping his commitment to ethanol," Mr. Grassley said Tuesday. Mr. Pruitt is "undercutting the president's promises."

The New York Times

https://www.nytimes.com/2018/04/25/us/politics/trump-travel-ban-supreme-court.html

Trump's Travel Ban Faces A Supreme Court Test

By Adam Liptak and Michael Shear, 4/25/18

WASHINGTON — The Supreme Court will hear a challenge on Wednesday to President Trump's latest effort to limit travel from countries said to pose a threat to the nation's security. The case, a major test of presidential power, will require the justices to decide whether Mr. Trump's campaign promises to impose a "Muslim ban" were reflected in executive orders that restricted travel from several predominantly Muslims nations.

Just a week after he took office, President Trump issued his first travel ban, causing chaos at the nation's airports and starting a cascade of lawsuits and appeals. Fifteen months later, after two revisions of the ban and a sustained losing streak in the lower courts, the Supreme Court took up the case in its last scheduled argument of the term. A decision is expected by late June.

The case, Trump v. Hawaii, No. 17-965, concerns Mr. Trump's third and most considered bid to make good on his campaign promise to secure the nation's borders. Challengers to the latest ban, issued as a presidential proclamation in September, said it was tainted by religious animus and not adequately justified by national security concerns.

But the administration said the third order was the product of careful study by several agencies of the security and information-sharing practices of nations around the world. Mr. Trump's lawyers urged the courts to ignore Mr. Trump's statements and Twitter posts and to focus solely on the text of the proclamation and the process that produced it.

Mr. Trump's first travel ban, issued in January 2017, was promptly blocked by courts around the nation. A second version, issued two months later, fared little better, though the Supreme Court allowed part of it go into effect in June when it agreed to hear the Trump administration's appeals from two appeals court losses. But the Supreme Court dismissed those appeals in October after the second ban expired.

The current ban initially restricted travel from eight nations — Iran, Libya, Syria, Yemen, Somalia, Chad, Venezuela and North Korea — six of which were predominantly Muslim. Chad was recently removed from the list.

The restrictions vary in their details, but, for the most part, citizens of the countries are prohibited from immigrating to the United States, and many are barred from working, studying or vacationing here.

In December, in a sign that the Supreme Court may uphold the latest order, the court allowed it to go into effect as the case moved forward. The decision effectively overturned a compromise in place since last June, when the court said travelers with connections to the United States could continue to travel here notwithstanding restrictions in an earlier version of the ban.

Justices Ruth Bader Ginsburg and Sonia Sotomayor dissented from the December ruling.

Hawaii, several individuals and a Muslim group challenged the latest ban's limits on travel from the predominantly Muslim nations; they did not object to the portions concerning North Korea and Venezuela. They prevailed before a

Federal District Court there and before a three-judge panel of the United States Court of Appeals for the Ninth Circuit, in San Francisco.

The appeals court ruled that Mr. Trump had exceeded the authority that Congress had given him over immigration and had violated a part of the immigration laws barring discrimination in the issuance of visas.

In a separate decision that is not directly before the justices, the United States Court of Appeals for the Fourth Circuit, in Richmond, Va., blocked the ban on different grounds, saying it violated the Constitution's prohibition of religious discrimination.

The Supreme Court said it would consider both the statutory and constitutional questions when it agreed to hear the case.

Lawyers for the challengers have said Mr. Trump's own statements provided powerful evidence of anti-Muslim animus. The latest order, they said, was infected by the same flaws as the previous ones.

The Washington Post

https://www.washingtonpost.com/politics/white-house-stands-by-embattled-nominee-to-lead-veterans-affairs/2018/04/24/3013860e-47a6-11e8-9072-f6d4bc32f223_story.html?utm_term=.e17d7add401d

Trump Rallies Behind VA Nominee After Suggesting He Drop Out Because Of 'Ugly' Process

By Josh Dawsey, Seung Min Kim, Lisa Rein and John Wagner, 4/24/18

The White House rallied around Ronny L. Jackson's nomination to lead the Department of Veterans Affairs late Tuesday as the president's doctor was besieged by accusations that he improperly dispensed drugs, created a hostile workplace and became intoxicated on duty.

The administration's decision to fight on in defense of the nomination came hours after President Trump publicly suggested that Jackson should consider pulling out because of the "abuse" he was facing. But by late afternoon, Trump had huddled with Jackson, and White House aides vowed to fight the charges.

"I don't want to put a man through a process like this," Trump had said earlier when asked about Jackson's nomination during a joint news conference with French President Emmanuel Macron. "It's too ugly, and it's too disgusting."

Trump added: "I said to Dr. Jackson, what do you need it for? To be abused by a bunch of politicians? . . . If I was him . . . I wouldn't do it."

Jackson's worsening problems flared into public view Tuesday when lawmakers nixed his confirmation hearing scheduled for Wednesday. The hearing was officially postponed by Sen. Johnny Isakson (Ga.), the Republican chairman of the Veterans' Affairs Committee, and Sen. Jon Tester (Mont.), the ranking Democrat.

Later Tuesday, Tester said during an interview with NPR that the committee had heard complaints from more than 20 current and former military members that Jackson had improperly dispensed drugs, become intoxicated on professional trips and belittled staff members.

"We were told stories where he was repeatedly drunk while on duty, where his main job was to take care of the most powerful man in the world," Tester said. "That's not acceptable."

Tester said concerns about the allegations were "bipartisan in nature," including from Isakson.

A spokeswoman for Isakson said the senator remained undecided about the nomination but continued to harbor serious concerns.

Hours after the president's news conference, more allegations emerged about Jackson, including a 2012 government report that said he exhibited "unprofessional behavior" and should be removed from his post.

"There is a severe and pervasive lack of trust in the leadership that has deteriorated to the point that staff walk on 'eggshells,' " the report found. It described morale under his leadership as in the doldrums and said the office was beset by fighting between Jackson and Jeffrey Kuhlman, President Barack Obama's doctor at the time.

It was another episode where a previously respected figure was lifted to prominence in Trump's orbit — only to have their sheen and reputation tarnished. Jackson had been widely hailed by three presidents and their aides as competent, charming and fiercely protective before Trump stunned Washington last month by picking the doctor to run the country's second-largest federal agency.

Jackson declined to comment on the accusations, and senior aides said he showed no willingness to drop out Tuesday afternoon as he trudged through meetings with senators on Capitol Hill. Privately, he dismissed some of the charges to senior aides, according to administration officials, and said he was being unfairly attacked.

"No, I'm looking forward to the hearing," Jackson said. "I was looking forward to doing it tomorrow, so I'm looking forward to getting it rescheduled and answering all the questions."

White House officials said they were aware of accusations that Jackson dispensed medicine to aides or others, including reporters, without rigorous scrutiny. But several senior officials said the drugs were usually nonnarcotic ones, such as Ambien. They also said that Jackson was never intoxicated or drinking while working in the White House near Trump, but may have had too much to drink on occasion while taking overseas trips.

The White House released several other reports that were laudatory regarding Jackson late Tuesday, including his performance reviews for the past four years.

"Ronny does a great job — genuine enthusiasm, poised under pressure, incredible work ethic and follow through. Ronny continues to inspire confidence with the care he provides to me, my family and my team. Continue to promote ahead of peers," a 2016 note from Obama read.

In a private meeting with Sen. Jerry Moran (R-Kan.) on Capitol Hill, Jackson denied any wrongdoing, according to the senator. During that meeting, the White House doctor also specifically denied ever drinking on duty, according to a spokesman for the senator.

"He does deny that he's done anything wrong in his service to the country and particularly his time at the White House as a physician in the medical unit," Moran said, adding that Jackson "indicated that he knows of nothing that would prohibit him from being qualified, capable and the right person to be secretary of the Department of Veterans Affairs."

Two senior officials said that Jackson's nomination had been handled "disastrously," in the words of one, who spoke on the condition of anonymity, and that it had been overshadowed by fights over secretary of state nominee Mike Pompeo and CIA director nominee Gina Haspel. In the future, one of these people said, more attention will be put on Jackson.

Senior White House officials said Trump was convinced by a coterie of aides, and Jackson, that the accusations were overblown. In the meeting Tuesday afternoon, Jackson offered to withdraw, a senior administration official said, but said he would prefer to push forward. Others present in the meeting included White House Chief of Staff John F. Kelly and press secretary Sarah Huckabee Sanders, an administration official said.

Jackson said the accusations were unfair "and just not true," a senior administration official said, describing the meeting.

Trump later told aides he had already taken a lot of flak for an un-or-tho-dox pick — and didn't want to give in.

"The president gave us the full green light to push back hard," the official said.

Jackson's nomination also marked the shattering of another norm in Trump's Washington: VA secretaries have historically been approved unanimously, even sometimes by a voice vote. The president nominated David Shulkin, who had led VA's health system under Obama, in the tradition of having a bipartisan Cabinet. But he soured on Shulkin and removed him after an inspector's general report showed that Shulkin took exorbitantly costly trips and misled others about them.

There was uncertain congressional support for Jackson, a longtime presidential physician with little management experience, even before questions were raised about his conduct.

It was unclear why White House aides had not reviewed the allegations before Jackson was nominated last month. He was picked seemingly on a whim by Trump, who fondly calls him "the Doc" and did not formally interview him before nominating him — and ousting Shulkin — by tweet.

Concerns about Jackson were bipartisan. Senate Majority Leader Mitch McConnell (R-Ky.) remained uncommitted to supporting the nominee, and a number of senior GOP aides on Capitol Hill estimated that his chances of confirmation were slim.

Isakson had called Kelly twice in recent days to express concerns about new information, spokeswoman Amanda Maddox said.

Isakson and Tester wrote to Trump on Tuesday morning, asking the White House to provide all documents related to Jackson's service in the White House medical unit as well as all communications between the Pentagon and the White House military office since 2006 that involve allegations or incidents connected to the physician. The senators also requested information the White House has about any allegations involving Jackson that were never relayed to the Pentagon.

In addition to Jackson's lack of management experience at a large organization, the physician had come under fire for his glowing appraisal of Trump's health after the president had his annual physical in January. Jackson declared that the president might live to the age of 200 with a healthier diet.

Isakson said the confirmation hearing is being delayed because the committee needs "some time to get more information."

"I'm concerned that the press is making up far too many stories that aren't true before we even get a chance to have a meeting," Isakson said after meeting privately with Tester on Tuesday morning. "So I think Mr. Jackson and myself and Senator Tester and everybody in Congress need to take a deep breath."

A leading veterans group said Tuesday that it was important for the Senate to fully vet a nominee to lead the department, which has had seven secretaries since the start of the war in Afghanistan.

"On this critical leadership position at this turbulent time, [the United States] cannot afford a misfire by the White House," said Paul Rieckhoff, the founder of Iraq and Afghanistan Veterans of America. "IAVA members nationwide are calling on the Senate to do its job at this defining time and ensure that any nominee for VA Secretary will live up to this awesome responsibility."

Sen. Patty Murray (D-Wash.), a member of the Veterans' Affairs Committee, said Trump didn't take the time to send over a fully vetted nominee.

"It is sloppy, it is disrespectful to our veterans, and it is wrong," Murray said.

TRUMP TWEETS

Donald J. Trump @realDonaldTrump · 1h

Congratulations to Republican Debbie Lesko on her big win in the Special Election for Arizona House seat. Debbie will do a Great Job! Press is so silent.

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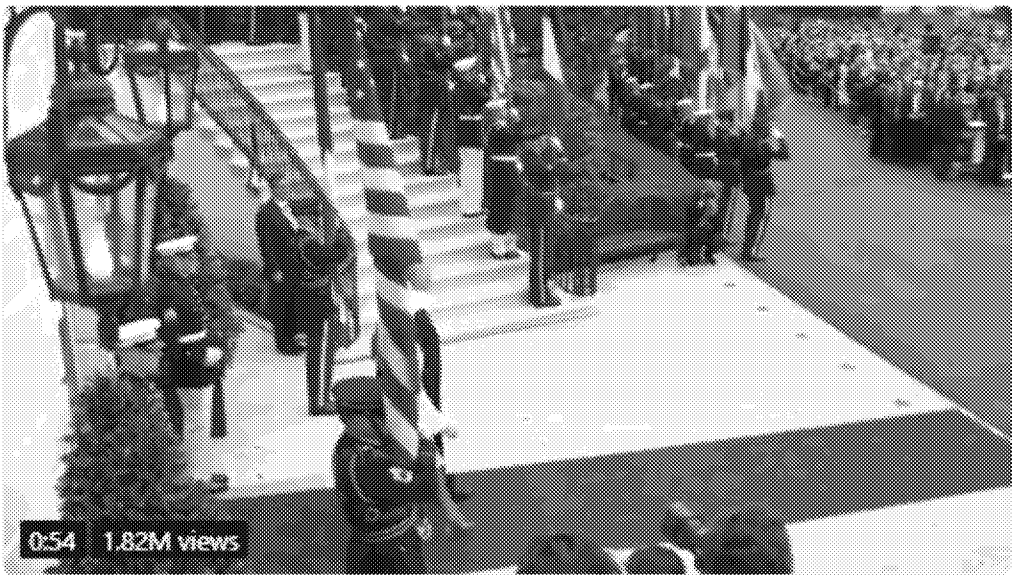
Donald J. Trump @realDonaldTrump · 17h

Our two great republics are linked together by the timeless bonds of history, culture, and destiny. We are people who cherish our values, protect our civilization, and recognize the image of God in every human soul.



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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Chemical, Oil Companies to Save Millions From Safety Program Rollback

Posted May 17, 2018, 4:00 PM Updated May 17, 2018, 4:58 PM
By Sam Pearson

- EPA administrator issues proposed rule in meeting with industry
- Revisions grant industry requests to tighten security, reduce audit burdens

Dow DuPont Inc., Chevron Corp., and other companies that own high-risk chemical facilities stand to benefit from relaxed safety provisions despite the concerns of first responders and communities close to these plants.

Live Updates From Scott Pruitt's Senate Appearance

Updated May 16, 2018, 1:14 PM
By Abby Smith and David Schultz

At a press conference shortly after senators grilled Scott Pruitt over four rounds of questions, Democratic Sens. Chris Van Hollen (Md.) and Tom Udall (N.M.) spoke about the EPA administrator's conduct that has brought about ethics questions and probes.

INSIDE EPA.COM ARTICLES

Wehrum sidesteps queries on SAB review of science rule

May 17, 2018
EPA air chief Bill Wehrum sidestepped questions from a Democratic lawmaker on whether the agency's Science Advisory Board (SAB) should review Administrator Scott Pruitt's science transparency rule, raising questions on whether officials will urge the board later this month to reject calls from one of its working groups to review the rule.

GREENWIRE ARTICLES

Who's donating to Pruitt's defense? Time will tell

Kevin Bogardus, E&E News reporter Published: Thursday, May 17, 2018

You may wait a long time to see who is contributing to EPA Administrator Scott Pruitt's legal defense fund. Like other federal officials, the EPA chief is required to report gifts, like travel and tickets to events, he has received on his public financial disclosure report. That also includes contributions to the legal defense fund established for his benefit, according to guidance on the Office of Government Ethics' website.

Emails: EPA all ears as industry pitched 'secret science'

Maxine Joselow, E&E News reporter

Published: Thursday, May 17, 2018

Industry groups pitched EPA a proposal last spring that closely resembled what became Administrator Scott Pruitt's "secret science" plan, according to emails released this week under Freedom of Information Act litigation.

Glyphosate study defender tapped to lead cancer agency

Corbin Hiar, E&E News reporter
Published: Thursday, May 17, 2018

This article was updated at 4:02 p.m. EDT.

The World Health Organization's leadership has tapped to lead its embattled cancer bureau a Brazilian researcher who has vigorously defended its controversial study of the herbicide glyphosate.

Chemicals could be making workers sick at coffee roasters

Published: Thursday, May 17, 2018

A Centers for Disease Control and Prevention investigation suggests chemicals in the air at coffee roasting operations could present a widespread health threat to employees. A small group of CDC researchers spent the last two years investigating tiny coffee shops and large roasters around the country.

NGO warns against rushing to alternative methods under TSCA

- Public consultation on US EPA's strategy attracts more than 1,500 comments
- 17 May 2018 / Alternative approaches to testing, New TSCA/LCSA, United States

NGO the Natural Resources Defense Council has voiced concern that new technologies will be deployed too fast under the US EPA's draft strategy for alternative test methods under TSCA.

PRTR 'critical' for Chinese hazardous chemicals management, report says

- 104 substances suggested for pollution monitoring
- 17 May 2018 / Chemical manufacturing, China, Electrical & electronics, Metals, Persistent, bioaccumulative & toxic, Persistent organic pollutants, Substance notification & inventories

The adoption of a pollutant release and transfer register system is critical for the management of hazardous chemicals in China, according to a recently released NGO report.

Echa 2025 goal to identify all harmful substances 'unrealistic'

- Agency's five-year plan needs clear commitments to address gaps, NGOs say
- 17 May 2018 / Alternatives assessment & substitution, Europe, REACH, Substances of concern, SVHCs

Doubts have been raised about Echa's ability to deliver its objective of identifying all substances of concern and to start action on them by 2025.

The agency set the goal in its recently published draft strategic plan for the next five years. This named new substance identification and data generation as top priorities.

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Message

From: E&E News [ealerts@eenews.net]
Sent: 5/17/2018 5:43:21 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: May 17 -- Greenwire is ready

Read today's Greenwire on the web

GREENWIRE

AN E&E NEWS PUBLICATION

GREENWIRE — Thu., May 17, 2018

READ FULL EDITION

1. INTERIOR:

Zinke tells greens he'll make 'grand pivot' to conservation

Interior Secretary Ryan Zinke yesterday huddled with more than two dozen conservation group leaders, including some of his staunchest critics, in his latest bid to generate both ideas and support for his ambitious departmental reorganization plans.

TOP STORIES

2. EPA:

Who's donating to Pruitt's defense? Time will tell

3. REGULATIONS:

Emails: EPA all ears as industry pitched 'secret science'

4. OCEANS:

An end to overfishing? NOAA offers an optimistic outlook

POLITICS

5. PUBLIC LANDS:

Zinke to send more officers to Mexican border

6. PEOPLE:

Glyphosate study defender tapped to lead cancer agency

NATURAL RESOURCES

7. COAL:

Greens ask feds to probe struggling company's cleanup promises

8. YELLOWSTONE:

NPS approves plan to send disease-free bison to other herds

9. WILDLIFE:

Enviro petition urges Wyo. to delay grizzly hunt

10. NATIONAL PARKS:

Utah investigates reports of tainted water at Bryce Canyon

11. FISHERIES:

Oyster farm in Wash. refuge goes back to drawing board

12. WILDLIFE:

Poaching ring was 'demented social club,' officials say

LAW

13. SUPREME COURT:

DOJ backs Wash. in row over fuel taxes, treaty rights

14. PUBLIC LANDS:

Groups sue Forest Service over Tongass timber sale

ENERGY

15. PIPELINES:

Minn. lawmakers vote to approve Line 3 project, bypass PUC

AIR AND WATER

16. COAL:

Feds toss challenge of utility's mine cleanup promises

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AN E&E NEWS PUBLICATION

GREENWIRE — Tue., March 20, 2018

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Negotiators aim to settle policy fights, post omnibus tonight

Congressional leaders hope to have massive omnibus spending legislation on the House floor by Thursday, assuming they can resolve a few dozen outstanding policy fights.

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Subject: Morning Energy, presented by America's Pledge: First SAB meeting to eye EPA reg rollbacks — Cramer hits Trump's legislative director — DOE: U.S. generally 'well prepared' for grid hacks

By Kelsey Tamborrino | 05/31/2018 05:43 AM EDT

With help from Eric Wolff

PRUITT'S SAB STORY: EPA's independent Science Advisory Board will meet today and Friday for the first time since Administrator Scott Pruitt barred scientists on the committee from receiving EPA grants and boosted its ranks with industry representatives — and the group's agenda is packed. The SAB will look at Pruitt's "secret science" proposal to bar EPA from using studies that don't make public all their data, as well as the Clean Power Plan repeal, Pruitt's decision to relax 2022-25 auto emissions standards, changes to the 2016 methane rule for new oil and gas wells and effort to repeal a rule regulating emissions from "glider" trucks — and that's not all.

A lot to dive into: The heavy slate of issues is unusual for the advisory board, Pro's Alex Guillén reports. Several current and former SAB members say it's unprecedented for the board to consider reviewing so many regulatory actions. But like green groups and critics of Pruitt, the SAB scientists say EPA has declined to share information about its regulatory rollbacks. "The agency has not been forthcoming about how they're developing the relevant science work products," said Chris Frey, a professor of environmental engineering at North Carolina State University and a SAB member since 2012.

EPA keeps quiet: SAB has been conducting twice-yearly reviews of EPA's planned regulatory actions since 2012, members said. It's an effort designed to enable the advisory board to help guide EPA before its rules are finalized. But this time around, the SAB's working groups say EPA wasn't being forthcoming with information. "Basically they just didn't provide us with any answers," said Frey. "That kind of put us in a position where all we can really do is say EPA has not identified the science or any plan to review it, and clearly there are science issues that are in the proposed rule."

What to expect: It's not immediately clear whether the full SAB will vote today to advance the reviews. But Frey noted that some of the members appointed by Pruitt had been on the working groups, giving him hope that the full board will back the recommendations to look deeper into the regulatory rollbacks. Should SAB adopt them, Alex reports, it likely would mean setting up special subcommittees that include current members plus outside experts to question EPA further. Read more here.

IT'S THURSDAY! I'm your host Kelsey Tamborrino, and Entergy's Rob Hall correctly identified former President William Howard Taft as the first to see a Major League Baseball game in his hometown of Cincinnati. For today: Name all the presidents who were married while in office. Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam,@Morning_Energy and @POLITICOPro.

Register for the Pro Summit: Join Pro subscribers, expert reporters and key decision-makers from the executive branch, federal agencies and Congress for a full day of incisive policy conversations on July 17. Learn more.

THE LONG AND SHORT OF IT: In an unusual attack on the White House's legislative affairs director, North Dakota Rep. Kevin Cramer blamed Marc Short explicitly for the party's legislative failures in the Senate, including ending the Obama rule on flaring and venting from oil and gas wells. After POLITICO published a story outlining the awkward dynamic between Heidi Heitkamp, Cramer and the White House, Cramer told North Dakota radio host Rob Port that he had done some digging and believes that there "are some people in the White House that think, you know, the president's too friendly too her," Burgess Everett recaps.

Moreover, Cramer laid specific blame at Short's feet for failed GOP efforts in the Senate to roll back an Obama-era regulation limiting flaring and venting, as well as repealing Obamacare. Heitkamp voted against gutting that flaring rule, something Cramer has criticized her for, in particular. "If Marc Short was very good at his job, you know, we'd have a repeal and replacement of Obamacare, we'd have a replacement of the venting and flaring rule," Cramer said. Read that story here.

PRUITT'S MEDIA BLITZ: The EPA administrator visited Rosslyn, Va., on Wednesday to sit for interviews with two conservative media outlets. One was conducted by Boris Epshteyn for his Sinclair Broadcasting segment, "Bottom Line with Boris." (Watch that here .) The other was with the Washington Free Beacon, where Pruitt repeated familiar talking points in defense of the ongoing scandals and investigations that have surrounded him over the past few months. Pruitt said he still has President Donald Trump's backing, noting that Trump has "spoken very strongly and consistently" about their working relationship. "It's been intense the last couple of months, but he's been very encouraging, very empathetic and very supportive rather consistently," Pruitt said. The administrator also discusses the Paris climate agreement, "The Bachelorette" and, of course, baseball in the 13-minute segment, which you can listen to here.

GRID AND BEAR IT: In response to an executive order signed last year, the Energy Department released a new report Wednesday that said senior government officials and electric sector executives don't know enough about how energy companies could recover from a disruptive cyberattack, and those companies aren't thinking about cyber threats enough when building out their supply chains. While the report mainly hammered home some long-known problems with the grid, DOE highlighted how grid resilience efforts suffer because of "gaps in incorporating cybersecurity concerns, including planning for long-term disruption events, into state emergency response and energy assurance planning." Generally, however, the report said the U.S. is "well prepared to manage most electricity disruptions." Read more from Pro's Eric Geller here.

WHERE'S PERRY? Energy Secretary Rick Perry delivers remarks this morning on critical infrastructure at DOE's Texas-Israel Cyber Security Conference in Dallas. The department also announced that Perry would address the DOE's annual Cyber Conference in Austin on Monday. During both events Perry is expected to discuss DOE's new Cybersecurity, Energy Security and Emergency Response office, as well as efforts at DOE to address cyber vulnerabilities in the energy sector.

ABOUT THAT GLIDER RULE: The New York Times' Eric Lipton tweeted out new documents late Wednesday that give new details into the controversial Tennessee Technological University study on truck emissions that Pruitt used to consider rewriting part of the Phase 2 truck rules. "The letters obtained via open records request show that the principal investigator at Tenn Tech who conducted study funded by Fitzgerald, the company that makes the so-called glider trucks, disavowed the work, saying that it had been distorted in a fraudulent way," Lipton tweeted.

BY THE NUMBERS: The federal government spent $13.2 billion across 19 agencies during fiscal 2017 on programs related to climate change, a report from the Government Accountability Office says. That's an overall $1.5 billion increase across the federal government over fiscal 2016, Pro's Anthony Adragna reports. And it's an increase of $4.4 billion since fiscal 2010, according to the report, which was request by House Science Chairman Lamar Smith. Read more .

CALIFORNIA GETS CHARGED UP FOR EVs: The California Public Utilities Commission is expected to approve a $589 million program for its four investor-owned utilities to build out their electric vehicle charging infrastructure. The plan is part of the implementation of California's aggressive greenhouse gas law passed in 2015. Most of the money — which will ultimately come from ratepayers — will go toward setting up electric vehicle charging stations and related infrastructure. California leads the nation by far in electric vehicle sales and adoption.

NO MAJOR FLAWS IN FERC PROCESS: Auditors in the DOE inspector general's office said they found no major flaws in FERC's process for reviewing interstate natural gas pipelines, according to a new report . But they also flagged concerns about FERC's transparency and how it handles public comments. The auditors said that "nothing came to our attention to indicate that FERC had not performed its due diligence" in how it balanced public benefits of a proposed project with its adverse impacts. But the report also said regulators' "had not fully ensured" that the certification process was transparent to those who want to participate, and it hit the agency's eLibrary documentation system as difficult to use, Pro's Darius Dixon reports.

FERC DENIES PENNEAST REHEARING: FERC on Wednesday denied a rehearing sought by the Delaware Riverkeeper Network and Sourland Conservancy on the controversial PennEast pipeline. Commissioner Richard Glick issued a separate statement on the agency's use of tolling orders. "This proceeding, in particular, illustrates the need for prompt action on rehearing requests," Glick wrote . " ... I also have serious concerns regarding the Commission's practice of issuing conditional certificates — which, notwithstanding their name, vest the pipeline developer with full eminent domain authority — in cases where the record does not contain adequate evidence to conclude definitively that the pipeline is in the public interest."

GREENS ENDORSE DE LEON OVER FEINSTEIN: 350.org co-founder Bill McKibben and 350 Action said Wednesday it is backing Kevin de León in his bid to challenge California Sen. Dianne Feinstein. McKibben said de León, a current California state senator, "has been a strong champion of clean energy — and an effective one, using his power in Sacramento to make change happen against the strong opposition of the fossil fuel industry." Read De León's candidate questionnaire answers here.

SELC SUES OMB OVER REORG: The Southern Environmental Law Center sued the Office of Management and Budget Wednesday for its failure to release information under FOIA on the reorganization at federal agencies that manage public lands. SELC says OMB has not provided requested information under a November 2017 FOIA request , nor has it made a determination or otherwise responded to the request, and has subsequently stopped communicating with SELC. The center is seeking "all records in the custody or control of OMB submitted in connection with Executive Order 13781 by any agency responsible for the management of federal public lands," including the Forest Service, National Park Service, BLM and the Fish and Wildlife Service. The EO in question directed each agency head to submit a report to OMB outlining proposed changes to their agency. Read the lawsuit.

CRES BACKS McMASTER IN SOUTH CAROLINA: Citizens for Responsible Energy Solutions will announce a $175,000 television and digital ad buy today highlighting South Carolina Gov. Henry McMaster's record on clean energy. "First as lieutenant governor and now as governor, his commitment to the development of advanced energy technologies like natural gas and solar power is helping the state's economy and job market thrive," CRES Chairman and Executive Director James Dozier said.

McCARTHY NAMED DIRECTOR OF HARVARD CENTER: Harvard T.H. Chan School of Public Health announced former EPA Administrator Gina McCarthy will lead its newly launched Center for Climate, Health,

and the Global Environment. Under McCarthy, C-CHANGE announced a collaboration between Harvard University and Google to reduce the use of harmful chemicals in construction and renovation projects. "C-CHANGE will ensure that cutting-edge science produced by Harvard Chan School is actionable — that the public understands it, and that it gets into the hands of decision-makers so that science drives decisions," McCarthy said in a statement.

MOVER, SHAKER: Mitch Schwartz started this week as communications director for Jason Crow's campaign in Colorado's 6th Congressional District. Schwartz previously worked for SKDKnickerbocker.

— **PUSH Buffalo, a sustainable housing group,** announced Rahwa Ghirmatzion as its new executive director as of August 2018. Ghirmatzion has served as the organization's deputy director since 2017.

QUICK HITS

— Exxon aims to boost production even with any climate rules, Associated Press.

— Buffett utility to be first in U.S. to reach 100 percent renewables, Reuters.

— Chevron shareholders reject climate change resolutions, Washington Examiner.

— It's not every day you see a tropical depression over Indiana — but here it is, The Washington Post.

— U.S. solar manufacturing poised to boom in wake of Trump tariffs, Bloomberg.

— Oil prices steady after big drop on OPEC talks, The Wall Street Journal.

HAPPENING TODAY

10:00 a.m. — The U.S. Energy Association forum on coal mine drainage as a domestic source of rare earth elements, 1300 Pennsylvania Ave NW

10:00 a.m. — The World Resources Institute webinar on "Guidance for Apparel and Footwear Sector Companies to Set Science-Based Targets," focusing on greenhouse gas emissions

12:00 p.m. — Women's Council on Energy and the Environment event on "Solar Jobs and Community Impact," 1350 I Street NW

12:00 p.m. — The Property Casualty Insurers Association of America briefing on "Hurricane Season: Preparedness, Response, and Recovery," 2044 Rayburn

5:00 p.m. — House Science Committee field hearing on "Earthquake Mitigation: Reauthorizing the National Earthquake Hazards Reduction Program," Huntington Beach, Calif.

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https://subscriber.politicopro.com/newsletters/morning-energy/2018/05/first-sab-meeting-set-to-begin-237617

Stories from POLITICO Pro

EPA boosts industry membership on key advisory boards Back

By Alex Guillén | 11/03/2017 01:41 PM EDT

EPA officially announced the new line ups for several key advisory boards today, bolstering their membership with employees of energy companies and state agencies just days after Administrator Scott Pruitt ordered scientists who have received agency grant money to give up their EPA funding or their seat.

As POLITICO reported on Tuesday, the Science Advisory Board's new additions include representatives from Phillips 66, Total, Southern Co., the American Chemistry Council and NERA Economic Consulting, a firm frequently hired by industry interests. Their additions boost the industry membership of SAB, although the panel had previously included members from Dow Chemical and other industries or companies.

The Clean Air Scientific Advisory Committee, which provides health advice for air quality standards, also has three new members. Aside from new Chairman Tony Cox, an independent consultant, the new members are Larry Wolk of the Colorado Department of Public Health and Environment and James Boylan of the Georgia Department of Natural Resources.

EPA also announced a slate of new additions to the Board of Scientific Counselors, which advises on research issues. The former chairwoman, Deborah Swackhamer of the University of Minnesota, is now listed as member, while Paul Gilman of waste-to-energy company Covanta has taken over as chair.

Other new BOSC members include representatives from the North Dakota Petroleum Council, Eli Lilly and Co., the Defense Threat Reduction Agency, the Arkansas Department of Environmental Quality, the California Energy Commission and the consulting firm Ramboll Environ.

To view online click here.

Back

EPA's science advisers turn eyes on Pruitt's rollbacks Back

By Alex Guillén | 05/31/2018 05:00 AM EDT

EPA's influential Science Advisory Board will meet on Thursday for its first time since Administrator Scott Pruitt filled it with a slate of industry representatives — and it's got a long list of controversial rule rollbacks to review.

The SAB plans to pore over the science EPA is using to justify rollbacks on emissions regulators for cars, trucks, power plants and oil and gas wells — as well as Pruitt's proposed "transparency" rule for scientific studies.

Several current and former SAB members told POLITICO that it was unprecedented for the board to consider diving into so many regulatory actions, but the heightened scrutiny from the outside experts came about because the agency stonewalled the scientists' questions about Pruitt's deregulatory decisions. That echoes the complaints from environmentalists and public advocacy groups who say EPA has declined to share information about how it was justifying easing the regulations put in place during the Obama administration.

"The agency has not been forthcoming about how they're developing the relevant science work products," said Chris Frey, a professor of environmental engineering at North Carolina State University and a SAB member since 2012.

In a move critics derided as an attempt to stack the 44-member board with industry-friendly voices, Pruitt last year broke with the tradition of reappointing first-term SAB members for second three-year stints by removing several advisers who received grants from the agency. In their places, he installed scientists from the fossil fuel and chemicals sectors and several Republican environmental officials. Among the new members are representatives from Phillips 66, Total, Southern Co., the American Chemistry Council and NERA Economic Consulting.

In addition to studying Pruitt's proposal to bar EPA from using studies that don't make public all their data, the SAB's working groups suggested the full group take a closer look at the repeal of the Clean Power Plan and EPA's reconsideration of its related rule limiting carbon emissions from future power plants. Also up for review are Pruitt's decision to relax 2022-2025 auto emissions standards, changes to the 2016 methane rule for new oil and gas wells, and EPA's effort to repeal a rule regulating emissions from "glider" trucks.

The working groups also deferred decisions on two other rulemakings: the Waters of the U.S. rewrite and rules on a special class of "persistent, bioaccumulative and toxic chemicals" under the Toxic Substances Control Act. SAB can decide whether to conduct a deeper review into those once EPA has reviewable regulatory language available, the groups said.

Frey, who has been a SAB member for six years, said having multiple rules up for review was very unusual for the board.

"It's very rare that we've recommended to the full Science Advisory Board that there should be an SAB action," he said.

SAB has been conducting twice-yearly reviews of EPA's planned regulatory actions since 2012, members said, an effort designed to enable the advisory board to help guide EPA before its rules are finalized.

In the early days, getting information from EPA was "like pulling teeth," said Kimberly Jones, a SAB member from 2011 through 2017 and the chair of environmental engineering at Howard University. But that quickly improved once EPA knew the scope of SAB inquiries, she added.

The SAB's working groups review how EPA uses scientific studies in its rulemakings, including whether and how a study was peer-reviewed and if EPA has properly accounted for uncertainties in the scientific findings. The groups typically find that further reviews aren't needed.

But this time around, the working groups said EPA didn't respond to their questions about many of Pruitt's highest-profile rollbacks.

"Basically, they just didn't provide us with any answers," Frey said. "That kind of put us in a position where all we can really do is say EPA has not identified the science or any plan to review it, and clearly there are science issues that are in the proposed rule."

Frey pointed to lengthy memos from the working groups that included multiple pages of questions that had been posed to EPA for each rulemaking. EPA responded with short statements promising to keep the issues in mind as it develops the final rules.

"The response from the agency was basically a non-response," Frey said.

An agency spokesman said in a statement that SAB "plays an important role" advising EPA.

"We value the Board's expertise, and we welcome feedback from the chartered panel on areas in which they are interested in getting additional scientific information that is relevant to the rulemaking process," the spokesman said.

It was not clear whether the full SAB will vote on Thursday to advance the reviews.

Frey noted that some of the members appointed by Pruitt had been on the working groups, giving him hope that the full board will back the recommendations to look deeper into the regulatory rollbacks.

Should SAB adopt them, it likely would mean setting up special subcommittees that include current members plus outside experts to question EPA further.

The board can advise EPA only on scientific matters, not policy or legal issues. In several cases, like with the repeals of the Clean Power Plan and the glider rule, EPA says it has a legal argument about statutory authority that does not rely on scientific issues.

But even then, Frey said, EPA must keep the science in mind.

"It's in the best interest of the agency to make sure that it's using appropriately developed and reviewed science in its rules," Frey said. "And the flip side of that is if the agency's not doing that, it could open itself up to legal challenges for not following appropriate procedures to develop the science."

To view online click here.

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GOP sweats Trump's Heitkamp flirtation Back

By Alex Isenstadt and Burgess Everett | 05/30/2018 05:08 AM EDT

When a small group of alarmed White House aides caught wind that Sen. Heidi Heitkamp — one of the most endangered Democrats up for reelection in 2018 — would be attending President Donald Trump's bill signing last week, they raced to stop it.

Word eventually reached Senate Majority Leader Mitch McConnell, who has made unseating Heitkamp a top priority. He opted not to intervene, and the invitation stood: As the president signed a banking deregulation bill into law before a national audience, Heitkamp was right next to him, the only Democrat in the room.

As the election year kicks into high gear, Republicans have grown increasingly frustrated with Trump's ongoing flirtation with the freshman senator. At a time when many in the GOP fear that the president's unpredictable style will undercut their best-laid midterm plans, the relationship has given Heitkamp — who is seeking reelection in a state where Trump won nearly two-thirds of the vote — fodder to portray herself as a presidential ally.

Her office keeps a running list of the dozen-plus meetings Heitkamp has had with Trump and his top advisers since the 2016 election. And the senator is fond of noting that she forged close ties with Trump's former top economist, Gary Cohn. The president met with Heitkamp in Trump Tower after the 2016 election to discuss a

possible Cabinet position, asked her to join him on Air Force One, and invited her onstage to join him and her Republican opponent, Rep. Kevin Cramer, during an appearance in North Dakota.

"Everyone is saying, 'What's she doing up here?'" the president said at the September event to sell his tax reform plan, which Heitkamp eventually opposed. "But I'll tell you what. Good woman, and I think we'll have your support, I hope we'll have your support. And thank you very much, senator, thank you for coming up."

After last week's bill signing, Heitkamp's allies raced to capitalize. The North Dakota Democratic Party sent out a tweet with an image of Cramer looking on uncomfortably as the president stood next to Heitkamp.

"At a bill signing today, @HeidiHeitkamp got a shout out and all @kevincramer got was a photo op next to a chair," the state party boasted.

"We will see footage of this on every platform," said Doug Heye, a former top Republican National Committee official. "It's a huge gift for her campaign."

Trump aggressively recruited Cramer to give up his House seat to take on Heitkamp, and his actions since have left some of Cramer's closest allies feeling snubbed. They note that while Trump has savaged Democratic incumbents Joe Donnelly of Indiana and Jon Tester of Montana and visited a growing list of states to pump up Republican Senate hopefuls — most recently Tennessee, where he appeared Tuesday on behalf of Rep. Marsha Blackburn — he has yet to make a campaign appearance with Cramer. Nor has the attack dog-in-chief attacked Heitkamp.

After Cramer learned last year that Heitkamp would be accompanying the president on Air Force One to North Dakota, he complained bitterly to the White House, according to two people with direct knowledge of the discussions. Heitkamp, Cramer predicted at the time, would try to use it to her political advantage. (A Cramer adviser, Pat Finken, denied that the congressman had complained about the senator riding on Air Force One.)

The administration has taken steps to assure Cramer that he has the president's full support. The congressman has been regularly in touch with White House political director Bill Stepien, and the two met earlier this month. Trump has agreed to hold a rally for Cramer later this year.

In an interview, Cramer shrugged off Heitkamp's attendance at the bill signing and said there would soon be "clarity" on who Trump supports in the race.

Yet the congressman declined to predict whether the president would go after Heitkamp aggressively, as Trump has done with other Democratic incumbents. Cramer seemed aware of the warmth between the president and the senator. Trump has asked Cramer whether he likes Heitkamp, and when the congressman responds yes, the president seems to be "relieved," Cramer said.

"Politically, North Dakota's a pretty nice state. So I don't know that turning it on her is necessarily politically helpful to me," Cramer said. "They may just be concerned that she's a woman and maybe that has an impact. I just don't know."

Heitkamp said she's proud of her ability to work with the president.

"I have a friendly relationship. I have a very important working relationship," she said in an interview, "not just with him but other members of the administration."

Trump's reluctance to go after Heitkamp stems in part from the simple fact that he needs her vote. With Republicans clinging to a narrow Senate majority, the White House has pushed for her support on several

contentious votes, including the recent confirmations of CIA Director Gina Haspel and Secretary of State Mike Pompeo. She also backed Trump's nominations of Supreme Court Justice Neil Gorsuch and Environmental Protection Agency Administrator Scott Pruitt.

Last week's signing ceremony was organized by White House Office of Legislative Affairs Director Marc Short. He said he extended an invitation to Heitkamp because she played a central role in passing the banking deregulation law.

"She was an original cosponsor of the bill," Short said. "But she's also someone who opposed tax relief, who opposed repeal of Obamacare, and someone who will always support Chuck Schumer. So you can be sure the president will be actively campaigning in North Dakota this cycle."

Cramer's February entry into the race followed an intense pursuit from Trump and top White House officials. After Cramer initially said in January that he wouldn't run for Senate, he received overtures from Trump, White House counselor Kellyanne Conway, and energy executive and Trump donor Harold Hamm within a three-day period. Trump also met with Cramer's wife, Kris.

Cramer said Trump told him at the time that he'll "be out there campaigning more than you are." Trump's entreaties, Republicans contend, helped to push Cramer into the contest. Cramer won his statewide, at-large House seat in 2012, the same year Heitkamp entered the Senate.

"The president leaned on him very hard. The president wanted the best candidate, and everyone in the state thought Kevin was the best candidate to beat Heidi," said Gary Emineth, a former North Dakota GOP chairman who is close with the congressman. "You know how the president is. He just doesn't quit."

Heitkamp predicted that Trump would attack her eventually. While she has maintained a positive working relationship with the president, she said it pales in comparison to Cramer's staunch loyalty.

"I don't think anyone can match his Trump credentials," Heitkamp said. "He is somebody who will always do what the president asks him to do, regardless of whether it's good for North Dakota."

As of late, the senator has been airing commercials that highlight her balancing act. "When I agree with the president I vote with him — and that's over half my votes," she says in a spot that began airing this month. "And if his policies hurt North Dakota, he knows I'll speak up."

Cramer accused Heitkamp of acting like a "Republican wannabe" with her occasional support for key Trump nominees.

"Her trying to cozy up to Donald Trump has resulted in good votes," Cramer said. "But every time she tries to become more like me, it's more flattering to me than it is to her."

Democrats, however, couldn't be happier to portray Cramer as a jilted lover.

Last week, the North Dakota Democratic Party released a video featuring a montage of clips of the president praising Heitkamp and shaking her hand as Cramer looks on — set to the sad sounds of R.E.M.'s "Everybody Hurts."

To view online click here.

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GOP Senate candidate lashes out at Trump's legislative director Back

By Burgess Everett | 05/30/2018 06:27 PM EDT

Rep. Kevin Cramer, one of the GOP's top Senate recruits, launched an unusual attack on the White House's legislative director Wednesday, blaming him explicitly for the party's legislative failures in the Senate.

The comments from Cramer (R-N.D.) come amid rising GOP angst over President Donald Trump's close relationship with his opponent in the North Dakota Senate race, Democratic Sen. Heidi Heitkamp.

Heitkamp was the only Democrat invited to the White House last week for a bank deregulation bill signing, alarming some White House aides and Republicans. After POLITICO published a story on Wednesday outlining the awkward dynamic between Heitkamp, Cramer and the White House, Cramer told North Dakota radio host Rob Port that he had done some digging and believes that there "are some people in the White House that think, you know, the president's too friendly too her."

Then Cramer laid into White House legislative affairs director Marc Short for two prominent failed GOP efforts in the Senate: Repeal of Obamacare and the rollback of an Obama-era regulation that would limit flaring and venting from oil and gas wells. Heitkamp voted against both and Cramer has criticized her in particular over the flaring vote.

"If Marc Short was very good at his job, you know, we'd have a repeal and replacement of Obamacare, we'd have a replacement of the venting and flaring rule," Cramer said.

In an interview last week with POLITICO, Cramer insisted he is not angry over Trump's political flirtations with Heitkamp: "Not the case at all. I've been fine with it. I just don't think it hurts me." And on Wednesday on Port's show, Cramer said the spat over Heitkamp's attendance at the banking bill signing "just seems to be an argument between Marc Short and other people in the White House."

Short extended an invitation to Heitkamp to the bill signing, but also has knocked Heitkamp for opposing the GOP's tax law. He did not respond to a request for comment for this story.

Heitkamp has tried to stay out of the back and forth, though she is playing up her collaborations with a president that won her state in 2016 by more than 35 points.

"The president has got bigger fish to fry and bigger problems to solve than whether Kevin likes him more than I do," Heitkamp said.

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DOE report: U.S. generally 'well prepared' for grid hacking, but gaps remain Back

By Eric Geller | 05/30/2018 06:05 PM EDT

Senior government officials and electric sector executives don't know enough about how energy companies could recover from a disruptive cyberattack, and those companies don't consider cyber threats enough when building out their supply chains, according to a new Energy Department report.

Grid resilience efforts also suffer because of "gaps in incorporating cybersecurity concerns, including planning for long-term disruption events, into state emergency response and energy assurance planning," said the report.

"The United States is, in general, well prepared to manage most electricity disruptions," the Energy Department said in its report. But gaps still exist in areas like situational awareness, workforce development, separation of roles and responsibilities and the coordinated use of resources like digital defense tools.

DOE completed the report last August as part of President Donald Trump's May 2017 cyber executive order but did not publish it until today.

The report mostly hammered home long-understood problems with protecting the power grid from hackers, including the challenges of sharing cyber threat data between partners

"The variation in infrastructure ownership and operation and the jurisdictional overlap add complexity to sharing actionable information in a timely manner," the report said. "These complexities are compounded when information is classified or sensitive due to the limited options and access to facilitate sharing."

It also warned of compounding problems in the event of a major power outage. For example, "as cyber incidents may impact disparate systems across the country, the impacted owner-operators may not be familiar with each other's systems and procedures."

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DOE working to stand up new cyber unit in fiscal 2018 Back

By Darius Dixon | 03/01/2018 01:11 PM EDT

The Energy Department is aiming to have its new cybersecurity office fired up before the end of the fiscal year, Bruce Walker, the agency's top electricity official, said today.

"We're working with Congress because we put it into the FY 2019 budget proposal ... and we're looking to stand it up earlier because of the importance and our sector-specific agency authority [for cyber incidents]," he told reporters after testifying before the Senate Energy and Natural Resources Committee.

Walker has previously noted that DOE wouldn't need additional congressional authority to create the office or a new assistant secretary job to lead it. Today, he also said that the design change is meant to elevate cyber issues as well as to divide up the agency's infrastructure work into short-term and long-term operations.

Creating the Office of Cybersecurity, Energy Security and Emergency Response is a reaction to a range of issues, including Congress giving DOE more emergency authorities in the 2015 FAST Act (H.R. 22 (114)), the relentless need to improve cyber defenses, and the deepening marriage between the natural gas and electric sectors.

Walker would still lead the electricity office, which would focus on long-term infrastructure plans and set research-and-development goals, including for cybersecurity. Meanwhile, the new CESER office would be "actionable, near-term and highly responsive" recovery work like the devastation in Puerto Rico or the immediate response to a cyberattack, he said.

"One basically feeds the other," Walker said. "[CESER] responds to the incidents, OE will design them out of the system on a going-forward basis."

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GAO: Government spent $13.2B on climate change last year Back

By Anthony Adragna | 05/30/2018 04:34 PM EDT

The federal government spent $13.2 billion across 19 agencies during fiscal 2017 for various programs related to climate change, according to a report from the Government Accountability Office released today.

Overall, climate change-related spending across the federal government rose $1.5 billion between fiscal 2016 and 2017 and grew $4.4 billion since fiscal 2010, according to the report.

GAO examined the budget justifications for six agencies accounting for 89 percent of all climate change spending and found just 18 of 533 programs within those agencies whose primary purpose is to address climate change. It further concluded that those programs primarily dedicated to addressing the problem "serve different purposes, target different audiences, or operate at different time periods and scales, which minimizes potential overlap or duplication." The other programs had multiple purposes beyond addressing climate change.

The White House Office of Management and Budget reports the government has spent over $154 billion since 1993 to understand and address climate change.

House Science Chairman Lamar Smith (R-Texas) requested the report.

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DOE IG: No big flaws in FERC pipeline review process, but transparency should improve Back

By Darius Dixon | 05/30/2018 03:21 PM EDT

Federal watchdogs said they found no major flaws in FERC's process for reviewing interstate natural gas pipelines, but they flagged concerns about its transparency and how it handles public comments, according to new report.

Auditors in the Energy Department inspector general's office who reviewed FERC's pipeline certification process said that "nothing came to our attention to indicate that FERC had not performed its due diligence" in how it balanced public benefits of a proposed project with its adverse impacts.

But the report said regulators' "had not fully ensured" that the certification process was transparent to those who want to participate and that its eLibrary documentation system was difficult to use. And it said FERC lacked a consistent method for tracking and addressing comments submitted on a proposed project.

"FERC had not specifically designed its public-facing systems for use by the general public," the IG report said, noting that "although available to the general public, eLibrary had been designed for use by practitioners, the legal community, and other stakeholders."

The report also said parts of the eLibrary website "did not contain a sufficient explanation of the entire process" and that a document for landowners who could be affected by a project was not clear about key aspects of the certification process.

"While nothing came to our attention to indicate that natural gas certification applications had been inappropriately approved or disapproved," watchdogs wrote, "FERC can take steps to improve aspects of the natural gas certification process."

WHAT'S NEXT: FERC is in the process of a broad review of its natural gas pipeline certification process but there's no established deadline.

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Message

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

EPA May Invite Hazard, Exposure Data on Dozens of Chemicals

By Pat Rizzuto

Posted May 15, 2018, 9:37 AM

The EPA may invite chemical manufacturers and others to submit toxicity and exposure information on dozens of chemicals already on its radar for potential scrutiny.

House Panel Refutes Trump, Proposes $12M for Chemical Board

By Bruce Rolfsen

Posted May 14, 2018, 6:15 PM

The Trump administration's proposal to disband the Chemical Safety and Hazard Investigation Board is once again running into opposition from Congress.

Pruitt Adds New EPA Office to Further Efficiency Effort

By Abby Smith

Posted May 14, 2018, 5:35 PM

EPA head Scott Pruitt's efficiency push throughout the agency will get its own office, the administrator announced May 14.

Industry Coalition Forms to Lobby For EPA Safer Labels Program (1)

By Pat Rizzuto

Posted May 14, 2018, 3:24 PMUpdated May 14, 2018, 5:53 PM

Companies making cleaners, automobile products, and other consumer chemicals are launching a coalition June 1 to support a threatened EPA labeling program that recognizes safer chemicals.

INSIDEEPA.COM ARTICLES

On Eve Of EPA Summit, Agencies At Odds Over Calculating PFAS Risks

On the eve of a major EPA summit over how to address contamination from widespread exposures to per- and polyfluoroalkyl substances (PFAS), EPA and other agencies are split over how to calculate the substances' risks, a division that recently prompted EPA and the Defense Department (DOD) to ask the White House to block a federal health agency from releasing draft risk values stricter than EPA's.

After Families' Push, EPA Plans To Finalize Obama-Era Paint-Stripper Ban

Amid lobbying by families of consumers and workers killed from exposure to the paint-stripper chemical methylene chloride, EPA has reversed course, saying it now intends to soon finalize an Obama-era rule expected to ban certain uses of the substance, though environmentalists are cautioning that the final rule should preserve the proposed ban.

IG Adds Data Quality, Reporting To List Of EPA's Management 'Challenges'

EPA's Inspector General (IG) is updating and adding two entries to its annual list of management "challenges" facing the agency, warning EPA that it needs to address "systemic" problems in the quality of data used in decisions and separately its inability to meet statutory deadlines for reports to Congress on various EPA programs.

EPA Sends Final TSCA Mercury Inventory Rule For White House Review

EPA has sent to White House review its final rule requiring workers who handle mercury to report those uses to the agency, a rule the agency is required to promulgate by June 22, per the 2016 law that reformed the Toxic Substances Control Act (TSCA).

CEQ Submits Draft NEPA Rule Update To OIRA For Review

The White House Council on Environmental Quality (CEQ) is advancing a long-anticipated measure to reform its National Environmental Policy Act (NEPA) implementing rules, submitting an advance notice of proposed rulemaking (ANPR) to the White House Office of Information& Regulatory Affairs (OIRA) for review.

Industry Urges OMB To Back EPA Rule Boosting Policy Cost Considerations

Industry groups are pressing the Office of Management and Budget (OMB) to support a draft preliminary EPA rule that would establish greater "consistency" when considering the costs of its regulatory policies, urging OMB to devote resources to the effort and broadly playing down legal obstacles to consideration of costs in future rules.

EPA Science Plan Skirted Usual Process, Raising Finalization, Legal Doubts

The Trump EPA's controversial plan requiring use of publicly available research to justify rules appears to have been developed by political appointees without following the agency's usual action development process (ADP) for crafting important rules, leaving career staff and program offices out of the loop but raising doubts about how it will be finalized without them.

House Floats $100 Million Cut To EPA In FY19 Targeting Regulatory Programs

House lawmakers are floating draft legislation to cut EPA's budget from its current $8.058 billion funding by $100 million down to $7.958 billion, a modest cut compared to prior GOP efforts to slash the agency's funding that primarily targets EPA's science and rulemaking accounts for reductions while boosting state grants and Superfund spending.

CPSC Guide Could Give EPA Alternative To Partial Methylene Chloride Ban

The Consumer Product Safety Commission's (CPSC) recent guidance calling for product labels to warn of acute inhalation hazards of paint strippers containing methylene chloride could give EPA an alternative to calls for a first-time ban on some uses of the substance, such as industry calls to promote risk management options.

CHEMICAL WATCH ARTICLES

State AGs request withdrawal of US EPA science proposal

14 May 2018 / Confidentiality & right-to-know, Data, United States

Attorneys General from seven states and the District of Columbia have requested the US EPA withdraw its 'science transparency' proposal, owing to the "far-reaching impact" it could have on the agency's core activities.

The proposed rule – which seeks to allow increased transparency and public validation of studies underpinning agency regulatory decisions – has met heavy criticism from NGOs who fear it could be used to discard important health and safety data.

And the state AGs have joined a chorus of stakeholders requesting that the agency put the brakes on it.

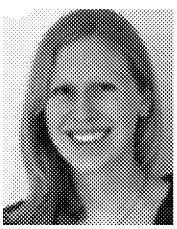
In a letter submitted to the public docket, the states' chief legal advisors noted concerns "both from the truncated timeline under which EPA seeks to change fundamental agency policy, and from the vagueness of the proposal".

They have requested the agency withdraw its proposed rule and begin a consultation with the National Academy of Sciences and other independent scientists before deciding whether changes are needed to the agency's current approaches.

Should the agency decline this path, the AGs requested that the EPA extend the consultation by at least 150 days. "A full six-month comment period would be consistent with past practice for matters of similar importance and complexity, and is necessary to provide the public and other stakeholders a meaningful opportunity to evaluate the proposal and its implications for the agency's ability to meet its obligation to protect public health and the environment under federal environmental laws," they wrote.

The current 30-day consultation is "woefully insufficient", they added. Unless extended, this is set to expire on 30 May.

The letter is co-signed by the AGs from New York, California, Delaware, Iowa, Maine, Minnesota, Pennsylvania, and Washington, DC.



Kelly Franklin

North America editor

Related Articles

- US EPA proposes controversial science transparency rule
- American Chemistry Council defends EPA 'secret science' proposal
- TSCA could be undercut by 'secret science' requirements
- Stakeholders demand US EPA extend 'secret science' consultation

Further Information:

- Comment

EU Commission publishes 11th ATP to CLP Regulation

14 May 2018 / Classification, labelling and packaging Regulation, Europe

The European Commission has published amendments to the Regulation on the classification, labelling and packaging of substances and mixtures (CLP).

This is the 11th adaptation to technical and scientific progress (ATP). It includes the chemical names of substances subject to harmonised classification and labelling listed in Table 3 of Annex VI CLP in all languages.

The 11th ATP has neither added substances nor amended information on any of the chemicals regulated under CLP. It was published in the *Official Journal* on 16 April and will apply from 1 December 2019.

The 10th ATP to CLP was published a year ago. It introduced new and revised entries for the harmonised classification and labelling of 37 substances.

Related Articles

- EU Commission publishes 10th ATP to CLP Regulation

Further Information:

- EU Official Journal

EU regulation of FCMs 'outdated and full of holes'

Industry efforts seen to be filling a void

14 May 2018 / Europe, Food & drink, Food contact, Food contact Regulation 10/2011

The EU's regulation of food contact materials is "outdated, ineffective and full of holes", a Chemical Watch Food Contact Regulations Europe summit has heard.

Speaking at last week's event in Brussels, Michael Warhurst, executive director of NGO CHEM Trust, said: "it's not a pretty picture. The public would be very surprised at the lack of effective food contact material regulations.

"They expect protection. The fact that it's not under control is a potential scandal, even if it's not visible at the moment."

Legislation

The overarching piece of FCM legislation is the 2004 EU Framework Regulation. This works in tandem with the good manufacturing practice for materials and articles intended to come into contact with food Regulation (GMP) from 2006.

Both harmonised and non-harmonised materials sit under the framework's umbrella. Harmonised materials, which include, for example, plastics, ceramics and regenerated cellulose, are subject to EU-wide rules. Non-harmonised

materials, which include adhesives, printing inks and paper, have no specific European legislation covering them, and are subject to member states' national provisions.

According to Dr Warhurst the regulatory approach in this area has not been systematically assessed since it was introduced in 1976. There has also been no formal evaluation work or reports done on the 2004 framework.

"The world is moving on," he said, "and Europe is rather a long way behind".

Review

Late last year the Commission consulted on a roadmap for evaluating the legislation. Among the responses were a number of calls for fully harmonised rules for all FCMs, including from Cefic and the European Printing Ink Association (EuPIA).

Peter Oldring, European regulatory affairs manager at coatings company Sherwin Williams, told the conference that the EU executive is now planning a study to determine how the present legislation is functioning. It is expected, he said, that a contractor will start work in the Autumn.

And, Dr Oldring (pictured) told the summit that industry is as frustrated as the NGOs at the lack of Commission action.

"We keep getting roadmaps," he said. "Somehow the Commission's roadmaps and actions are subject to delays – often considerable – against their original target. We need to come up with a strategy to show those outside the Commission that something needs to be done."

To this end Dr Oldring directed the summit's attention to the work of an industry cross-sector group that has been in existence for 18 months and takes in 25 associations.

"The Commission is overloaded and the rate of progress is perhaps not as much as industry would like," he said. "In the absence of legislation, industry has been trying to tackle this problem so that we can fill a void that is there."

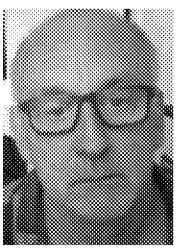
Fit for purpose?

However, Anna Gergely (also pictured), director of environment, health and safety regulatory at law firm Steptoe and Johnson, drew attention to the role REACH plays in the regulation of FCMs.

In response to the question "is the food contact regime fit for purpose?" she answered that there is great complexity to the legislation and FCMs are not exempt from REACH restrictions.

"Don't let people spread the news that food contact materials are not properly regulated," she said.

"There are some exemptions for food and feed in the REACH Regulation, and they include food additives, but there are no such exemptions for food contact materials. So don't be mistaken, packaging is not exempt in any way from the Regulation."



Nick Hazlewood

News editor

Related Articles

- Trade groups call for harmonised EU regulations for FCMs

Further Information:

- Food contact regulations Europe 2018
- EU FCM Regulation

Northern Ireland to ban microbeads in rinse-off cosmetics

14 May 2018 / Alternatives assessment & substitution, Microplastics, Personal care, United Kingdom

Northern Ireland is to ban the manufacture and sale of rinse-off cosmetics and personal care products containing plastic microbeads, from September this year.

The UK government implemented the first phase of its ban, which applies to the manufacture of such items, in January. The second phase will prohibit their sale from the end of June.

In its notification to the European Commission, Northern Ireland said there are currently no known manufacturers using plastic microbeads in the region, which prompted it to implement the ban on manufacture and sale at the same time.

The regulations apply to Northern Ireland only. However, the various UK administrations have developed legislation collaboratively to ensure the definition of the ban is consistent. The objective is that it will eventually apply across the UK.

The devolved governments of Scotland and Wales have submitted separate notifications, with their bans coming into effect on 19 June and 30 June respectively.

The difference between the various UK regions is in the enforcement regime, according to the notification from Northern Ireland.

Related Articles

- UK microbeads ban enters into force
- Scotland announces microbeads ban
- Wales to ban microbeads from June

Further Information:

- Notification

OTHER ARTICLES

What the Research Says About 10 Controversial Cosmetics Ingredients

SELF

Between all the scary headlines about “toxic chemicals” in everyday products, and new items on the drugstore shelves marketed as XYZ-free, ...

Message

From: Hewitt, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41B19DD598D340BB8032923D902D4BD1-HEWITT, JAM]
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Subject: EPA News Highlights 3.30.18

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EPA News Highlights 3.30.18

Casper Start-Tribune: EPA head Scott Pruitt visits major Wyoming coal mine, preaches end of 'war on fossil fuels'
Two days after a crowd of 300 gathered in Gillette to debate the Environmental Protection Agency's authority to regulate emissions at the cost of the coal industry, the head of that agency stood 20 miles away in one of the largest surface coal mines in the country: Black Thunder. Scott Pruitt, the controversial leader of the EPA, came to Wyoming at the invitation of Sens. John Barrasso and Mike Enzi to see the coal industry first hand. The state provides about 40 percent of the thermal coal burned in the U.S. for power and would be uniquely affected by a carbon dioxide rule like the Clean Power Plan. The rule's goal of cutting carbon dioxide emissions in the electricity sector by about 30 percent compared to 2005 levels would have pressured utilities that buy Wyoming coal, wiping away customers that the coal industry around Wright and Gillette depend on.

Gillette News Record: EPA chief Pruitt visits Campbell County, touts importance of coal exports
The future of Powder River Basin coal lies overseas, something EPA Administrator Scott Pruitt stressed during a Thursday morning visit to the heart of Wyoming coal country. As the guest of U.S. Sens. Mike Enzi and John Barrasso, both R-Wyoming, Pruitt toured Arch Coal's Black Thunder mine south of Wright, the second-largest producing thermal coal mine in the world. Pruitt said he was impressed by the "size and scope" of the operation. Black Thunder produced 70.5 million tons of coal in 2017. "Look at this and how impressive it is," he said. "To see what is done here with the amount of production, the automation, the technology and the commitment of the employees. … It was just impressive to see. And the most impressive were the people."

Breitbart: Scott Pruitt Is #Winning, Bans Junk Science from Environmental Protection Agency
Junk science is no longer welcome at the Environmental Protection Agency. Administrator Scott Pruitt has declared war on what he calls "secret science" – the process whereby EPA regulators have been able to craft rules using non-publicly-available science data…This decision will correct a longstanding injustice at the EPA, perpetrated against the U.S. taxpayer. For years the EPA has been able to behave as a law unto itself, cavalierly passing regulations which restrict freedoms, hamper business and hold back the U.S. economy for reasons which have much more to do with left-leaning environmentalist politics than with objective science.

New York Times: E.P.A. Prepares to Roll Back Rules Requiring Cars to Be Cleaner and More Efficient
The Trump administration is expected to launch an effort in coming days to weaken greenhouse gas emissions and fuel economy standards for automobiles, handing a victory to car manufacturers and giving them ammunition to potentially roll back industry standards worldwide. The move — which undercuts one of President Barack Obama's signature efforts to fight climate change — would also propel the Trump administration toward a courtroom clash with California, which has vowed to stick with the stricter rules even if Washington rolls back federal standards. That fight could end up creating one set of rules for cars sold in California and the 12 states that follow its lead, and weaker rules for the rest of the states, in effect splitting the nation into two markets.

Bloomberg: EPA Chief's $50-a-Night Rental Raises White House Angst
Environmental Protection Agency Administrator Scott Pruitt's lease at a Washington apartment owned by a lobbyist friend allowed him to pay $50 a night for a single bedroom -- but only on the nights when he actually slept there. White House officials are growing dismayed about the questions surrounding Pruitt's living arrangement, including his initial inability to produce any documentation about his lease or his actual payments, according to three officials. The landlord provided EPA officials with a copy of the lease and proof of the payments Pruitt made. The questions follow criticism of Pruitt for traveling first class on airline flights.

National News Highlights 3.30.18

The Wall Street Journal: Trump Dilemma: Give Businesses More Low-Skilled Work Visas or Not

Demand for low-skilled worker visas for the summer season starting Sunday is again far outstripping supply, with the Trump administration forced to choose between helping businesses seeking more visas or trying to save those jobs for American workers. Some lawmakers tried and failed this month to secure an increase in the number of H-2B visas available for this summer as part of a large spending bill. One Senate proposal would have permanently raised the annual cap from 66,000 to 90,000, with no limits for certain jobs in areas affected by disasters. A House version would have increased the annual cap to 132,000. The White House warned some lawmakers not to kick the decision to the Department of Homeland Security as they did in 2017, congressional aides said. "We did not want the discretion," an administration official said.

Politico: Trump's VA pick blindsides staff, deepens agency disarray

The timing of President Donald Trump's announcement to name Rear Admiral Ronny Jackson to lead Veterans Affairs was a snap decision that surprised his own chief of staff and knocked the government's second-largest agency, already bedeviled by scandal, deeper into disarray. White House chief of staff John Kelly had spoken with David Shulkin by phone Wednesday morning, reassuring the now-former VA secretary that he wouldn't be fired by tweet that afternoon. Hours later, Kelly had to phone Shulkin again telling him plans had changed. Trump declared Jackson's nomination on Twitter at 5:31 p.m. The tweet was big news — not just to the public, but to some senior aides, according to one White House official.

TRUMP TWEETS

The Casper Star-Tribune

http://trib.com/business/energy/epa-head-scott-pruitt-visits-major-wyoming-coal-mine-preaches/article_81c4e5f5-3cd9-569a-89fd-71cd4f9d91b1.html

EPA head Scott Pruitt visits major Wyoming coal mine, preaches end of 'war on fossil fuels'

By Heather Richards, 3/29/18

Two days after a crowd of 300 gathered in Gillette to debate the Environmental Protection Agency's authority to regulate emissions at the cost of the coal industry, the head of that agency stood 20 miles away in one of the largest surface coal mines in the country: Black Thunder.

Scott Pruitt, the controversial leader of the EPA, came to Wyoming at the invitation of Sens. John Barrasso and Mike Enzi to see the coal industry first hand. The state provides about 40 percent of the thermal coal burned in the U.S. for power and would be uniquely affected by a carbon dioxide rule like the Clean Power Plan.

The rule's goal of cutting carbon dioxide emissions in the electricity sector by about 30 percent compared to 2005 levels would have pressured utilities that buy Wyoming coal, wiping away customers that the coal industry around Wright and Gillette depend on.

Those in favor of the rule are largely concerned about emissions' contribution to climate change. Those opposed see it as an attack on the coal industry.

Pruitt echoed that sentiment in an interview after touring Black Thunder. He said it was time for the agency to reverse what he described as a political attack on the fossil fuel industry. The review of the Clean Power Plan, a signature regulation from the Obama administration, is part of that, he said

"Our job is not to coerce markets," Pruitt said. "Our job is not to come in and say this type of fuel is good or this fuel is not good."

The EPA's regulations and guidelines should follow behind industry choices, not dictate them, he said.

President Donald Trump, who appointed Pruitt, made repealing the emissions-cutting plan a central tenet of his campaign, promising a return of coal jobs.

Pruitt said Thursday the final decision on the Clean Power Plan is not certain. The agency would review the new round of comments on repeal and move forward.

"What we are in the process of doing is providing regulatory certainty," he said. "Then we need to look forward and say what authority do we have?"

However, Pruitt also said the Clean Power Plan appeared to be outside the bounds of the agency's authority under the Clean Air Act.

That is a position shared by others present at the mine Thursday including the senators, Gillette mayor Louise Carter King, Campbell County Commissioner Mark Christensen and the mayor of nearby Wright, Ralph Kingan.

"We cannot allow this incredible resource to be stranded in the ground," Barrasso said. "There is just so much energy here."

Enzi, once the mayor of Gillette, thanked Pruitt for coming in person. It's one thing to tell people about the size and scope of a mine like Black Thunder, owned by Arch Coal. But a visit to coal country, he said, "is worth a thousand pictures."

The Gillette News Record

http://www.gillettenewsrecord.com/news/article_21c9accd-9375-55b1-8716-d1e050b33078.html

EPA chief Pruitt visits Campbell County, touts importance of coal exports

By Greg Johnson, 3/29/18

The future of Powder River Basin coal lies overseas, something EPA Administrator Scott Pruitt stressed during a Thursday morning visit to the heart of Wyoming coal country.

As the guest of U.S. Sens. Mike Enzi and John Barrasso, both R-Wyoming, Pruitt toured Arch Coal's Black Thunder mine south of Wright, the second-largest producing thermal coal mine in the world.

Pruitt said he was impressed by the "size and scope" of the operation. Black Thunder produced 70.5 million tons of coal in 2017.

"Look at this and how impressive it is," he said. "To see what is done here with the amount of production, the automation, the technology and the commitment of the employees. … It was just impressive to see. And the most impressive were the people."

Since being named to head the EPA shortly after President Donald Trump took office, Pruitt said his agency has been working to pull back after acting beyond its mission during the Barack Obama administration.

"We were overstepping. Now we're correcting it," he said. "We have a job to do and I think what's been done the last several years was not the job of the agency. They were picking winners and losers, using regulatory power to influence and penalize certain forms of energy to help others.

"That's not the job of the EPA."

He said regulations like the Clean Power Plan are more punitive than helpful.

"Nowhere in the statute does it say 'penalize coal' or 'penalize fossil fuels,'" he said about the EPA's mandate.

Export potential

Pruitt also said coal should play a significant role in a balanced energy portfolio. Also, because of its low sulfur content, Powder River Basin coal can be a key to drastically reducing power plant emissions worldwide.

"If we really care about our air quality, we'll export Powder River Basin coal," he said. "The reason you want to export Powder River Basin coal is because countries internationally are using coal from Indonesia and other places, and it's not as good as it is here.

"Guess what that impacts? Our air quality. We have to figure out a way to get this coal exported to (those) countries. The demand is there. We're working on that, as others are."

That export bottleneck, where Wyoming coal can't be moved to or out of West Coast ports, is a priority for the EPA as well as the state, Pruitt said.

"We've got to get it worked out and we're looking at all options," he said. "We're on it. If you care about air quality, and I think we do as a country, then you want to export Powder River Basin coal."

Enzi expanded on that thought, saying that just burning a better quality coal will have a trickle down impact for West Coast states that are actively anti-coal.

"We could really clean up California, Oregon and Washington if we could get our coal to China and Japan," he said. "They're having to burn really bad stuff over there and the wind blows this way. It doesn't blow from out here to California, it blows from China to California.

"So, they really ought to be concerned about the pollution in China."

Seeing is believing

Enzi also thanked Pruitt for visiting the Black Thunder mine.

"We have been inviting secretaries of everything to Wyoming for a long time," he said. "This is a major coup to actually get him to come and see us."

He said visiting Gillette and the surrounding area does more to bust myths about coal mining than any amount of lobbying.

"I've said for a long time, a picture's worth 1,000 words, but a visit is worth 1,000 pictures," Enzi said. "Just with the size of the coal wall itself, it's hard to see a picture of that and get a feel for what this is all about."

Barrasso agreed, saying even more impressive than the scale of mining that happens here is the people who do it.

"You talk about dedicated, committed, conscientious people proud of the job they're doing to power America," he said. "There's no way words can describe what (Pruitt) saw here."

Before capping off his whirlwind visit to southern Campbell County, Pruitt said he believes the market should determine success or failure for the oil, gas and coal industries, not government policy.

"We're out of the business of picking winners and losers," he said.

Breitbart

http://www.breitbart.com/big-government/2018/03/29/delingpole-winning-scott-pruitt-bans-junk-science-from-environmental-protection-agency/

Scott Pruitt Is #Winning, Bans Junk Science from Environmental Protection Agency

By James Delingpole, 3/29/18

Junk science is no longer welcome at the Environmental Protection Agency. Administrator Scott Pruitt has declared war on what he calls "secret science" – the process whereby EPA regulators have been able to craft rules using non-publicly-available science data.

Pruitt told Daily Caller:

> "We need to make sure their data and methodology are published as part of the record. Otherwise, it's not transparent. It's not objectively measured, and that's important."

This decision will correct a longstanding injustice at the EPA, perpetrated against the U.S. taxpayer. For years the EPA has been able to behave as a law unto itself, cavalierly passing regulations which restrict freedoms, hamper business and hold back the U.S. economy for reasons which have much more to do with left-leaning environmentalist politics than with objective science.

The problem dates back to the early 1990s when the EPA decided it wanted to regulate fine particulate matter known as PM2.5 but couldn't find any hard scientific evidence proving it was harmful.

Steve Milloy takes up the story in the Wall Street Journal:

> PM2.5 was not known to cause death, but by 1994 EPA-supported scientists had developed two lines of research purporting to show that it did. When the studies were run past the EPA's Clean Air Science Advisory Committee, it balked. It believed the studies relied on dubious statistical analysis and asked for the underlying data. The EPA ignored the request.
>
> As the EPA prepared to issue its proposal for PM2.5 regulation in 1996, Congress stepped in. Rep. Thomas Bliley, chairman of the House Commerce Committee, sent a sharply written letter to Administrator Carol Browner asking for the data underlying studies. Ms. Browner delegated the response to a subordinate, who told Mr. Bliley the EPA saw "no useful purpose" in obtaining the data. Congress responded by inserting a provision in a 1998 bill requiring that data used to support federal regulation must be made available to the public via the Freedom of Information Act. But it was hastily written, and a federal appellate court held the law unenforceable in 2003.
>
> The controversy went dormant until 2011, when a newly Republican Congress took exception to the Obama EPA's anticoal rules, which relied on the same PM2.5 studies. Again the EPA was defiant. Administrator Gina McCarthy refused requests for the data sets and defied a congressional subpoena.

The EPA has form here. Its first administrator, William Ruckelshaus banned the use of DDT in the U.S. despite copious evidence that it was not harmful to human life. A seven month EPA hearing, presided over by Judge Edmund Sweeney, concluded in a 9,000 page document:

> "DDT is not a carcinogenic hazard to man...DDT is not a mutagenic or teratogenic hazard to man...The use of DDT under the regulations involved here do not have a deleterious effect on freshwater fish, estuarine organisms, wild birds or other wildlife."

Ruckelshaus simply ignored it because it did not suit the result he wanted.

Needless to say, the environmentalists are furious that the EPA now has to stick to science rather than political activism.

The New York Times has billed it as "an attack on science" – as if, somehow, scientific experiments conducted in secret for political ends are somehow more representative of "science" than experiments which are both open and independently reproducible.

Milloy, who has followed this scandal more closely than any journalist, has had great fun parsing the more absurd claims made by the NYT.

His comments on the article (in bold) can be found at his Junk Science website:

> Under the proposed policy, the agency would no longer consider scientific research unless the underlying raw data can be made public for other scientists and industry groups to examine. As a result, regulators crafting future rules would quite likely find themselves restricted from using some of the most consequential environmental research of recent decades, such as studies linking air pollution to premature deaths or work that measures human exposure to pesticides and other chemicals. [If you read my book "Scare Pollution," you cannot escape reaching the conclusion that the "studies linking air pollution to premature death" are not science, but fraud. After all, what reputable scientist would hide their data from public scrutiny for 20+ years? Only frauds do that. The NYTimes has elevated this fraud to the status of "research" when it has never been fairly reviewed or replicated.]
>
> Opponents and supporters agree that the proposed new policy has its roots in the fossil fuel industry's opposition to a groundbreaking 1993 Harvard University study that definitively linked polluted air to premature deaths. ["Definitively"? Really? Total ignorance on the part of the NYTimes or just, gotta keep that narrative going.] The "Six Cities" study, widely considered one of the most influential public health examinations ever conducted, tracked thousands of people for nearly two decades and ultimately formed the backbone of federal air pollution regulations. [The Six City Study is and always has been total fraud. That's why the Harvard researchers been hiding their data for 24 years. It has two types of defenders — the ignornant and the lying.]
>
> In that study, which began in the mid-1970s, scientists signed confidentiality agreements so they could track the private medical and occupational histories of more than 22,000 individuals in six cities around the country. They combined that personal data with home air-quality data in order to study the link between chronic exposure to air pollution and mortality. [Half of this study population were smokers or former smokers and virtually all were exposed to secondhand smoke. The exposure to PM2.5 from tobacco smoke far outweighs (by orders of magnitude) and PM2.5 in the outdoor air. Once again, no one cares about their personal information.]

Never mind the leftist #fakenews spin, though. For the moment – possibly for the first time since the organization was founded by Richard Nixon – genuine, reproducible science reigns at the EPA.

On energy and the environment, thanks to able administrators like Scott Pruitt, President Trump is most definitely #winning.

The New York Times

https://www.nytimes.com/2018/03/29/climate/epa-cafe-auto-pollution-rollback.html

E.P.A. Prepares to Roll Back Rules Requiring Cars to Be Cleaner and More Efficient

By Coral Davenport and Hiroko Tabuchi, 3/29/18

The Trump administration is expected to launch an effort in coming days to weaken greenhouse gas emissions and fuel economy standards for automobiles, handing a victory to car manufacturers and giving them ammunition to potentially roll back industry standards worldwide.

The move — which undercuts one of President Barack Obama's signature efforts to fight climate change — would also propel the Trump administration toward a courtroom clash with California, which has vowed to stick with the stricter rules even if Washington rolls back federal standards. That fight could end up creating one set of rules for cars sold in California and the 12 states that follow its lead, and weaker rules for the rest of the states, in effect splitting the nation into two markets.

Scott Pruitt, the head of the Environmental Protection Agency, is expected to frame the initiative as eliminating a regulatory burden on automakers that will result in more affordable trucks, vans and sport utility vehicles for buyers, according to people familiar with the plan.

An E.P.A. spokeswoman confirmed that Mr. Pruitt had sent a draft of the 16-page plan to the White House for approval.

The particulars of the plan are still being worked out. Those specifics, which are expected this year, could substantially roll back the Obama-era standards, according to two people familiar with the deliberations.

"This is certainly a big deal," said Robert Stavins, director of the Harvard environmental economics program. "The result will be more gas-guzzling vehicles on the road, greater total gasoline consumption, and a significant increase in carbon dioxide emissions."

According to two people familiar with the E.P.A.'s plans, Mr. Pruitt was scheduled to formally announce his proposal on Tuesday at an auto dealership in the Virginia suburbs, but the schedule remained in flux.

Major automakers would welcome the change. They are prepared to participate in making new rules that meet "our customers' needs for affordable, safe, clean and fuel-efficient transportation," said Gloria Bergquist, a spokeswoman for the Alliance of Automobile Manufactures, which represents many of the world's largest automakers.

In California, state lawyers said they were expecting a fight. The state has a special waiver under the 1970 Clean Air Act empowering it to enforce stronger air pollution standards than those set by the federal government, a holdover from California's history of setting its own air pollution regulations before the federal rules came into force. "We're prepared to do everything we need to defend the process," said Xavier Becerra, the attorney general of California, in an interview.

The California waiver gives the state considerable power to require automakers to stick to stricter standards. Not only is California a huge car market itself, but 12 other states including New York, Massachusetts and Pennsylvania have historically followed its lead. Together they represent more than a third of the domestic auto market.

"We're going to defend first and foremost existing federal greenhouse gas standards," Mr. Becerra said. "We're defending them because they're good for the entire nation. No one should think it's easy to undo something that's been not just good for the country, but good for the planet."

Mr. Pruitt has signaled that he is ready to take on such a challenge. "California is not the arbiter of these issues," he said in an interview with Bloomberg TV this month.

Under the Obama administration, the federal government toughened tailpipe pollution standards to match California's. Mr. Pruitt said the state standards "shouldn't and can't dictate to the rest of the country what these levels are going to be."

The E.P.A.'s senior clean air adviser, William Wehrum, this week traveled to California and met with the state's top clean air official, Mary Nichols. Both sides declined to detail what was discussed.
On Wednesday, a coalition of free-market groups including the Competitive Enterprise Institute urged Mr. Pruitt to take California on. "It is time for the E.P.A. to act," the groups said. If the agency did not act quickly, the groups said, "people across the state of California will be facing unrealistic and costly mandates which threaten their basic right to choose."

President Trump has also spoken about rolling back the efficiency rules, known as Corporate Average Fuel Economy, or Cafe. "I'm sure you've all heard the big news that we're going to work on the Cafe standards so you can make cars in America again," Mr. Trump said at a Detroit auto research facility in March last year. "We want to be the car capital of the world again. We will be, and it won't be long."

The rules, aimed at cutting tailpipe emissions of carbon dioxide, a major contributor to global warming, were one of the two pillars of Mr. Obama's climate change legacy. Put forth in 2012, they would have required automakers to nearly double the average fuel economy of new cars and trucks to 54.5 miles per gallon by 2025.

If fully implemented, the rules would have cut oil consumption by about 12 billion barrels and reduced carbon dioxide pollution by about six billion tons over the lifetime of all the cars affected by the regulations, according to E.P.A. projections.

The rules also would have put the United States, historically a laggard in fuel economy regulations, at the forefront worldwide in the manufacture of electric and highly fuel efficient vehicles. The United States and Canada are the only major nations that have adopted mandatory emissions standards through 2025. The European Union has only recently proposed standards for 2025 and 2030, while China has only started to work on standards for those years.

Less restrictive regulations in the United States could provide an opening for automakers to push for more lenient standards elsewhere as well, leading to the emission of more pollution by cars around the world. While sales of electric vehicles are starting to take off, they still represent barely 1 percent of global car sales. A shift among car buyers toward larger cars and trucks is already impeding progress in fuel economy.

"The concern is that automakers will go around the world basically trying to lobby regulators, saying, look, because the United States has reduced the pace, everywhere else should too," said Anup Bandivadekar, a researcher at the International Council on Clean Transportation, a think tank that focuses on clean car technology and policy. Global carmakers "apply developments in one region to lobby for changes in other regions."

American automakers initially accepted the plan by Mr. Obama in 2009 to harmonize what was then a hodgepodge of pollution and efficiency standards set by the E.P.A., the National Highway Traffic Safety Administration and California. And the automakers weren't in much of a position to resist; they had just taken an $80 billion bailout to survive a global economic crisis.

The plan would have spurred automakers to speed their development of highly fuel-efficient vehicles including hybrid and electric cars. But within weeks of Mr. Trump's inauguration last year, the chief executives of the nation's Big Three auto companies met with him in the Oval Office to say that the Obama tailpipe standard was too difficult to achieve.

Mr. Trump directed the E.P.A. under Mr. Pruitt to craft a new, less strict set of standards. The announcement expected on Tuesday would represent the first legal step in the process.

While Mr. Pruitt's proposal to open up the Obama rules to review isn't expected to include specific targets, "The proposed rollback is going to be quite a significant number," said Myron Ebell, who led Mr. Trump's E.P.A. transition team and directs the energy and environment policy at the Competitive Enterprise Institute, a Washington research organization that questions the established science of human-caused climate change. "It will be more than a couple m.p.g.," he said.

If the legal fight between California and the Trump administration escalates, one possibility is that the federal government might try to revoke the waiver allowing California to set its own rules. Some presidents, including George W. Bush, have considered revoking the waiver, but none have tried.

The announcement by Mr. Pruitt was not expected to include a decision on challenging the waiver.

Mr. Ebell suggested that one possible legal tactic for the Trump administration could be to announce that it will refuse to renew the current waiver on tailpipe emissions, which expires in 2025, rather than to revoke it outright. That would likely delay a court fight until California moves to set standards that go beyond 2025.

But such a move would also likely formalize, at least for the time being, two different sets of rules in the United States — the federal emissions rules, and California's stricter ones — a logistical headache for the industry.

While California and its ally states have long followed separate smog standards, those have been easier for automakers to meet because a car can be brought into compliance by adding a catalytic converter, for example. Designing for separate mileage standards is more difficult, because fuel economy is dependent on a car's weight and design.

A divided market could require substantially different car designs, experts say, putting the American auto industry into uncharted territory. It remains unclear how the issue might be resolved. One possibility is that two very different auto markets emerge, one with cleaner cars generally along the coasts, and another with more polluting cars concentrated in Middle America. On the other hand, automakers might also opt to generally adhere to the stricter California standards nationwide, blunting the impact of any Trump administration rollback of federal rules.

The automakers had hoped to avoid these complex scenarios by using their clout with the Trump administration to force California to go along with a relaxation of federal regulations. But "if they thought this would end by California rolling over and giving up its more stringent standards," said Kevin Poloncarz, a San Francisco lawyer who focuses on air and climate change law, "that was a miscalculation."

As a result, the automakers' victory might come with unexpected headaches for them, said Jody Freeman, a Harvard law professor and former counsel to the Obama administration.

For instance, if the rest of the world moves toward stricter rules anyway, the American market could find itself an industry laggard, ceding leadership in clean vehicle technology to markets like China or the European Union. "I don't really know if the auto industry wants what this administration might be doing," she said. "It might be like the dog that caught the car."

North Jersey

https://www.northjersey.com/story/news/environment/2018/03/28/epa-begins-monitoring-air-residential-areas-fumes-wafting-edgewater-superfund-site/458747002/

EPA begins monitoring air in residential areas for fumes wafting from Edgewater Superfund site By Scott Fallon, 3/29/18

Environmental regulators have begun monitoring the air at residential developments near the Quanta Superfund site to see if elevated levels of a potentially dangerous chemical are wafting from cleanup work on the property that residents have been complaining about for months, officials said Wednesday.

The news came as more than 100 people packed a public meeting at Borough Hall where U.S. Environmental Protection Agency officials detailed steps they are taking to control fumes from the site, including elevated levels of naphthalene.

Agency officials said they would suppress the fumes with foam, air misters along the fence, plastic sheeting and other methods. EPA officials maintained that the naphthalene levels are not a public health risk although many in the audience remained skeptical.

"You have to take responsibility," Jane Hoffman, who lives adjacent to the site, said at the meeting to EPA officials. "There are people who have spent their life savings to buy a home here."

Residents have been complaining about the fumes for months, saying they are unrelenting even when work at the site has been halted. As a result, the EPA has established a new 24-hour hotline that residents can call if they smell odors from the site: 201-807-0991.

The site is undergoing a controversial $78 million cleanup by Honeywell and supervised by EPA where workers have to dig up contaminated soil to pump in cement that will keep coal tar, arsenic and oil byproducts from migrating offsite. Many residents had wanted the pollution excavated at the Hudson River site not entombed in perpetuity under a proposed housing complex.

Elevated levels of naphthalene have been emanating from the site almost every work day since May, according to air monitoring data provided by Honeywell.

Naphthalene continued to exceed the site's risk screening level of 4.62 micrograms per cubic meter in March with a high in recent weeks of 120 micrograms per cubic meter on March 19, which is 26 times the screening level.

EPA has begun taken air samples at three residential developments near the Quanta site – City Place, iPark and Independence Harbor. Two samples taken this month – one at City Place and another at iPark – had naphthalene levels slightly above 4.62 micrograms per cubic meter. The rest were either below the level or no naphthalene was detected. Samples taken last year did not exceed any risk levels, EPA officials said.

Naphthalene is "reasonably anticipated" to be a human carcinogen by the U.S. Department of Health and Human Services because studies showed that lab rats formed lung and nose tumors when breathing in the chemical daily. The EPA and the World Health Organization classify naphthalene as a possible human carcinogen.

EPA has said even the highest levels of naphthalene recorded at Quanta – 1,000 micrograms per cubic meter on Sept. 15 – do not present a health risk.

The screening level is based on the assumption that an individual is located at the perimeter of the Quanta site for 10 hours per day, five days per week, for 1½ years, regulators said.

"It's meant to be very conservative," Lora Smith, an EPA human health risk assessor, said of the 4.62 level. She said the Occupational Health and Safety Administration's exposure limit for workers is 50,000 micrograms per cubic meter and that is why workers do not wear respirators on site.

"Exceedances are not unexpected and they do not indicate there is an imminent public health threat," she said.

But residents have argued that condos, apartments, restaurants, stores and a hotel surround the Quanta site allowing prolonged exposure to the fumes in close proximity. Work at the site was temporarily halted following an article in The Record detailing the site's problems.

Dana Prigge, who lives near the site, said the fumes from Quanta can be noxious. She said she was overcome one day last month while walking near River Road.

"My eyes were burning, my nose was burning, my lungs were pulling in," she said in an interview before the meeting. "I knew there were chemicals in the air because I never react this way."

The fumes have become so bad that Prigge plans to move out of Edgewater when her lease is up in a few months.

"If I could move out tomorrow, I would," she said.

Bloomberg

https://www.bloomberg.com/news/articles/2018-03-30/epa-chief-s-50-a-night-rental-said-to-raise-white-house-angst

EPA Chief's $50-a-Night Rental Raises White House Angst

By Jennifer Dlouhy and Jennifer Jacobs

Environmental Protection Agency Administrator Scott Pruitt's lease at a Washington apartment owned by a lobbyist friend allowed him to pay $50 a night for a single bedroom -- but only on the nights when he actually slept there.

White House officials are growing dismayed about the questions surrounding Pruitt's living arrangement, including his initial inability to produce any documentation about his lease or his actual payments, according to three officials. The landlord provided EPA officials with a copy of the lease and proof of the payments Pruitt made.

The questions follow criticism of Pruitt for traveling first class on airline flights.

In all, Pruitt paid $6,100 to use the room for roughly six months, according to copies of the checks reviewed by Bloomberg. Those checks show varying amounts paid on sporadic dates -- not a traditional monthly "rent payment" of the same amount each month.

That was because of the unusual rent schedule -- not a single monthly amount, but a daily amount charged only for days used for a single bedroom in the two-bedroom unit just blocks from the Capitol. The owner is a health care lobbyist, Vicki Hart. Her husband J. Steven Hart, is also a lobbyist and his firm represents clients in industries regulated by the EPA.

One person familiar with the lease compared it to an Airbnb-style arrangement, but Pruitt wasn't a transient and instead made the apartment his home on nights he was in Washington. The lease -- reviewed by Bloomberg -- says that he was charged $50 a night "based on days of actual occupancy."

Six Canceled Checks
Bloomberg reviewed six canceled checks paid by Pruitt totaling $6,100 from March 18 through Sept 1, 2017. He paid $450 on March 18, $900 on April 26, $850 on May 15, $700 on June 4, $1,500 on July 22 and $1,700 on Sept 1.

Justina Fugh, who has been ethics counsel at the EPA for a dozen years, said the arrangement wasn't an ethics issue because Pruitt paid rent. An aide said the agency had not reviewed the arrangement in advance.

The payments covered Pruitt's room in the two-bedroom unit, but did not afford him liberal use of common areas, where the owners had dinner parties and other functions, according to a person familiar with the situation. Someone else rented the other bedroom. According to the lease agreement, Pruitt's bedroom could not be locked.

After ABC News reported the living arrangement on Thursday, EPA aides had to seek documentation from the building's owners to prove he had paid rent, raising concerns at the White House, said two of the people, who asked not to be named discussing a sensitive matter involving a Cabinet secretary. Pruitt was in Wyoming on Thursday.

Related: Bumped? EPA Chief Signals He Will Be Flying Coach After Backlash

The disclosure follows revelations about Pruitt's reliance on first-class flights to travel around the globe and a series of pricey trips, including a visit by Pruitt and agency staff to Italy that cost $120,249. EPA officials have defended Pruitt's use of first-class flights on security grounds, but after a series of reports, he shifted to coach.

J. Steven Hart is the chairman of Williams & Jensen, a firm with a stable of energy industry clients including Oklahoma Gas & Electric Co., which paid the firm $400,000 in 2017, according to data compiled from the Environmental Integrity Project from disclosure forms.

Pruitt, the former attorney general of Oklahoma, has been an enthusiastic crusader against Obama-era regulations meant to combat climate change and limit air pollution. When Pruitt was in Oklahoma, he sued the EPA more than a dozen times.

Hart's individual lobbying clients include liquefied natural gas exporter Cheniere Energy Inc., the American Automotive Policy Council and Smithfield Foods Inc. But the Department of Energy -- not the EPA -- plays the major federal role overseeing LNG exports, and it is not clear Hart had direct contact with the EPA on behalf of any of his lobbying clients in 2017, according to a Bloomberg News review of disclosures.

"At the very least, it doesn't look good for the administrator of EPA to have rented an apartment from the wife of an energy industry lobbyist who represents companies regulated by EPA," said Eric Schaeffer, director of the Environmental Integrity Project.

Schaeffer called on EPA's inspector general and Congress to investigate.

Fugh, the EPA's ethics counsel, said no gift was involved. It was a routine business arrangement between Pruitt and an individual, not a lobbying firm, she added.

"He paid a fair price for what amounts to just a room," Fugh said. "So I don't even think that the fact that the house is owned by a person whose job is to be a lobbyist causes us concern."

The Wall Street Journal

https://www.wsj.com/articles/trump-dilemma-give-businesses-more-low-skilled-work-visas-or-not-1522407601

Trump Dilemma: Give Businesses More Low-Skilled Work Visas or Not

By Laura Meckler, 3/30/18

Demand for low-skilled worker visas for the summer season starting Sunday is again far outstripping supply, with the Trump administration forced to choose between helping businesses seeking more visas or trying to save those jobs for American workers.

Some lawmakers tried and failed this month to secure an increase in the number of H-2B visas available for this summer as part of a large spending bill. One Senate proposal would have permanently raised the annual cap from 66,000 to 90,000, with no limits for certain jobs in areas affected by disasters. A House version would have increased the annual cap to 132,000.

The White House warned some lawmakers not to kick the decision to the Department of Homeland Security as they did in 2017, congressional aides said. "We did not want the discretion," an administration official said.

Nonetheless, DHS is now under pressure from the business community to provide more visas after the spending bill authorized the department's Secretary Kirstjen Nielsen to offer tens of thousands of extra visas if she sees fit.

A DHS spokeswoman, Katie Waldman, said no decision has been made. "We are currently looking at last year's implementation of the H-2B plus-up to determine how best to proceed this fiscal year," she said.

The H-2B visas, issued for low-skilled, seasonal foreign workers, are typically employed by landscaping companies, Alaskan fisheries, ski resorts and vacation spots, including some of President Donald Trump's properties.

Backers say the program provides needed foreign workers, often in remote locations where Americans are scarce. They say the problem is particularly acute given the current unemployment rate of 4.1%, the lowest in a decade.

"We rebranded 8,000 vehicles and put 'now hiring' on everything we own. We cannot get enough workers," said Todd Chambers, chief marketing officer for BrightView Landscapes, LLC, a large landscaping company that has used H-2B workers for more than a decade.

Opponents say businesses should try harder and raise wages if needed. "We should want the labor market to tighten and employers have to work overtime trying to entice American workers, especially those who've dropped out of the labor market," said Mark Krikorian of the conservative Center for Immigration Studies.

Ultimately, Democratic leaders killed the proposals to increase the visas, congressional aides in both parties said. Democratic aides said that was partly because they weren't willing to import more foreign workers at a time when Congress was failing to protect hundreds of thousands of young undocumented immigrants brought to the U.S. as children, known as Dreamers.

By statute, a total of 66,000 H-2B visas are available each year, divided evenly between winter and summer seasons. In past years, Congress has effectively raised the cap by exempting workers who are returning to jobs they had in previous seasons, but didn't do so last year nor this year.

For this summer season, businesses filed requests for more than 81,000 workers with the Labor Department on Jan. 1, the first day possible, a record, and more since then. Many firms tried to file applications after midnight on New Year's Eve to be near the front of the line.

This year, for the first time, DHS conducted a lottery among early applicants to pick winners, saying it was only fair given the crush of demand. Administration officials said that applications cleared by the Labor Department by mid-February were eligible. But several people who use the program said they were confused about why some petitions were included in the draw and others weren't.

BrightView Landscapes filed 94 petitions requesting a total of 3,500 visas, but was awarded fewer than 500, compared with 1,600 last year, said Sarah Powenski, vice president and associate general counsel at the company.

Company officials say they are frustrated that the program has been caught up in the larger immigration debate. "This thing has become more of an immigration issue in people's minds," said Mr. Chambers. "It's been attached to a third rail issue."

Faced with the same situation last year, John Kelly, then DHS secretary and now White House chief of staff, fumed. He argued that if Congress wanted more visas, then lawmakers should have approved them.

Many lawmakers lobbied him to approve additional visas. His boss, President Donald Trump, ran for office promising to protect American workers against foreign competition, and White House officials pressured him against it, according to people familiar with the decision making.

Ultimately, Mr. Kelly allowed up to 15,000 additional visas for guest workers, though not until the summer was half over. He set a high bar for businesses that wanted to apply and described the approval as a "one-time" move.

Politico

https://www.politico.com/story/2018/03/29/trumps-veterans-pick-agency-451219

Trump's VA pick blindsides staff, deepens agency disarray

By Lorraine Woellert, Eliana Johnson, and Connor O'Brien, 3/29/18

The timing of President Donald Trump's announcement to name Rear Admiral Ronny Jackson to lead Veterans Affairs was a snap decision that surprised his own chief of staff and knocked the government's second-largest agency, already bedeviled by scandal, deeper into disarray.

White House chief of staff John Kelly had spoken with David Shulkin by phone Wednesday morning, reassuring the now-former VA secretary that he wouldn't be fired by tweet that afternoon. Hours later, Kelly had to phone Shulkin again telling him plans had changed.

Trump declared Jackson's nomination on Twitter at 5:31 p.m. The tweet was big news — not just to the public, but to some senior aides, according to one White House official.

The chaos — by now a typical part of the president's management style — has for months upended Kelly's attempts to ensure that an unorthodox White House adheres to traditional processes. But while White House aides are left unpacking the day's events, the drama at the VA is just beginning.

Deputy Secretary Thomas Bowman, a Trump appointee who is the agency's No. 2, is widely expected to leave soon, either by choice or by force. Kelly and other aides wanted Bowman gone before Shulkin left to avoid installing the deputy at the helm, even temporarily. Bowman had pushed back on broad privatization efforts, leading Trump to berate him in an Oval Office meeting for his lack of loyalty.

Trump got around the Bowman problem by naming Robert Wilkie, an undersecretary at the Department of Defense, to the temporary job. A Capitol Hill veteran and member of Trump's transition team, Wilkie is a former senior adviser to Sen. Thom Tillis (R-N.C.), who supports expanding service members' access to private doctors.

"He's got a department that's in turmoil. It's in crisis. There's warfare there," said Anthony Principi, who led the agency under former President George W. Bush. "And you have an acting secretary who doesn't know the VA."

But if and when Bowman departs, Wilkie will be left with a shallow bench at an agency already paralyzed by political mistrust, some veterans' advocates say. The VA's health and benefit agencies — which administer tens of billions of dollars in health programs, pensions, survivor benefits and other forms of assistance to some 9 million service members — have been without Senate-confirmed officials since the Obama administration.

Veterans Affairs is the second-largest federal agency, behind only the Department of Defense, with 377,000 employees. And it has proven unwieldy even when led by highly decorated, experienced administrators such as Eric Shinseki, a retired four-star Army general who resigned during the Obama administration amid a scandal over lengthy wait times and faulty scheduling practices for medical appointments.

Shinseki was followed by Bob McDonald, an Army veteran and former Procter & Gamble CEO. Shulkin, McDonald's successor, was the first non-veteran to lead the VA.

As recently as two weeks ago, the Trump White House was still making overtures to potential candidates for the top job, according to a person with direct knowledge of the inquiries. Trump reportedly agonized over the decision, changing his mind several times, a senior administration official said.

"Instead of going through the paces to convince the best possible person to take this job, they're going with the person who's still on active duty in the Navy and can't say no to the commander in chief," said one Obama White House aide, who spoke highly of Jackson as a doctor and individual. "You could look at it as them giving up trying to find a competent commander or manager to fix the problems."

Shulkin had come under fire after a VA inspector general's report accused him of improperly accepting tickets to the Wimbledon tennis tournament and using his agency staff to arrange a sightseeing tour of Denmark and England. He repaid the VA for the trip. The longtime hospital administrator, who was engaged in open warfare with conservatives in the department intent on privatizing the VA, contended he was set up.

Veterans' groups remained loyal to Shulkin, whom they saw as their best line of defense of against privatization. During his campaign, Trump made promises that veterans would be allowed to seek medical treatment outside the VA's system, statements taken by some to mean a step toward handing the system to commercial companies to manage.

Jackson, while well-liked by both Republicans and Democrats, is a cipher on privatization and other policy issues. With no agency experience to speak of, veterans suspect he could be installed as a figurehead, leaving lower-level appointees to steer the agency toward privatization.

"He's a blank slate. Nobody knows really anything about his competency or capacity for this job," said Paul Rieckhoff, CEO of Iraq and Afghanistan Veterans of America. "We especially know that being a veteran doesn't qualify you to run the VA any more than being a soldier qualifies you to run the DoD."

Principi urged Jackson to move quickly on his own agenda.

"The new secretary, really, if he wants to accomplish anything, has to hit the deck running and has to bring in some very, very good people," he said. "I hope and pray he's a success. Because if he's not, American veterans are going to be the losers."

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EPA News Highlights 3.30.18

Casper Start-Tribune: EPA head Scott Pruitt visits major Wyoming coal mine, preaches end of 'war on fossil fuels'

Two days after a crowd of 300 gathered in Gillette to debate the Environmental Protection Agency's authority to regulate emissions at the cost of the coal industry, the head of that agency stood 20 miles away in one of the largest surface coal mines in the country: Black Thunder. Scott Pruitt, the controversial leader of the EPA, came to Wyoming at the invitation of Sens. John Barrasso and Mike Enzi to see the coal industry first hand. The state provides about 40 percent of the thermal coal burned in the U.S. for power and would be uniquely affected by a carbon dioxide rule like the Clean Power Plan. The rule's goal of cutting carbon dioxide emissions in the electricity sector by about 30 percent compared to 2005 levels would have pressured utilities that buy Wyoming coal, wiping away customers that the coal industry around Wright and Gillette depend on.

Gillette News Record: EPA chief Pruitt visits Campbell County, touts importance of coal exports

The future of Powder River Basin coal lies overseas, something EPA Administrator Scott Pruitt stressed during a Thursday morning visit to the heart of Wyoming coal country. As the guest of U.S. Sens. Mike Enzi and John Barrasso, both R-Wyoming, Pruitt toured Arch Coal's Black Thunder mine south of Wright, the second-largest producing thermal coal mine in the world. Pruitt said he was impressed by the "size and scope" of the operation. Black Thunder produced 70.5 million tons of coal in 2017. "Look at this and how impressive it is," he said. "To see what is done here with the amount of production, the automation, the technology and the commitment of the employees. … It was just impressive to see. And the most impressive were the people."

Breitbart: Scott Pruitt Is #Winning, Bans Junk Science from Environmental Protection Agency

Junk science is no longer welcome at the Environmental Protection Agency. Administrator Scott Pruitt has declared war on what he calls "secret science" – the process whereby EPA regulators have been able to craft rules using non-publicly-available science data…This decision will correct a longstanding injustice at the EPA, perpetrated against the U.S. taxpayer. For years the EPA has been able to behave as a law unto itself, cavalierly passing regulations which restrict freedoms, hamper business and hold back the U.S. economy for reasons which have much more to do with left-leaning environmentalist politics than with objective science.

New York Times: E.P.A. Prepares to Roll Back Rules Requiring Cars to Be Cleaner and More Efficient

The Trump administration is expected to launch an effort in coming days to weaken greenhouse gas emissions and fuel economy standards for automobiles, handing a victory to car manufacturers and giving them ammunition to potentially roll back industry standards worldwide. The move — which undercuts one of President Barack Obama's signature efforts to fight climate change — would also propel the Trump administration toward a courtroom clash with California, which has vowed to stick with the stricter rules even if Washington rolls back federal standards. That fight could end up creating one set of rules for cars sold in California and the 12 states that follow its lead, and weaker rules for the rest of the states, in effect splitting the nation into two markets.

Bloomberg: EPA Chief's $50-a-Night Rental Raises White House Angst

Environmental Protection Agency Administrator Scott Pruitt's lease at a Washington apartment owned by a lobbyist friend allowed him to pay $50 a night for a single bedroom -- but only on the nights when he actually slept there. White House officials are growing dismayed about the questions surrounding Pruitt's living arrangement, including his initial inability to produce any documentation about his lease

or his actual payments, according to three officials. The landlord provided EPA officials with a copy of the lease and proof of the payments Pruitt made. The questions follow criticism of Pruitt for traveling first class on airline flights.

National News Highlights 3.30.18

The Wall Street Journal: Trump Dilemma: Give Businesses More Low-Skilled Work Visas or Not
Demand for low-skilled worker visas for the summer season starting Sunday is again far outstripping supply, with the Trump administration forced to choose between helping businesses seeking more visas or trying to save those jobs for American workers. Some lawmakers tried and failed this month to secure an increase in the number of H-2B visas available for this summer as part of a large spending bill. One Senate proposal would have permanently raised the annual cap from 66,000 to 90,000, with no limits for certain jobs in areas affected by disasters. A House version would have increased the annual cap to 132,000. The White House warned some lawmakers not to kick the decision to the Department of Homeland Security as they did in 2017, congressional aides said. "We did not want the discretion," an administration official said.

Politico: Trump's VA pick blindsides staff, deepens agency disarray
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TRUMP TWEETS

The Casper Star-Tribune
http://trib.com/business/energy/epa-head-scott-pruitt-visits-major-wyoming-coal-mine-preaches/article_81c4e5f5-3cd9-569a-89fd-71cd4f9d91b1.html
EPA head Scott Pruitt visits major Wyoming coal mine, preaches end of 'war on fossil fuels'
By Heather Richards, 3/29/18

Two days after a crowd of 300 gathered in Gillette to debate the Environmental Protection Agency's authority to regulate emissions at the cost of the coal industry, the head of that agency stood 20 miles away in one of the largest surface coal mines in the country: Black Thunder.

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The rule's goal of cutting carbon dioxide emissions in the electricity sector by about 30 percent compared to 2005 levels would have pressured utilities that buy Wyoming coal, wiping away customers that the coal industry around Wright and Gillette depend on.

Those in favor of the rule are largely concerned about emissions' contribution to climate change. Those opposed see it as an attack on the coal industry.

Pruitt echoed that sentiment in an interview after touring Black Thunder. He said it was time for the agency to reverse what he described as a political attack on the fossil fuel industry. The review of the Clean Power Plan, a signature regulation from the Obama administration, is part of that, he said

"Our job is not to coerce markets," Pruitt said. "Our job is not to come in and say this type of fuel is good or this fuel is not good."

The EPA's regulations and guidelines should follow behind industry choices, not dictate them, he said.

President Donald Trump, who appointed Pruitt, made repealing the emissions-cutting plan a central tenet of his campaign, promising a return of coal jobs.

Pruitt said Thursday the final decision on the Clean Power Plan is not certain. The agency would review the new round of comments on repeal and move forward.

"What we are in the process of doing is providing regulatory certainty," he said. "Then we need to look forward and say what authority do we have?"

However, Pruitt also said the Clean Power Plan appeared to be outside the bounds of the agency's authority under the Clean Air Act.

That is a position shared by others present at the mine Thursday including the senators, Gillette mayor Louise Carter King, Campbell County Commissioner Mark Christensen and the mayor of nearby Wright, Ralph Kingan.

"We cannot allow this incredible resource to be stranded in the ground," Barrasso said. "There is just so much energy here."

Enzi, once the mayor of Gillette, thanked Pruitt for coming in person. It's one thing to tell people about the size and scope of a mine like Black Thunder, owned by Arch Coal. But a visit to coal country, he said, "is worth a thousand pictures."

The Gillette News Record
http://www.gillettenewsrecord.com/news/article_21c9accd-9375-55b1-8716-d1e050b33078.html

EPA chief Pruitt visits Campbell County, touts importance of coal exports

By Greg Johnson, 3/29/18

The future of Powder River Basin coal lies overseas, something EPA Administrator Scott Pruitt stressed during a Thursday morning visit to the heart of Wyoming coal country.

As the guest of U.S. Sens. Mike Enzi and John Barrasso, both R-Wyoming, Pruitt toured Arch Coal's Black Thunder mine south of Wright, the second-largest producing thermal coal mine in the world.

Pruitt said he was impressed by the "size and scope" of the operation. Black Thunder produced 70.5 million tons of coal in 2017.

"Look at this and how impressive it is," he said. "To see what is done here with the amount of production, the automation, the technology and the commitment of the employees. ... It was just impressive to see. And the most impressive were the people."

Since being named to head the EPA shortly after President Donald Trump took office, Pruitt said his agency has been working to pull back after acting beyond its mission during the Barack Obama administration.

"We were overstepping. Now we're correcting it," he said. "We have a job to do and I think what's been done the last several years was not the job of the agency. They were picking winners and losers, using regulatory power to influence and penalize certain forms of energy to help others.

"That's not the job of the EPA."

He said regulations like the Clean Power Plan are more punitive than helpful.

"Nowhere in the statute does it say 'penalize coal' or 'penalize fossil fuels,'" he said about the EPA's mandate.

Export potential

Pruitt also said coal should play a significant role in a balanced energy portfolio. Also, because of its low sulfur content, Powder River Basin coal can be a key to drastically reducing power plant emissions worldwide.

"If we really care about our air quality, we'll export Powder River Basin coal," he said. "The reason you want to export Powder River Basin coal is because countries internationally are using coal from Indonesia and other places, and it's not as good as it is here.

"Guess what that impacts? Our air quality. We have to figure out a way to get this coal exported to (those) countries. The demand is there. We're working on that, as others are."

That export bottleneck, where Wyoming coal can't be moved to or out of West Coast ports, is a priority for the EPA as well as the state, Pruitt said.

"We've got to get it worked out and we're looking at all options," he said. "We're on it. If you care about air quality, and I think we do as a country, then you want to export Powder River Basin coal."

Enzi expanded on that thought, saying that just burning a better quality coal will have a trickle down impact for West Coast states that are actively anti-coal.

"We could really clean up California, Oregon and Washington if we could get our coal to China and Japan," he said. "They're having to burn really bad stuff over there and the wind blows this way. It doesn't blow from out here to California, it blows from China to California.

"So, they really ought to be concerned about the pollution in China."

Seeing is believing

Enzi also thanked Pruitt for visiting the Black Thunder mine.

"We have been inviting secretaries of everything to Wyoming for a long time," he said. "This is a major coup to actually get him to come and see us."

He said visiting Gillette and the surrounding area does more to bust myths about coal mining than any amount of lobbying.

"I've said for a long time, a picture's worth 1,000 words, but a visit is worth 1,000 pictures," Enzi said. "Just with the size of the coal wall itself, it's hard to see a picture of that and get a feel for what this is all about."

Barrasso agreed, saying even more impressive than the scale of mining that happens here is the people who do it.

"You talk about dedicated, committed, conscientious people proud of the job they're doing to power America," he said. "There's no way words can describe what (Pruitt) saw here."

Before capping off his whirlwind visit to southern Campbell County, Pruitt said he believes the market should determine success or failure for the oil, gas and coal industries, not government policy.

"We're out of the business of picking winners and losers," he said.

Breitbart

http://www.breitbart.com/big-government/2018/03/29/delingpole-winning-scott-pruitt-bans-junk-science-from-environmental-protection-agency/

Scott Pruitt Is #Winning, Bans Junk Science from Environmental Protection Agency

By James Delingpole, 3/29/18

Junk science is no longer welcome at the Environmental Protection Agency. Administrator Scott Pruitt has declared war on what he calls "secret science" – the process whereby EPA regulators have been able to craft rules using non-publicly-available science data.

Pruitt told Daily Caller:

> "We need to make sure their data and methodology are published as part of the record. Otherwise, it's not transparent. It's not objectively measured, and that's important."

This decision will correct a longstanding injustice at the EPA, perpetrated against the U.S. taxpayer. For years the EPA has been able to behave as a law unto itself, cavalierly passing regulations which restrict

freedoms, hamper business and hold back the U.S. economy for reasons which have much more to do with left-leaning environmentalist politics than with objective science.

The problem dates back to the early 1990s when the EPA decided it wanted to regulate fine particulate matter known as PM2.5 but couldn't find any hard scientific evidence proving it was harmful.

Steve Milloy takes up the story in the Wall Street Journal:

> PM2.5 was not known to cause death, but by 1994 EPA-supported scientists had developed two lines of research purporting to show that it did. When the studies were run past the EPA's Clean Air Science Advisory Committee, it balked. It believed the studies relied on dubious statistical analysis and asked for the underlying data. The EPA ignored the request.
>
> As the EPA prepared to issue its proposal for PM2.5 regulation in 1996, Congress stepped in. Rep. Thomas Bliley, chairman of the House Commerce Committee, sent a sharply written letter to Administrator Carol Browner asking for the data underlying studies. Ms. Browner delegated the response to a subordinate, who told Mr. Bliley the EPA saw "no useful purpose" in obtaining the data. Congress responded by inserting a provision in a 1998 bill requiring that data used to support federal regulation must be made available to the public via the Freedom of Information Act. But it was hastily written, and a federal appellate court held the law unenforceable in 2003.
>
> The controversy went dormant until 2011, when a newly Republican Congress took exception to the Obama EPA's anticoal rules, which relied on the same PM2.5 studies. Again the EPA was defiant. Administrator Gina McCarthy refused requests for the data sets and defied a congressional subpoena.

The EPA has form here. Its first administrator, William Ruckelshaus banned the use of DDT in the U.S. despite copious evidence that it was not harmful to human life. A seven month EPA hearing, presided over by Judge Edmund Sweeney, concluded in a 9,000 page document:

> "DDT is not a carcinogenic hazard to man...DDT is not a mutagenic or teratogenic hazard to man...The use of DDT under the regulations involved here do not have a deleterious effect on freshwater fish, estuarine organisms, wild birds or other wildlife."

Ruckelshaus simply ignored it because it did not suit the result he wanted.

Needless to say, the environmentalists are furious that the EPA now has to stick to science rather than political activism.

The New York Times has billed it as "an attack on science" – as if, somehow, scientific experiments conducted in secret for political ends are somehow more representative of "science" than experiments which are both open and independently reproducible.

Milloy, who has followed this scandal more closely than any journalist, has had great fun parsing the more absurd claims made by the NYT.

His comments on the article (in bold) can be found at his Junk Science website:

Under the proposed policy, the agency would no longer consider scientific research unless the underlying raw data can be made public for other scientists and industry groups to examine. As a result, regulators crafting future rules would quite likely find themselves restricted from using some of the most consequential environmental research of recent decades, such as studies linking air pollution to premature deaths or work that measures human exposure to pesticides and other chemicals. [If you read my book "Scare Pollution," you cannot escape reaching the conclusion that the "studies linking air pollution to premature death" are not science, but fraud. After all, what reputable scientist would hide their data from public scrutiny for 20+ years? Only frauds do that. The NYTimes has elevated this fraud to the status of "research" when it has never been fairly reviewed or replicated.]

Opponents and supporters agree that the proposed new policy has its roots in the fossil fuel industry's opposition to a groundbreaking 1993 Harvard University study that definitively linked polluted air to premature deaths. ["Definitively"? Really? Total ignorance on the part of the NYTimes or just, gotta keep that narrative going.] The "Six Cities" study, widely considered one of the most influential public health examinations ever conducted, tracked thousands of people for nearly two decades and ultimately formed the backbone of federal air pollution regulations. [The Six City Study is and always has been total fraud. That's why the Harvard researchers been hiding their data for 24 years. It has two types of defenders — the ignornant and the lying.]

In that study, which began in the mid-1970s, scientists signed confidentiality agreements so they could track the private medical and occupational histories of more than 22,000 individuals in six cities around the country. They combined that personal data with home air-quality data in order to study the link between chronic exposure to air pollution and mortality. [Half of this study population were smokers or former smokers and virtually all were exposed to secondhand smoke. The exposure to PM2.5 from tobacco smoke far outweighs (by orders of magnitude) and PM2.5 in the outdoor air. Once again, no one cares about their personal information.]

Never mind the leftist #fakenews spin, though. For the moment – possibly for the first time since the organization was founded by Richard Nixon – genuine, reproducible science reigns at the EPA.

On energy and the environment, thanks to able administrators like Scott Pruitt, President Trump is most definitely #winning.

The New York Times

https://www.nytimes.com/2018/03/29/climate/epa-cafe-auto-pollution-rollback.html

E.P.A. Prepares to Roll Back Rules Requiring Cars to Be Cleaner and More Efficient

By Coral Davenport and Hiroko Tabuchi, 3/29/18

The Trump administration is expected to launch an effort in coming days to weaken greenhouse gas emissions and fuel economy standards for automobiles, handing a victory to car manufacturers and giving them ammunition to potentially roll back industry standards worldwide.

The move — which undercuts one of President Barack Obama's signature efforts to fight climate change — would also propel the Trump administration toward a courtroom clash with California, which has vowed to stick with the stricter rules even if Washington rolls back federal standards. That fight could

end up creating one set of rules for cars sold in California and the 12 states that follow its lead, and weaker rules for the rest of the states, in effect splitting the nation into two markets.

Scott Pruitt, the head of the Environmental Protection Agency, is expected to frame the initiative as eliminating a regulatory burden on automakers that will result in more affordable trucks, vans and sport utility vehicles for buyers, according to people familiar with the plan.

An E.P.A. spokeswoman confirmed that Mr. Pruitt had sent a draft of the 16-page plan to the White House for approval.

The particulars of the plan are still being worked out. Those specifics, which are expected this year, could substantially roll back the Obama-era standards, according to two people familiar with the deliberations.

"This is certainly a big deal," said Robert Stavins, director of the Harvard environmental economics program. "The result will be more gas-guzzling vehicles on the road, greater total gasoline consumption, and a significant increase in carbon dioxide emissions."

According to two people familiar with the E.P.A.'s plans, Mr. Pruitt was scheduled to formally announce his proposal on Tuesday at an auto dealership in the Virginia suburbs, but the schedule remained in flux.

Major automakers would welcome the change. They are prepared to participate in making new rules that meet "our customers' needs for affordable, safe, clean and fuel-efficient transportation," said Gloria Bergquist, a spokeswoman for the Alliance of Automobile Manufactures, which represents many of the world's largest automakers.

In California, state lawyers said they were expecting a fight. The state has a special waiver under the 1970 Clean Air Act empowering it to enforce stronger air pollution standards than those set by the federal government, a holdover from California's history of setting its own air pollution regulations before the federal rules came into force. "We're prepared to do everything we need to defend the process," said Xavier Becerra, the attorney general of California, in an interview.

The California waiver gives the state considerable power to require automakers to stick to stricter standards. Not only is California a huge car market itself, but 12 other states including New York, Massachusetts and Pennsylvania have historically followed its lead. Together they represent more than a third of the domestic auto market.

"We're going to defend first and foremost existing federal greenhouse gas standards," Mr. Becerra said. "We're defending them because they're good for the entire nation. No one should think it's easy to undo something that's been not just good for the country, but good for the planet."

Mr. Pruitt has signaled that he is ready to take on such a challenge. "California is not the arbiter of these issues," he said in an interview with Bloomberg TV this month.

Under the Obama administration, the federal government toughened tailpipe pollution standards to match California's. Mr. Pruitt said the state standards "shouldn't and can't dictate to the rest of the country what these levels are going to be."

The E.P.A.'s senior clean air adviser, William Wehrum, this week traveled to California and met with the state's top clean air official, Mary Nichols. Both sides declined to detail what was discussed.
On Wednesday, a coalition of free-market groups including the Competitive Enterprise Institute urged Mr. Pruitt to take California on. "It is time for the E.P.A. to act," the groups said. If the agency did not act quickly, the groups said, "people across the state of California will be facing unrealistic and costly mandates which threaten their basic right to choose."

President Trump has also spoken about rolling back the efficiency rules, known as Corporate Average Fuel Economy, or Cafe. "I'm sure you've all heard the big news that we're going to work on the Cafe standards so you can make cars in America again," Mr. Trump said at a Detroit auto research facility in March last year. "We want to be the car capital of the world again. We will be, and it won't be long."

The rules, aimed at cutting tailpipe emissions of carbon dioxide, a major contributor to global warming, were one of the two pillars of Mr. Obama's climate change legacy. Put forth in 2012, they would have required automakers to nearly double the average fuel economy of new cars and trucks to 54.5 miles per gallon by 2025.

If fully implemented, the rules would have cut oil consumption by about 12 billion barrels and reduced carbon dioxide pollution by about six billion tons over the lifetime of all the cars affected by the regulations, according to E.P.A. projections.

The rules also would have put the United States, historically a laggard in fuel economy regulations, at the forefront worldwide in the manufacture of electric and highly fuel efficient vehicles. The United States and Canada are the only major nations that have adopted mandatory emissions standards through 2025. The European Union has only recently proposed standards for 2025 and 2030, while China has only started to work on standards for those years.

Less restrictive regulations in the United States could provide an opening for automakers to push for more lenient standards elsewhere as well, leading to the emission of more pollution by cars around the world. While sales of electric vehicles are starting to take off, they still represent barely 1 percent of global car sales. A shift among car buyers toward larger cars and trucks is already impeding progress in fuel economy.

"The concern is that automakers will go around the world basically trying to lobby regulators, saying, look, because the United States has reduced the pace, everywhere else should too," said Anup Bandivadekar, a researcher at the International Council on Clean Transportation, a think tank that focuses on clean car technology and policy. Global carmakers "apply developments in one region to lobby for changes in other regions."

American automakers initially accepted the plan by Mr. Obama in 2009 to harmonize what was then a hodgepodge of pollution and efficiency standards set by the E.P.A., the National Highway Traffic Safety Administration and California. And the automakers weren't in much of a position to resist; they had just taken an $80 billion bailout to survive a global economic crisis.

The plan would have spurred automakers to speed their development of highly fuel-efficient vehicles including hybrid and electric cars. But within weeks of Mr. Trump's inauguration last year, the chief executives of the nation's Big Three auto companies met with him in the Oval Office to say that the Obama tailpipe standard was too difficult to achieve.

Mr. Trump directed the E.P.A. under Mr. Pruitt to craft a new, less strict set of standards. The announcement expected on Tuesday would represent the first legal step in the process.

While Mr. Pruitt's proposal to open up the Obama rules to review isn't expected to include specific targets, "The proposed rollback is going to be quite a significant number," said Myron Ebell, who led Mr. Trump's E.P.A. transition team and directs the energy and environment policy at the Competitive Enterprise Institute, a Washington research organization that questions the established science of human-caused climate change. "It will be more than a couple m.p.g.," he said.

If the legal fight between California and the Trump administration escalates, one possibility is that the federal government might try to revoke the waiver allowing California to set its own rules. Some presidents, including George W. Bush, have considered revoking the waiver, but none have tried.

The announcement by Mr. Pruitt was not expected to include a decision on challenging the waiver.

Mr. Ebell suggested that one possible legal tactic for the Trump administration could be to announce that it will refuse to renew the current waiver on tailpipe emissions, which expires in 2025, rather than to revoke it outright. That would likely delay a court fight until California moves to set standards that go beyond 2025.

But such a move would also likely formalize, at least for the time being, two different sets of rules in the United States — the federal emissions rules, and California's stricter ones — a logistical headache for the industry.

While California and its ally states have long followed separate smog standards, those have been easier for automakers to meet because a car can be brought into compliance by adding a catalytic converter, for example. Designing for separate mileage standards is more difficult, because fuel economy is dependent on a car's weight and design.

A divided market could require substantially different car designs, experts say, putting the American auto industry into uncharted territory. It remains unclear how the issue might be resolved. One possibility is that two very different auto markets emerge, one with cleaner cars generally along the coasts, and another with more polluting cars concentrated in Middle America. On the other hand, automakers might also opt to generally adhere to the stricter California standards nationwide, blunting the impact of any Trump administration rollback of federal rules.

The automakers had hoped to avoid these complex scenarios by using their clout with the Trump administration to force California to go along with a relaxation of federal regulations. But "if they thought this would end by California rolling over and giving up its more stringent standards," said Kevin Poloncarz, a San Francisco lawyer who focuses on air and climate change law, "that was a miscalculation."

As a result, the automakers' victory might come with unexpected headaches for them, said Jody Freeman, a Harvard law professor and former counsel to the Obama administration.

For instance, if the rest of the world moves toward stricter rules anyway, the American market could find itself an industry laggard, ceding leadership in clean vehicle technology to markets like China or the

European Union. "I don't really know if the auto industry wants what this administration might be doing," she said. "It might be like the dog that caught the car."

North Jersey

https://www.northjersey.com/story/news/environment/2018/03/28/epa-begins-monitoring-air-residential-areas-fumes-wafting-edgewater-superfund-site/458747002/

EPA begins monitoring air in residential areas for fumes wafting from Edgewater Superfund site By Scott Fallon, 3/29/18

Environmental regulators have begun monitoring the air at residential developments near the Quanta Superfund site to see if elevated levels of a potentially dangerous chemical are wafting from cleanup work on the property that residents have been complaining about for months, officials said Wednesday.

The news came as more than 100 people packed a public meeting at Borough Hall where U.S. Environmental Protection Agency officials detailed steps they are taking to control fumes from the site, including elevated levels of naphthalene.

Agency officials said they would suppress the fumes with foam, air misters along the fence, plastic sheeting and other methods. EPA officials maintained that the naphthalene levels are not a public health risk although many in the audience remained skeptical.

"You have to take responsibility," Jane Hoffman, who lives adjacent to the site, said at the meeting to EPA officials. "There are people who have spent their life savings to buy a home here."

Residents have been complaining about the fumes for months, saying they are unrelenting even when work at the site has been halted. As a result, the EPA has established a new 24-hour hotline that residents can call if they smell odors from the site: 201-807-0991.

The site is undergoing a controversial $78 million cleanup by Honeywell and supervised by EPA where workers have to dig up contaminated soil to pump in cement that will keep coal tar, arsenic and oil byproducts from migrating offsite. Many residents had wanted the pollution excavated at the Hudson River site not entombed in perpetuity under a proposed housing complex.

Elevated levels of naphthalene have been emanating from the site almost every work day since May, according to air monitoring data provided by Honeywell.

Naphthalene continued to exceed the site's risk screening level of 4.62 micrograms per cubic meter in March with a high in recent weeks of 120 micrograms per cubic meter on March 19, which is 26 times the screening level.

EPA has begun taken air samples at three residential developments near the Quanta site – City Place, iPark and Independence Harbor. Two samples taken this month – one at City Place and another at iPark – had naphthalene levels slightly above 4.62 micrograms per cubic meter. The rest were either below the level or no naphthalene was detected. Samples taken last year did not exceed any risk levels, EPA officials said.

Naphthalene is "reasonably anticipated" to be a human carcinogen by the U.S. Department of Health and Human Services because studies showed that lab rats formed lung and nose tumors when breathing in the chemical daily. The EPA and the World Health Organization classify naphthalene as a possible human carcinogen.

EPA has said even the highest levels of naphthalene recorded at Quanta – 1,000 micrograms per cubic meter on Sept. 15 – do not present a health risk.

The screening level is based on the assumption that an individual is located at the perimeter of the Quanta site for 10 hours per day, five days per week, for 1½ years, regulators said.

"It's meant to be very conservative," Lora Smith, an EPA human health risk assessor, said of the 4.62 level. She said the Occupational Health and Safety Administration's exposure limit for workers is 50,000 micrograms per cubic meter and that is why workers do not wear respirators on site.

"Exceedances are not unexpected and they do not indicate there is an imminent public health threat," she said.

But residents have argued that condos, apartments, restaurants, stores and a hotel surround the Quanta site allowing prolonged exposure to the fumes in close proximity. Work at the site was temporarily halted following an article in The Record detailing the site's problems.

Dana Prigge, who lives near the site, said the fumes from Quanta can be noxious. She said she was overcome one day last month while walking near River Road.

"My eyes were burning, my nose was burning, my lungs were pulling in," she said in an interview before the meeting. "I knew there were chemicals in the air because I never react this way."

The fumes have become so bad that Prigge plans to move out of Edgewater when her lease is up in a few months.

"If I could move out tomorrow, I would," she said.

Bloomberg

https://www.bloomberg.com/news/articles/2018-03-30/epa-chief-s-50-a-night-rental-said-to-raise-white-house-angst

EPA Chief's $50-a-Night Rental Raises White House Angst

By Jennifer Dlouhy and Jennifer Jacobs

Environmental Protection Agency Administrator Scott Pruitt's lease at a Washington apartment owned by a lobbyist friend allowed him to pay $50 a night for a single bedroom -- but only on the nights when he actually slept there.

White House officials are growing dismayed about the questions surrounding Pruitt's living arrangement, including his initial inability to produce any documentation about his lease or his actual

payments, according to three officials. The landlord provided EPA officials with a copy of the lease and proof of the payments Pruitt made.

The questions follow criticism of Pruitt for traveling first class on airline flights.

In all, Pruitt paid $6,100 to use the room for roughly six months, according to copies of the checks reviewed by Bloomberg. Those checks show varying amounts paid on sporadic dates -- not a traditional monthly "rent payment" of the same amount each month.

That was because of the unusual rent schedule -- not a single monthly amount, but a daily amount charged only for days used for a single bedroom in the two-bedroom unit just blocks from the Capitol. The owner is a health care lobbyist, Vicki Hart. Her husband J. Steven Hart, is also a lobbyist and his firm represents clients in industries regulated by the EPA.

One person familiar with the lease compared it to an Airbnb-style arrangement, but Pruitt wasn't a transient and instead made the apartment his home on nights he was in Washington. The lease -- reviewed by Bloomberg -- says that he was charged $50 a night "based on days of actual occupancy."

Six Canceled Checks
Bloomberg reviewed six canceled checks paid by Pruitt totaling $6,100 from March 18 through Sept 1, 2017. He paid $450 on March 18, $900 on April 26, $850 on May 15, $700 on June 4, $1,500 on July 22 and $1,700 on Sept 1.

Justina Fugh, who has been ethics counsel at the EPA for a dozen years, said the arrangement wasn't an ethics issue because Pruitt paid rent. An aide said the agency had not reviewed the arrangement in advance.

The payments covered Pruitt's room in the two-bedroom unit, but did not afford him liberal use of common areas, where the owners had dinner parties and other functions, according to a person familiar with the situation. Someone else rented the other bedroom. According to the lease agreement, Pruitt's bedroom could not be locked.

After ABC News reported the living arrangement on Thursday, EPA aides had to seek documentation from the building's owners to prove he had paid rent, raising concerns at the White House, said two of the people, who asked not to be named discussing a sensitive matter involving a Cabinet secretary. Pruitt was in Wyoming on Thursday.

Related: Bumped? EPA Chief Signals He Will Be Flying Coach After Backlash

The disclosure follows revelations about Pruitt's reliance on first-class flights to travel around the globe and a series of pricey trips, including a visit by Pruitt and agency staff to Italy that cost $120,249. EPA officials have defended Pruitt's use of first-class flights on security grounds, but after a series of reports, he shifted to coach.

J. Steven Hart is the chairman of Williams & Jensen, a firm with a stable of energy industry clients including Oklahoma Gas & Electric Co., which paid the firm $400,000 in 2017, according to data compiled from the Environmental Integrity Project from disclosure forms.

Pruitt, the former attorney general of Oklahoma, has been an enthusiastic crusader against Obama-era regulations meant to combat climate change and limit air pollution. When Pruitt was in Oklahoma, he sued the EPA more than a dozen times.

Hart's individual lobbying clients include liquefied natural gas exporter Cheniere Energy Inc., the American Automotive Policy Council and Smithfield Foods Inc. But the Department of Energy -- not the EPA -- plays the major federal role overseeing LNG exports, and it is not clear Hart had direct contact with the EPA on behalf of any of his lobbying clients in 2017, according to a Bloomberg News review of disclosures.

"At the very least, it doesn't look good for the administrator of EPA to have rented an apartment from the wife of an energy industry lobbyist who represents companies regulated by EPA," said Eric Schaeffer, director of the Environmental Integrity Project.

Schaeffer called on EPA's inspector general and Congress to investigate.

Fugh, the EPA's ethics counsel, said no gift was involved. It was a routine business arrangement between Pruitt and an individual, not a lobbying firm, she added.

"He paid a fair price for what amounts to just a room," Fugh said. "So I don't even think that the fact that the house is owned by a person whose job is to be a lobbyist causes us concern."

The Wall Street Journal

https://www.wsj.com/articles/trump-dilemma-give-businesses-more-low-skilled-work-visas-or-not-1522407601

Trump Dilemma: Give Businesses More Low-Skilled Work Visas or Not

By Laura Meckler, 3/30/18

Demand for low-skilled worker visas for the summer season starting Sunday is again far outstripping supply, with the Trump administration forced to choose between helping businesses seeking more visas or trying to save those jobs for American workers.

Some lawmakers tried and failed this month to secure an increase in the number of H-2B visas available for this summer as part of a large spending bill. One Senate proposal would have permanently raised the annual cap from 66,000 to 90,000, with no limits for certain jobs in areas affected by disasters. A House version would have increased the annual cap to 132,000.

The White House warned some lawmakers not to kick the decision to the Department of Homeland Security as they did in 2017, congressional aides said. "We did not want the discretion," an administration official said.

Nonetheless, DHS is now under pressure from the business community to provide more visas after the spending bill authorized the department's Secretary Kirstjen Nielsen to offer tens of thousands of extra visas if she sees fit.

A DHS spokeswoman, Katie Waldman, said no decision has been made. "We are currently looking at last year's implementation of the H-2B plus-up to determine how best to proceed this fiscal year," she said.

The H-2B visas, issued for low-skilled, seasonal foreign workers, are typically employed by landscaping companies, Alaskan fisheries, ski resorts and vacation spots, including some of President Donald Trump's properties.

Backers say the program provides needed foreign workers, often in remote locations where Americans are scarce. They say the problem is particularly acute given the current unemployment rate of 4.1%, the lowest in a decade.

"We rebranded 8,000 vehicles and put 'now hiring' on everything we own. We cannot get enough workers," said Todd Chambers, chief marketing officer for BrightView Landscapes, LLC, a large landscaping company that has used H-2B workers for more than a decade.

Opponents say businesses should try harder and raise wages if needed. "We should want the labor market to tighten and employers have to work overtime trying to entice American workers, especially those who've dropped out of the labor market," said Mark Krikorian of the conservative Center for Immigration Studies.

Ultimately, Democratic leaders killed the proposals to increase the visas, congressional aides in both parties said. Democratic aides said that was partly because they weren't willing to import more foreign workers at a time when Congress was failing to protect hundreds of thousands of young undocumented immigrants brought to the U.S. as children, known as Dreamers.

By statute, a total of 66,000 H-2B visas are available each year, divided evenly between winter and summer seasons. In past years, Congress has effectively raised the cap by exempting workers who are returning to jobs they had in previous seasons, but didn't do so last year nor this year.

For this summer season, businesses filed requests for more than 81,000 workers with the Labor Department on Jan. 1, the first day possible, a record, and more since then. Many firms tried to file applications after midnight on New Year's Eve to be near the front of the line.

This year, for the first time, DHS conducted a lottery among early applicants to pick winners, saying it was only fair given the crush of demand. Administration officials said that applications cleared by the Labor Department by mid-February were eligible. But several people who use the program said they were confused about why some petitions were included in the draw and others weren't.

BrightView Landscapes filed 94 petitions requesting a total of 3,500 visas, but was awarded fewer than 500, compared with 1,600 last year, said Sarah Powenski, vice president and associate general counsel at the company.

Company officials say they are frustrated that the program has been caught up in the larger immigration debate. "This thing has become more of an immigration issue in people's minds," said Mr. Chambers. "It's been attached to a third rail issue."

Faced with the same situation last year, John Kelly, then DHS secretary and now White House chief of staff, fumed. He argued that if Congress wanted more visas, then lawmakers should have approved them.

Many lawmakers lobbied him to approve additional visas. His boss, President Donald Trump, ran for office promising to protect American workers against foreign competition, and White House officials pressured him against it, according to people familiar with the decision making.

Ultimately, Mr. Kelly allowed up to 15,000 additional visas for guest workers, though not until the summer was half over. He set a high bar for businesses that wanted to apply and described the approval as a "one-time" move.

Politico

https://www.politico.com/story/2018/03/29/trumps-veterans-pick-agency-451219

Trump's VA pick blindsides staff, deepens agency disarray

By Lorraine Woellert, Eliana Johnson, and Connor O'Brien, 3/29/18

The timing of President Donald Trump's announcement to name Rear Admiral Ronny Jackson to lead Veterans Affairs was a snap decision that surprised his own chief of staff and knocked the government's second-largest agency, already bedeviled by scandal, deeper into disarray.

White House chief of staff John Kelly had spoken with David Shulkin by phone Wednesday morning, reassuring the now-former VA secretary that he wouldn't be fired by tweet that afternoon. Hours later, Kelly had to phone Shulkin again telling him plans had changed.

Trump declared Jackson's nomination on Twitter at 5:31 p.m. The tweet was big news — not just to the public, but to some senior aides, according to one White House official.

The chaos — by now a typical part of the president's management style — has for months upended Kelly's attempts to ensure that an unorthodox White House adheres to traditional processes. But while White House aides are left unpacking the day's events, the drama at the VA is just beginning.

Deputy Secretary Thomas Bowman, a Trump appointee who is the agency's No. 2, is widely expected to leave soon, either by choice or by force. Kelly and other aides wanted Bowman gone before Shulkin left to avoid installing the deputy at the helm, even temporarily. Bowman had pushed back on broad privatization efforts, leading Trump to berate him in an Oval Office meeting for his lack of loyalty.

Trump got around the Bowman problem by naming Robert Wilkie, an undersecretary at the Department of Defense, to the temporary job. A Capitol Hill veteran and member of Trump's transition team, Wilkie is a former senior adviser to Sen. Thom Tillis (R-N.C.), who supports expanding service members' access to private doctors.

"He's got a department that's in turmoil. It's in crisis. There's warfare there," said Anthony Principi, who led the agency under former President George W. Bush. "And you have an acting secretary who doesn't know the VA."

But if and when Bowman departs, Wilkie will be left with a shallow bench at an agency already paralyzed by political mistrust, some veterans' advocates say. The VA's health and benefit agencies — which administer tens of billions of dollars in health programs, pensions, survivor benefits and other forms of assistance to some 9 million service members — have been without Senate-confirmed officials since the Obama administration.

Veterans Affairs is the second-largest federal agency, behind only the Department of Defense, with 377,000 employees. And it has proven unwieldy even when led by highly decorated, experienced administrators such as Eric Shinseki, a retired four-star Army general who resigned during the Obama administration amid a scandal over lengthy wait times and faulty scheduling practices for medical appointments.

Shinseki was followed by Bob McDonald, an Army veteran and former Procter & Gamble CEO. Shulkin, McDonald's successor, was the first non-veteran to lead the VA.

As recently as two weeks ago, the Trump White House was still making overtures to potential candidates for the top job, according to a person with direct knowledge of the inquiries. Trump reportedly agonized over the decision, changing his mind several times, a senior administration official said.

"Instead of going through the paces to convince the best possible person to take this job, they're going with the person who's still on active duty in the Navy and can't say no to the commander in chief," said one Obama White House aide, who spoke highly of Jackson as a doctor and individual. "You could look at it as them giving up trying to find a competent commander or manager to fix the problems."

Shulkin had come under fire after a VA inspector general's report accused him of improperly accepting tickets to the Wimbledon tennis tournament and using his agency staff to arrange a sightseeing tour of Denmark and England. He repaid the VA for the trip. The longtime hospital administrator, who was engaged in open warfare with conservatives in the department intent on privatizing the VA, contended he was set up.

Veterans' groups remained loyal to Shulkin, whom they saw as their best line of defense of against privatization. During his campaign, Trump made promises that veterans would be allowed to seek medical treatment outside the VA's system, statements taken by some to mean a step toward handing the system to commercial companies to manage.

Jackson, while well-liked by both Republicans and Democrats, is a cipher on privatization and other policy issues. With no agency experience to speak of, veterans suspect he could be installed as a figurehead, leaving lower-level appointees to steer the agency toward privatization.

"He's a blank slate. Nobody knows really anything about his competency or capacity for this job," said Paul Rieckhoff, CEO of Iraq and Afghanistan Veterans of America. "We especially know that being a veteran doesn't qualify you to run the VA any more than being a soldier qualifies you to run the DoD."

Principi urged Jackson to move quickly on his own agenda.

"The new secretary, really, if he wants to accomplish anything, has to hit the deck running and has to bring in some very, very good people," he said. "I hope and pray he's a success. Because if he's not, American veterans are going to be the losers."

Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 4/25/2018 9:56:19 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy: Perry's latest bid to save coal — NEPA focus of hearing today — More on the Pruitt front

By Kelsey Tamborrino | 04/25/2018 05:54 AM EDT

With help from Anthony Adragna

PERRY'S LATEST BID TO SAVE COAL: So far, Energy Secretary Rick Perry has had no success in his effort to construct a safety net to keep alive coal-fired and nuclear power plants threatened with shutdowns — a mission that's come straight from President Donald Trump. And Perry's latest potential gambit to use the 1950 Defense Production Act in hopes of designating the plants as crucial for national security may not fare better than his previous efforts, energy experts tell Pro's Eric Wolff.

Experts say the bid would stretch the definition of the law and almost certainly draw legal challenges. Plus invoking the act that was last used by the Obama administration to push advanced biofuels would probably hit a snag in Congress, since lawmakers would need to approve perhaps billions of dollars in funding to keep the plants afloat, the experts say.

Using the Korean War-era law to protect the plants could be a novel approach to aiding power plants, Eric writes, especially after Perry failed to gain FERC's support for his proposal to give the plants financial backing. And since Energy Department lawyers stymied a push last year to invoke the agency's authority under the Federal Power Act to force the plants to run, Perry and his staff appear to have very few viable options left.

But the fresh take on the act doesn't necessarily mean it'll work. "To me, it's a tough argument to make. It's a specious argument on its surface that seems like a perversion of the intended use of the Defense Production Act," said Tom Hicks, a former acting undersecretary of the U.S. Navy under former President Barack Obama and now a principal at the advisory firm The Mabus Group. Read more.

WELCOME TO WEDNESDAY! I'm your host Kelsey Tamborrino, and James Daniel was the first to guess the most recent senator to appear on a U.S. postage stamp. It was Maine's Margaret Chase Smith, who appeared during the Distinguished Americans Issue in 2007, worth a whopping 58 cents face value. A geography question for today: The Blue Nile and the White Nile combine to form the Nile River at which capital city? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

POLITICO's Ben White is bringing Morning Money to the Milken Institute Global Conference to provide coverage of the day's events and evening happenings. The newsletter will run April 29 — May 2, 2018. Sign up to keep up with your daily conference coverage.

DON'T FEAR THE NEPA? House Natural Resources will hold an oversight hearing this afternoon on what it calls the "weaponization" of the National Environmental Policy Act, and it could be a doozy. The committee notice calls NEPA — the seminal law that requires an environmental review on all federal actions — activists' "weapon of choice." Republicans have long-sought to undo parts of the law, and today's hearing will likely echo some of the rhetoric out of the Trump administration, which has supported faster NEPA reviews as part of its infrastructure push . The hearing will review challenges from NEPA and will evaluate reforms to "de-

weaponize" the law to "minimize opportunities for bad faith litigation, and restore the law to its original intent," according to a committee notice.

The committee previously took up the topic last year, holding a similar hearing in November on modernizing the law for the 21st century. James Coleman, a law professor at the Southern Methodist University, is expected to say the current NEPA process is "broken" and that bipartisan efforts to fix the problem have failed. "As President Obama's regulatory czar put it, 'If the permitting bureaucracy were a supervillain, it would be the Blob,'" he'll say, according to his testimony. "Right now, the Blob is winning: We have lost decades of investment while environment reviews grow longer and longer. How can we ensure that the U.S. does not fall behind our global competitors?"

Meanwhile, Laura Alice Watt of Sonoma State University, who says she is a proponent of environmental reviews that are conducted consistently, will discuss the effect of NEPA on the Point Reyes National Seashore, where a review over the last 20 years has contributed to the erosion of active ranches. Melissa Hamsher of Eclipse Energy Resource Corporation and former CEQ official Horst Greczmiel will also testify. Democratic Rep. Donald McEachin , ranking member of the Oversight subcommittee, will say that he'll hold the administration and Republicans to account on NEPA. "Many communities — and especially vulnerable minority and low-income communities — have had to endure a decades-long pattern of environmental injustice, in no small part because they were denied a say in important decisions that affected them," McEachin is expected to say. **If you go:** The hearing kicks off at 2 p.m. in 1324 Longworth.

SPEAKING OF NEPA: The League of Conservation Voters sent this letter to House members Tuesday urging them to oppose H.R. 3144 (115), which LCV says would "attack" the Endangered Species Act and NEPA by "mandating dam operations harmful to endangered salmon and steelhead in the Pacific Northwest."

ADD THIS TO THE LIST: Two days before two House hearings and fresh off an announcement on EPA's plan to bar scientific studies that don't publicly disclose data, Administrator Scott Pruitt got another appointment to testify on his agency's budget. This time Pruitt will appear in May before the Senate appropriations subcommittee that oversees EPA's budget, Lisa Murkowski said Tuesday.

OH, TO BE A FLY ON THE WALL: Sen. Shelley Moore Capito, one of the Republican EPW members open to a hearing with Pruitt, told ME Tuesday she has a "well-timed" phone call with him scheduled for this week. "I think he wants to talk about some regulatory measures," she said. "But I'm going to probably ask him questions on the current state of some of the things that I've read and we'll see where it goes." She said the call had been set up last week.

McConnell voices support ... again: Majority Leader Mitch McConnell told reporters Tuesday he remained a supporter of Pruitt's, while noting the EPA chief's busy Thursday on the Hill. "We'll just see," he said. "I expect there will be a lot of interest."

PERROTTA WORKED FOR TRUMP-BACKED MEDIA COMPANY: Pasquale "Nino" Perrotta — the Secret Service veteran who heads Pruitt's security detail — previously worked on assignments for the tabloid publishing company American Media Inc. during the 2016 presidential campaign, The New York Times reported Tuesday. While it is unclear when Perrotta started working at AMI, the Times reports some of his activities at the company included physical security, cybersecurity and investigative services involving litigation. Read more.

OLD AD-AGE: The Natural Resources Defense Council is sponsoring an ad today in The Washington Post that calls for Pruitt's ouster. The ad — which says: "President Trump promised to drain the swamp. He should start with EPA Administrator Scott Pruitt" — will run as an insert in 3,000 copies of the Post and will be delivered to Capitol Hill on Thursday. See it.

IF YOU PLAY YOUR CARDS RIGHT: The Environmental Defense Fund mapped out what it says are Pruitt's unanswered questions surrounding scandals while he helms EPA and during his time as Oklahoma attorney general — 86 of them to be exact. The group will also hand out a deck of "Non Trivial Pruitt Questions" during Thursday's hearings with a sampling of the ethical questions. See the cards here.

Rally cry: Separately, the American Federation of Government Employees will hold a rally today from noon until 1 p.m. in support of EPA workers. Democratic Reps. Salud Carbajal, Don Beyer, Bill Foster, Sheila Jackson Lee, Alan Lowenthal, Grace Meng, Jamie Raskin and Debbie Wasserman Schultz are all set to attend the rally, which will take place outside of EPA headquarters.

MACRON ADDRESS LAWMAKERS: French President Emmanuel Macron hits the Hill this morning to address a joint session of Congress. Earlier this week, the French president said he'd call for continued U.S. intervention in Syria in his speech. "I will advocate for multilateralism," Macron said in an interview on "Fox News Sunday." But it's also possible issues concerning climate will come up — which would likely receive a welcome reception from Democrats.

Macron, a staunch supporter of the Paris accord, also briefly mentioned climate during a joint press conference with the president Tuesday. "We also talked about the climate. And here, also, we know where we stand," Macron said vaguely. "France will continue to work on major pieces, including the global compact for the environment. But I think I can say that our economic — our businesses, our researchers can continue to work on — can create solutions in the field." Both he and Trump are "attached to that," he said.

Bold move: It's probably not an indication of environmental topics to come, but Apple CEO Tim Cook brought former EPA chief Lisa Jackson to Tuesday's state dinner with Macron. Jackson, who now works as vice president of environment, policy and social initiatives at Apple, has attended events with Cook in the past — but it's an interesting move considering Jackson's not been known to mince words about the Trump administration. For what its worth, Cook will meet today with Trump in the Oval Office.

MORE NOMS: Trump sent James Hubbard's nomination to be undersecretary of Agriculture for natural resources and the environment to the Senate Tuesday. Hubbard, of Colorado, replaces Robert Bonnie, who resigned from the post.

DEMOCRATS CITE SAFETY: Three Energy and Commerce Democratic leaders on Tuesday called on the Government Accountability Office to probe EPA's enforcement of federal health and environmental safeguards. "We are concerned that President Trump's and Administrator Pruitt's policies to 'streamline' permitting processes, reduce regulatory 'burdens' for industry, and defer to states on enforcement will lead to more environmental law violations due to lax enforcement at both the state and federal level," ranking member Frank Pallone and Reps. Diana DeGette and Paul Tonko write in a letter to GAO Comptroller Gene Dodaro. Read it here.

MAIL CALL! GOING NUCLEAR: Former national security officials and nonproliferation experts will send this letter today to congressional foreign affairs leadership stating that for national security reasons, it is in the U.S.' best interest to have a nuclear cooperation agreement — a so-called 123 Agreement — with Saudi Arabia.

— **Democratic Sens. Maria Cantwell and Jeff Merkley** and Reps. Raúl Grijalva and Jared Huffman sent a letter to Interior Secretary Ryan Zinke on Tuesday, calling on him to undo plans for a 2019 lease sale in Alaska's Beaufort Sea. Read it here.

— **Sen. John Barrasso, chairman of the Senate EPW Committee and Capito,** subcommittee chairwoman on clean air and nuclear safety, sent a letter to Pruitt and Perry, asking them to protect the confidential business information of U.S. small refineries. Read the letter here.

AT IT AGAIN: Michigan GOP Rep. Fred Upton officially filed for reelection in the state's 6th District, MLive reports. "We are full steam ahead and excited about the future," the Energy and Commerce lawmaker said in a statement.

A TANGLED WEB: The Environmental Data & Governance Initiative is out with a new monitoring report this morning that says EPA removed pages related to "international priorities" and "international grants and cooperative agreements," as well as corresponding links, from its International Cooperation web page. The page in question listed priority areas including "strong environmental institutions," "climate change" and "clean water," among other terms, which EDGI says were removed in December 2017. Read the report here and see screenshots here.

GROUPS TO SUE OVER DRINKING WATER IN NEW JERSEY: The NRDC and Newark Education Workers Caucus say they will sue the city of Newark, N.J., and Catherine McCabe, the acting commissioner of the New Jersey Department of Environmental Protection, over lead contamination in the city's drinking water, Pro New Jersey's Danielle Muoio reports. A Newark city official said Tuesday that the complaint filed by the groups is "absolutely and outrageously false."

OLYMPIANS HEAD TO HILL FOR CLIMATE: Five Winter Olympians will brief House and Senate offices today on the impact of climate change on winter sports and outdoor recreation. Cross-country skier Jessie Diggins, freestyle skier David Wise, halfpipe snowboarder Arielle Gold, biathlete Maddie Phaneuf and alpine skier Stacey Cook all will appear on the panel, which is co-hosted by nonprofit Protect Our Winters, Citizens Climate Lobby, and Sens. Michael Bennet and Susan Collins. **If you go** : The briefing begins at 12:30 p.m. in 538 Dirksen.

CORRECTION: The April 24 edition of Morning Energy misstated the purpose of H.R. 3144 (115). The bill would codify the 2014 Biological Opinion until 2022, while the NEPA and the environmental impact statement processes continue.

QUICK HITS

— Trump White House offered to help prep Pruitt for hearings. EPA told the White House to "get lost," The New York Times.

— Shaheen questions Air Force secretary on PFAS health study, Seacoast Online.

— Harassment targeted; more disciplinary actions could follow, E&E News.

— Provisions in FAA bill could strip endangered species protections, The Hill.

— Zinke put birther conspiracy theorist on super PAC board, CNN.

— Mines owned by Gov. Justice missed deadline for installing safety tech, Charleston Gazette-Mail.

HAPPENING TODAY

8:30 a.m. — Microsoft and the delegation of the European Union to the U.S. discussion on the future of the EU electricity market, 901 K Street NW

10:00 a.m. — Senate Commerce Committee hearing on "Enhancing the Marine Mammal Protection Act," 253 Russell

11:30 a.m. — The World Resources Institute forum on "activism for energy," 10 G Street NE

12:30 p.m. — Olympians brief Congress about impact of climate change on winter sports, 538 Dirksen

2:00 p.m. — Resources for the Future webinar on "What Research Says on Key Fracking Debate Issues."

2:00 p.m. — House Natural Resources Committee hearing on "The Weaponization of the National Environmental Policy Act and the Implications of Environmental Lawfare," 1324 Longworth

2:00 p.m. — Senate Appropriations Energy and Water Development Subcommittee hearing on proposed budget estimates and justification for FY 2019 for the Nuclear Regulatory Commission, 430 Dirksen

2:00 p.m. — The Heritage Foundation discussion on "Saving 'Endangered' Species or Regulating with Bad Data," 214 Massachusetts Avenue NE

2:30 p.m. — Senate Indian Affairs Committee hearing on a pair of bills, including H.R. 1491 (115), 628 Dirksen

3:30 p.m. — Bloomberg Government and the Norwegian-American Chamber of Commerce conversation on "Investing In A Sustainable Energy Future," New York City

5:30 p.m. — The National Academy of Sciences lecture on "Distress Signals: Historical Waypoints in Northwest Atlantic Fisheries Since 1850," 2101 Constitution Avenue NW

6:30 p.m. — The Carnegie Institution for Science lecture on the sustainable use of the ocean, 1530 P Street NW

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Stories from POLITICO Pro

Perry's latest bid to help coal faces uphill battle Back

By Eric Wolff | 04/25/2018 05:08 AM EDT

Energy Secretary Rick Perry's latest idea to protect coal-fired and nuclear power plants may not fare much better than his previous efforts, according to energy experts.

Perry is considering invoking the 1950 Defense Production Act to keep money-losing power plants running by designating them as crucial for national security. But that would stretch the definition of the law and almost certainly draw legal challenges — and it would hit a big hurdle in Congress, which would need to approve perhaps billions of dollars in funding to keep the plants afloat, the experts said.

At the urging of President Donald Trump, Perry has sought to keep open coal and nuclear power plants that are threatened with shutdowns amid the stagnant demand for power — and even as natural gas and renewable power sources grab a growing share of the market.

So far, Perry's had no luck. FERC earlier this year rejected his proposal to give the plants financial support, and Energy Department lawyers stymied a push last year to invoke the agency's authority under the Federal Power Act to force the plants to run.

Some experts said any attempt to use the DPA is likely to meet the same fate.

"To me, it's a tough argument to make. It's a specious argument on its surface that seems like a perversion of the intended use of the Defense Production Act," said Tom Hicks, a former acting undersecretary of the Navy under former President Barack Obama and now a principal at the advisory firm The Mabus Group. "Defense Production Act is on the vanguard of the need for resources, not on the back end for an industry being challenged by economic forces."

But the effort has been a priority for Trump and Perry, who sees saving coal-fired power generation as vital to U.S. security, according to a source familiar with the conversations on the issue.

The Cold War-era law grants the federal government powerful authorities to inject cash into companies essential for national defense in order to preserve domestic supplies of key products. But DOE will have to make the case that electricity produced specifically from coal and nuclear power plants, and not other types of power, is a critical resource.

Using the act to protect the plants when there appeared to be no immediate shortage of power supplies would be a novel application that would almost certainly face legal challenge.

"If the administration uses DPA, they're going to be using it very creatively," said Ari Peskoe, director of the Electricity Law Initiative at the Harvard Law School Environmental and Energy Law Program. "They may come up with reasoning for higher rates and who's going to pay for it. Whether that will hold up, I don't know."

Perry and his staff appear to have very few viable options for bailing out coal and nuclear power, a major energy priority for Trump, who has promised to revive the coal industry. DOE has opened a comments process for interested parties to weigh in on its use of the Federal Power Act's 202(c) emergency provisions, though that would require the agency to go through FERC, which unanimously rejected a similar Perry effort in January.

The 202(c) effort has been pushed by coal magnate Bob Murray, owner of Murray Energy, and by FirstEnergy Solutions, the unit of of FirstEnergy Corp. that is in bankruptcy proceedings and which expects to shut down four coal and nuclear power plants. That company asked DOE to use the emergency authority to save not only its plants, but all 85 coal and nuclear power plants in the PJM Interconnection power market.

The DPA was last used by the Obama administration starting in 2012 to help spur the biofuels industry to develop the kind of advanced biofuels that could power ships and aircraft. The government can purchase capital equipment for the cause of national security, and it can fund advertising to support the effort.

And it allows the government to become the buyer of last resort, which could put Washington on the hook to buy excess power generated by coal and nuclear plants. Technically, this electricity could only be purchased at the "cost of production," a level that in the past has been determined by a team within the Defense Department.

While no hard estimate for the cost of a DPA subsidy exists, consultants analyzing Perry's previous bailout proposal estimated costs between $4 billion and $10.6 billion annually.

That's a far higher level than Congress typically allocates for the DPA. It provided $67.4 million in the omnibus passed in March, H.R. 1625 (115), down slightly from the $76 million it provided for all projects in 2017, according to a report submitted to Congress.

And Congress — and the Republican Party — is deeply divided on using government subsidies to save these plants. Rep. David McKinley (R-W.Va.) has some allies from other coal districts for the effort, but other free market-oriented lawmakers like Rep. Pete Olson (R-Texas) say they want to see markets function unimpeded.

McKinley's staff has been in touch with DOE and the White House, as has West Virginia Sen. Joe Manchin (D).

"I think it's an emergency national concern for the national defense of our country. I think Rick Perry agrees with it, and I think the president does also," Manchin told POLITICO.

PJM has itself said the retirement of FirstEnergy's coal plants did not pose a threat to the region's power supplies, and that it had ample generation to meet demand. It has opposed any effort to mandate to require the plants to stay online.

"We believe that a market-oriented approach consistent with the American free-enterprise system offers better results than government-mandated subsidies," said PJM spokesman Jeff Shields.

Anthony Adragna contributed to this report.

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Pruitt scales back EPA's use of science Back

By Emily Holden and Annie Snider | 04/24/2018 03:28 PM EDT

Environmental Protection Agency chief Scott Pruitt announced Tuesday he would seek to bar the agency from relying on studies that don't publicly disclose all their data, a major policy change that has long been sought by conservatives that will sharply reduce the research the agency can rely on when crafting new regulations.

The unveiling of the proposed rule delivers a win to Republicans like House Science Chairman Lamar Smith (R-Texas), who unsuccessfully pushed legislation to impose the same type of change. The move also demonstrates Pruitt's persistence in pursuing President Donald Trump's anti-regulation agenda just two days before the embattled EPA chief is due to face fierce questioning from lawmakers about his hefty spending, expanded security detail and cheap condominium rental from the wife of an energy lobbyist.

At an invitation-only meeting at EPA headquarters with Smith, Sen. Mike Rounds (R-S.D.) and other supporters of the policy, Pruitt said the proposed rule was critical in ensuring that the agency was transparent about how it is making decisions to justify costly new regulations. It is the latest step Pruitt has taken to fundamentally shift the agency's approach to science.

"It is a codification of an approach that says as we do our business at the agency the science that we use is going to be transparent, it's going to be reproduceable, it's going to be able to be analyzed by those in the marketplace. And those who watch what we do can make informed decisions about whether we've drawn the proper conclusions or not," Pruitt said.

Text of the proposed rule was not immediately available.

The proposal, based on legislation pushed by Smith, is intensely controversial, and scientists and public health groups say it will prevent federal regulators from enacting health and safety protections. Nearly 1,000 scientists, including former EPA career staffers, signed a letter opposing the policy sent by the Union of Concerned Scientists to Pruitt on Monday.

Their primary concern was that many of the country's bedrock air and water quality regulations are based on research that cannot disclose raw data because it includes the personal health information.

But industry has its own version of the same problem. EPA often relies on industry studies that are considered by companies to be confidential business information when determining whether new pesticides and toxic chemicals are safe to use. Internal EPA emails obtained under the Freedom of Information Act show that EPA political officials, including Nancy Beck, who became the chief of the agency's chemical safety office last year after working for years at a chemical industry lobbying group, worried that the new policy would limit the agency's ability to consider industry data or would force companies to make this proprietary data public.

"We will need to thread this one real tight!" Richard Yamada, political official who led work on the new policy wrote to Beck after she raised the concerns.

It was not immediately clear if the new proposed rule included measures to address those concerns.

Rush Holt, CEO of the American Association for the Advancement of Science, said Pruitt's changes could keep the agency from revising public health regulations as problems arise or new data comes to light.

"On the surface it sounds so innocuous or even beneficial. What could be wrong with transparency? Well it's clear to me that this is not based on an effort to be transparent. It is rather based on an effort to be just the opposite," he said.

"EPA is particularly important because when science is misused, people die," he added.

Pruitt has been discussing the new scientific policy publicly for weeks, but it only went to the White House for interagency review last week. Such swift review is very rare for the Office of Management and Budget, which often takes months to vet a new policy. At least one group, the Environmental Defense Fund, has requested a meeting with OMB officials to discuss the rule, but OMB's website shows that no meetings have been scheduled with interested groups.

Many public health studies can't be replicated without exposing people to contaminants, and environmental disasters such as the Deepwater Horizon oil spill cannot be recreated, the group said, raising intellectual property, proprietary and privacy concerns.

Pruitt's predecessor Gina McCarthy, and her air chief Janet McCabe, in an op-ed in The New York Times in March said concerns about studies are dealt with through the existing peer-review process, which ensures scientific integrity.

"[Pruitt] and some conservative members of Congress are setting up a nonexistent problem in order to prevent the E.P.A. from using the best available science," they said.

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Murkowski: Pruitt will testify to Senate appropriators Back

By Anthony Adragna | 04/24/2018 03:03 PM EDT

EPA Administrator Scott Pruitt is scheduled to testify in May before the Senate appropriations subcommittee that oversees his budget, Sen. Lisa Murkowski (R-Alaska), who chairs the panel, said today.

Murkowski did not elaborate on her plans for the hearing or how much it would delve into Pruitt's ethics and spending. But she said it was "absolutely appropriate" for the Environment and Public Works Committee to hold an oversight hearing on the administrator's conduct in office, an idea that has been endorsed by multiple Republicans on the authorization committee.

"I'm hoping they move on it sooner than later," Murkowski said of the EPW committee.

EPW Chairman John Barrasso (R-Wyo.) said today he has "serious questions" about how Pruitt has handled taxpayer dollars but stopped short of announcing plans for Pruitt to testify.

"We'll see what comes out of the hearings this Thursday," Barrasso said, referring to Pruitt's scheduled appearance of two House hearings that day.

Barrasso said he planned to send additional letters to EPA, following his recent request for details on the administrator's use of four separate email accounts. In response to that earlier letter, EPA told him all of Pruitt's accounts are searched in response to public records requests.

"You want to make sure taxpayers are getting value for their dollars," Barrasso told reporters today. "We want to make sure money is being spent appropriately."

WHAT'S NEXT: Murkowski declined to say when Pruitt would appear before her Appropriations Subcommittee on Interior, Environment and Related Agencies, but she has said previously it was expected to be the week of May 7.

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Pruitt support in Senate erodes as GOP lawmakers seek hearings Back

By Anthony Adragna | 04/23/2018 08:32 PM EDT

Scott Pruitt's wall of GOP support is developing new cracks, with three key Senate defenders calling for hearings into the embattled EPA administrator's recent controversies — and Sen. Lisa Murkowski announcing Tuesday that she plans to bring him before her appropriations panel in May.

Three other Republicans, including staunch Pruitt ally Sen. Jim Inhofe (R-Okla.), told POLITICO on Monday that they would also support hearings by the Senate Environment and Public Works Committee to look into the former Oklahoma attorney general's actions. Their words came as Pruitt, who has managed to hold onto President Donald Trump's public support for now, faces a pair of House hearings Thursday that could be make-or-break for his hopes of remaining in the Cabinet.

"I think that a couple of us on the committee think it's appropriate to have a hearing in so far as any accusation having to do with his office is concerned," Inhofe told POLITICO.

Inhofe said he was troubled by a report over the weekend in The New York Times detailing a sweetheart deal Pruitt received on an Oklahoma City home previously owned by a lobbyist while serving in a state government. The Oklahoma Republican declined to discuss which allegations he found disturbing, but said "there are some things in there that I'd like to check out and see."

Joining his call for a Senate hearing were two other senior GOP members of the EPW panel, Sens. Shelley Moore Capito (W.Va.) and John Boozman (Ark.).

"Most people have concerns about some of the allegations," Boozman said. "At some point he'll be before the committee and we'll dig deeper and see exactly what's going on."

EPW Chairman John Barrasso (R-Wyo.) said Tuesday that he has "serious questions" about how Pruitt has handled taxpayer dollars, but he stopped short of announcing plans for Pruitt to testify.

"We want to make sure money is being spent appropriately," Barrasso said.

Murkowski (R-Alaska), who chairs the subcommittee that oversees EPA's appropriations, did not elaborate on her plans for her own hearing with Pruitt, or how much it would delve into his ethics and spending. But she said it would be "absolutely appropriate" for Barrasso's panel to hold an oversight hearing on the administrator's conduct in office, an idea that multiple Republicans on the authorization committee have endorsed.

"I'm hoping they move on it sooner than later," Murkowski said of the EPW Committee.

To date, four House Republicans have called on Pruitt to resign, along with scores of elected Democrats. And Sen. Susan Collins (R-Maine), has said Pruitt was "the wrong person" to lead the agency based on his policies.

Pruitt has drawn criticism about his ethics and lavish spending in recent months. Three congressional committees, the White House and EPA's inspector general are all probing his behavior, ranging from his security expenses, high pay raises for aides, first-class travel and meetings with a coal group.

The House Oversight Committee has requested interviews with five senior agency aides. The White House said it would formally investigate Pruitt's expenses after the Government Accountability Office last week found EPA broke the law by failing to notify Congress about a $43,000 privacy booth Pruitt had built in his office.

Pruitt will go to the Hill on Thursday to testify before a House Energy and Commerce subcommittee in the morning and at a House Appropriations subpanel in the afternoon. Those appearances will mark his first time before Congress since the recent allegations broke.

Both Inhofe and Capito said they thought those House hearings would prove pivotal for Pruitt's long-term future in the administration.

"It's really important," Capito said. "He's going to have to answer some tough questions. I'm sure they'll be put to him by both sides and we'll see what his response is."

Meanwhile, EPW ranking member Tom Carper (D-Del.) said he had a good conversation with House Oversight Chairman Trey Gowdy (R-S.C.) regarding Pruitt, but he said there was no formal bipartisan agreement to work together on an investigation.

"I just gave him plenty of encouragement that he's doing the right thing," he said.

But the mounting public criticism from Republicans suggests GOP lawmakers' patience in defending the EPA chief's behavior is waning.

"Some of the things that he's done and that he's been alleged to do are just indefensible," Sen. John Kennedy (R-La.) said. "You just can't put lipstick on those pigs. You can't."

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French president to call for American role in Syria Back

By Ian Kullgren | 04/22/2018 10:03 AM EDT

French President Emmanuel Macron said Sunday he will call for continued U.S. intervention in Syria before a joint session of Congress this week.

"I will advocate for multilateralism," Macron said in an interview on "Fox News Sunday."

Macron is visiting Washington this week in the first official state visit of the Trump presidency. In an interview with Chris Wallace at the presidential palace in Paris, Macron said he has a "special relationship" with President Donald Trump, describing them both as political outsiders.

"Both of us are probably the maverick of the systems on both sides," Macron said. "President Trump's election was unexpected in your country and probably my election was unexpected in my country."

Macron said that the United States is still an indispensable player for achieving peace in the Middle East, adding that France will rely on the U.S. in Syria once the conflict comes to an end.

"We will have to build a new Syria afterwards," he said.

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Apple's Tim Cook attending White House state dinner for Macron Back

By POLITICO Pro Staff | 04/24/2018 07:15 PM EDT

Apple CEO Tim Cook is attending tonight's White House state dinner for French President Emmanuel Macron.

Cook was spotted arriving for the dinner with former EPA Administrator Lisa Jackson, who is now vice president of environment, policy and social initiatives for Apple, according to a pool report.

Jackson served as head of the EPA under former President Barack Obama.

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TSCA

As-it-happens update - April 24, 2018

NEWS

Rollout of Lautenberg law divides senators who championed it

E&E News

Their quick retreat from common ground to familiar opposition positions is an indication to policy experts that the **TSCA** reform deal was an extraordinary agreement that would be impossible to make today — and one which is now being viewed very differently by the lawmakers who pushed to enshrine it ...

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Systematic Failures of Chemical Safety Research at Environmental Protection Agency

Competitive Enterprise Institute (blog)

We have now a much better alternative, EPA's newly reformed chemicals program under the Toxic Substances Control Act. I have expressed concerns about **TSCA** reform because the standards in the prior law were strong and change can be risky. But the revised law still contains some good language ...

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Scott Pruitt's new science transparency rule may seriously backfire

ThinkProgress

Beck also worried that requiring public data could disrupt registration for chemicals under the Toxic Substances Control Act (**TSCA**). Under an update to **TSCA** passed in 2016, the EPA has to make an affirmative finding that a particular chemical does not pose a threat to human health before approving it ...

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Subject: Morning Energy: Another mess for Pruitt — Virgin Islands party boss: Zinke ties improved hurricane response — Coal magnate delivered draft orders to Trump

By Kelsey Tamborrino | 06/07/2018 05:41 AM EDT

With help from Darius Dixon, Anthony Adragna and Annie Snider

ANOTHER MESS FOR PRUITT: Scott Pruitt has an appetite for food from the White House mess — a U.S. Navy-run restaurant for use only by White House officials, Cabinet members and other dignitaries. In fact, he loves eating there so much, the White House asked him to stop coming by so often, POLITICO's Emily Holden, Andrew Restuccia and Anthony Adragna report.

The message was clear, according to one person close to Pruitt: "We love having Mr. Pruitt, but it's not meant for everyday use." A member of the White House's Cabinet affairs team told agency chiefs of staff last year that their bosses shouldn't treat the mess like their personal dining hall — a comment that came in response to Pruitt's recurring use of the restaurant, sources said.

Pruitt's allies privately disputed that the warning about overuse of the mess was aimed squarely at him, but nobody contests that he's a frequent presence at the establishment in the basement of the West Wing. The White House did not respond when asked about his lunch habits, and EPA declined to comment.

A billing statement from July 2017 offered a glimpse into Pruitt's trips to the mess, racking up a bill of $400 over nine trips that month — a relative bargain in downtown Washington considering the menu. A cheeseburger at the White House runs just $6.35, according to Pruitt's bill. Compare that to the $17 you'd pay for a burger from another favorite Pruitt spot, French bistro Le Diplomate. Read more.

Support for Pruitt is also falling on Capitol Hill, Anthony and Emily report, in the wake of this week's news that Pruitt sought to buy a used mattress from the Trump Hotel and inquired about securing a Chick-fil-A franchise for his wife. Two more top aides to Pruitt — scheduler Millan Hupp and counsel Sarah Greenwalt — also are leaving the agency. "I'm not going to come down here, just because he happens to be a nominee of a president I support or a nominee from my party, and try to defend the indefensible," Sen. John Neely Kennedy said. More here.

On the other hand, Cory Gardner, who heads the Senate GOP campaign arm, told reporters he doesn't think Pruitt's ongoing ethics woes will harm his party in the midterms. "The states like Missouri, Indiana, North Dakota have benefited from a regulatory approach this administration has taken," Gardner said.

Environmentalists' "Boot Pruitt" campaign will gather a "group of cows" outside the Capitol South Metro station today from 8 a.m. to 9:15 a.m. to hand out fake Chick-fil-A coupons for a free chicken sandwich with a donation to Pruitt's legal defense fund. They'll hold signs reading: "Breeth Mor Carbun" and "What the Cluck, Pruitt?"

VIRGIN ISLANDS BOSS PLAYS UP ZINKE RELATIONSHIP: The head of the Virgin Islands Republican Party suggested his fundraising group's longstanding relationship with Interior Secretary Ryan Zinke helped improve the department's response to last year's hurricanes that struck the island territory, Pro's

Ben Lefebvre reports. John Canegata said he had direct access to Interior officials after the storm thanks to money his group raised for Zinke when he was a member of Congress.

Calling Zinke a "close friend," Canegata boasted of his connections in a televised appearance that aired in the Virgin Islands last month but has not received widespread attention outside of the territory. While numerous officials played a role in helping the islands recover from hurricanes Maria and Irma, "behind the scenes, trust me, a lot of telephone calls, a lot of maneuvering was going on because, I think, some of the relationships we built," Canegata said of Zinke.

Interior acknowledged that officials contacted Canegata after the hurricanes but said they did so as part of a wider effort to contact business leaders based in the territory and Zinke did not call him personally. Canegata works for Cruzan Rum, but a company representative told Ben he was not involved in coordinating its relief efforts. Interior expedited the reimbursement of taxes on Virgin Islands rum following the storms, but it was unclear whether Canegata influenced that decision; he did not respond to a request for comment.

For his part, Zinke has known Canegata since at least 2015, Ben reports. The secretary previously came under fire for a fundraiser for the VIGOP, as the group is known, during an official trip to the islands in his first month in President Donald Trump's Cabinet. Read more.

IT'S THURSDAY! I'm your host Kelsey Tamborrino. NRECA's Dan Riedinger correctly identified John Tyler as the only president to have not been a resident of the U.S. when he died. Tyler resided in Virginia at the time, which was part of the Confederate States of America. Today's question: Which Congress had the largest number of veterans in office? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

MURRAY DELIVERED EXECUTIVE ORDERS TO TRUMP: Coal magnate Bob Murray handed off drafts of six executive orders that would roll back Obama-era environmental regulations to Trump during the beginning of his administration, according to documents from DOE released under FOIA. The documents include a letter to Energy Secretary Rick Perry from Murray praising Trump's March 2017 energy independence executive order, and included a note where Murray wrote, "we have developed the enclosed materials for your review and consideration, consisting of: six (6) Executive Orders further rescinding anti-coal regulations of the Obama administration; and one (1) memorandum outlining the legal rationale for each of these action, and others."

While Trump did not sign those exact orders, the administration has moved to enact similar policies, Pro's Darius Dixon reports. The documents, which were sent to DOE the day Trump signed his energy independence order and one day before Murray met with Perry and DOE chief of staff Brian McCormack, also included concepts about grid security and "resiliency" that Perry later touted as part of his push to stop coal power plants from closing. Read more.

BAILOUT ON HIS MIND: In private remarks given during his visit to FEMA headquarters Wednesday, Trump mentioned a slew of topics that had nothing to do with hurricanes, The Washington Post reports, while only briefly mentioning Puerto Rico. Trump instead encouraged Perry to make an announcement about rescuing economically struggling coal and nuclear power plants, the Post reports. "I'd love to put it out — 'clean coal, nuclear,' it's a very important message," he said, telling Perry he needed to hold a news conference.

WRDA MOVES AHEAD: The House passed the Water Resources Development Act of 2018 (H.R. 8 (115)) last night, marking the first major piece of infrastructure legislation to move under the Trump administration, Pro's Annie Snider reports. Lawmakers signed off on the measure on a broadly bipartisan vote of 408-2. The bill — markedly narrower than the Senate's measure — would authorize six new Army Corps of Engineers projects and enact a suite of policy reforms at the red tape-laden agency.

What about the Senate? For those wondering, EPW Chairman John Barrasso told ME he'd not yet locked down a time for the Senate to consider its broader version of the water resources infrastructure legislation. Separately, Sen. Tammy Baldwin sent this letter to Trump, calling on him to urge Congress to include a permanent Buy America provision in the legislation.

MUM'S THE WORD: Barrasso, whose state produces a lot of coal and uranium, told ME he isn't ready to back Trump's proposed bailout for coal and nuclear power plants. "I've read the article but I want to actually see what the proposal is," he said. DOE is still formulating the details of how it would intervene to save the struggling plants.

RESCISSIONS VOTE TODAY: The House is set to vote today on Trump's $15 billion rescissions bill, Pro's Sarah Ferris reports. The House Rules Committee teed up the bill, H.R. 3 (115), on Wednesday, a quick turnaround that surprised even some GOP lawmakers.

ALL ABOARD: After the rescissions package, the House is ready to start debate on its "minibus" appropriations package, which includes energy and water, legislative branch and military construction-VA spending bills, Pro's Kaitlyn Burton reports. The Rules Committee has set up floor votes on 50 amendments to the energy and water title. A final vote on the overall bill is expected Friday.

SHIMKUS SPEAKS: Rep. John Shimkus, one of the most ardent Yucca Mountain champions in Congress, said his loud floor dispute with Paul Ryan on Tuesday was simply a dispute over "strategy going forward." Other members suggested it had to do with the timing of the Energy-Water bill, since Shimkus thinks delaying until after the midterms might allow Yucca language to make it into the title. The Senate has avoided tackling Yucca due to Sen. Dean Heller's close reelection contest.

POWER OF THE PEN: The House Appropriations Committee agreed to bar EPA from spending more than $50 on a fountain pen. The amendment — an apparent reference to the $1,560 Pruitt spent on a dozen fancy writing implements — passed on a voice vote at Wednesday's markup. The panel cleared its version of the fiscal 2019 EPA-Interior bill, on a vote of 25-20. Committee Republicans blocked an effort from Democrats to boost EPA's Office of Inspector General by $12 million, but approved an amendment that would change revenue sharing for drilling in the Arctic National Wildlife Refuge. And while the pen amendment passed, the committee shot down another amendment from Democratic Rep. Mike Quigley related to Pruitt's travel.

MEETING WITH A FULL DECK: The last time the leadership of FERC and the Nuclear Regulatory Commission got together, there were just enough commissioners between the two agencies to fill one five-member board. Fast-forward to today, and it's a full house for the first time in years thanks to confirmation of two new NRC leaders last month. The get-together is slated to run for just over two hours. An agenda hasn't been released but the meetings usually involve staff presentations on grid reliability — and how it might be impacted by the retirement of nuclear plants — and cybersecurity regulations. Finding the areas where an

economic regulator overlaps with a safety watchdog isn't always obvious. The meeting is slated to run from 9 a.m. to 11:15 a.m. at FERC headquarters, and will be webcast.

ROYALTY RUMPUS: Interior's Royalty Policy Committee approved recommendations Wednesday aimed at expanding energy lease sales and lowering royalty rates, Ben recaps. But during the advisory committee's meeting, two members questioned whether it had the power to suggest changes to federal environmental review. "NEPA is not referred to in the [committee] charter," Rod Eggert, a professor at the Colorado School of Mines, said during the meeting. "The text in the charter refers to royalties and collections of royalties." Read more here.

Later Wednesday, BLM sent out a memo instructing field offices to look for ways to speed up permit processing, including by using categorical exclusions, Ben reports.

— **Meanwhile, the Central Arizona Project will meet today** on proposals for sourcing cheaper power to run the Navajo Generating Station. The Bureau of Land Reclamation last week sought to delay the coal-fired power plant's closure, arguing that a 1968 law gives Zinke the authority to require the Arizona water project buy energy from the power plant. Reuters has the rundown here.

GROUPS WARY OF INTERIOR DRAFT BILL: A coalition of sportsmen's groups is concerned about draft legislation that appeared before the House Natural Resources Energy Subcommittee on Wednesday. According to the draft bill, it would enable Interior to recover the costs of administrative protests to oil and gas lease sales, drilling permits and other applications. The bill, they say, would make it more difficult for sportsmen and women to comment on oil and gas lease sales on public land.

BLANKENSHIP IS BACK: Former coal baron Don Blankenship hasn't given up hope to take on the establishment and earn himself a spot in the Senate. After losing a primary bid to West Virginia Attorney General Patrick Morrisey, Blankenship's campaign announced Wednesday it is petitioning to gain ballot access for the general election as the nominee for the Constitution Party.

BIPARTISAN LETTER ASKS PRUITT TO DROP 'SECRET SCIENCE': More than 100 lawmakers — including Republican Reps. Brian Fitzpatrick, Carlos Curbelo, Ryan Costello and Ileana Ros-Lehtinen — signed onto a letter to Pruitt today, asking him to withdraw EPA's so-called secret science proposal to bar EPA from using studies that don't make public all their data. Read the letter here.

DEMS WARN AGAINST E15: Democratic Sens. Tom Udall and Peter Welch are calling on EPA to abide "by all legal and regulatory requirements" as the Trump administration weighs the year-round sale of 15 percent ethanol blends of gasoline. "We are very concerned that career EPA officials may be being directed to reverse over 25 years of the agency's position to manufacture legal and scientific justifications for a politically-directed decision on E15," they write. Read the letter.

MAIL CALL! RELEASE THE STUDY: A coalition of environmental groups will send this letter today to HHS Secretary Alex Azar, calling on him to release the controversial federal chemical pollution study blocked by EPA officials.

— **Nineteen environmental groups filed a letter** to the House in opposition of H.R. 5895 (115), the so-called minibus, which they say sets up an improper use of water and natural resources, and undermines safe nuclear waste disposal. Read it here.

FOR YOUR RADAR: The International Wildlife Conservation Council, which came under fire for the big-game trophy hunters added to its ranks, will hold its next meeting June 19 in Atlanta, according to the Federal Register.

ON THE WEB: The Center for American Progress is launching a new website today that is dedicated to tracking legal challenges to the Trump administration's conservation agenda. See it here.

QUICK HITS

— The heat is back on high: May smashes U.S. temperature records, Associated Press.

— Man dies at Randolph County mine, Charleston Gazette-Mail.

— Hurricanes are traveling more slowly — which makes them even more dangerous, The Washington Post.

— Trump falsely claims "We're now exporting energy for the first time," The New York Times.

— Trump's move to please farmers on biofuels reform draws refinery union ire, Reuters.

HAPPENING TODAY

8:00 a.m. — Exchange Monitor holds Decommissioning Strategy Forum, Nashville

8:30 a.m. —New Energy Update holds U.S. Offshore Wind conference, Boston

9:00 a.m. — The Atlantic Council and the American Council on Renewable Energy discussion on "The State of America's Energy Transition: Renewable Energy Policy Network for the 21st Century Renewable Global Status Report," 1030 15th Street NW

9:00 a.m. — Industry Exchange holds Mexico Gas Summit, San Antonio, Texas

9:00 a.m. — The Federal Energy Regulatory Commission and the Nuclear Regulatory Commission joint meeting, 888 First Street NE

11:00 a.m. — House Energy and Commerce Committee hearing on "Improving the Hydropower Licensing Process," 2123 Rayburn

11:00 a.m. — House Transportation Coast Guard and Maritime Transportation Subcommittee hearing on "Maritime Transportation in the Arctic: The U.S. Role," 2167 Rayburn

12:00 p.m. — Hill briefing on "The Export Subsidy RIN: A Valueless Dead End," 608 Dirksen

12:30 p.m. — Women of Renewable Industries and Sustainable Energy lunch and learn, 1501 M St NW

1:00 p.m. — House Science Energy Subcommittee hearing on the electric grid, 2318 Rayburn

2:00 p.m. — House Natural Resources Oversight Subcommittee hearing on "Wildfire Risk, Forest Health, and Associated Management Priorities of the U.S. Forest Service," 1324 Longworth

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Another mess for Pruitt: Overstaying his White House welcome at lunch Back

By Emily Holden, Andrew Restuccia and Anthony Adragna | 06/06/2018 10:17 PM EDT

EPA Administrator Scott Pruitt loves eating at the White House mess, an exclusive U.S. Navy-run restaurant open only to White House officials, Cabinet members and other dignitaries.

But apparently he liked it too much, and the White House asked him to please eat elsewhere sometimes.

In response to Pruitt's recurring use of the restaurant next to the Situation Room in the basement of the West Wing, a member of the White House's Cabinet affairs team told agency chiefs of staff in a meeting last year that Cabinet members shouldn't treat the mess as their personal dining hall, according to three people with knowledge of the issue.

The message was clear, according to one person close to Pruitt: "We love having Mr. Pruitt, but it's not meant for everyday use." Another person added that the White House asked Cabinet members to visit the mess only occasionally because there are few tables available.

A renovation to update the West Wing HVAC last August included the mess kitchen and may have limited space, one person said. The renovation came shortly after the president tapped John Kelly as chief of staff, and he implemented several day-to-day changes to bring order to the White House.

The White House did not respond to a request for comment and EPA declined to comment. Pruitt's allies privately disputed that the warning about overuse of the mess was aimed squarely at him, but nobody contests that he's a frequent presence at the White House for lunch.

Pruitt has been known to complain that EPA headquarters has no cafeteria of its own and no private dining quarters, according to multiple sources, who said Pruitt still often heads to the White House for lunch. One source said EPA officials called the White House to explain that Pruitt didn't have a place to eat at EPA and would like to continue to visit. Pruitt's EPA office is only a few blocks up Pennsylvania Avenue from the White House.

A billing statement from July 2017 offered a glimpse into Pruitt's use of the mess, showing the EPA chief or people linked to him dined at the mess at least nine times that month, racking up a bill of $400, a relative bargain in downtown Washington. Pruitt and his guests dined on dishes like "cowboy" skirt steak, popcorn chicken and waffles, spinach strawberry salad and beer-braised brisket tacos.

While the food is considered to be top-notch, the prices are a real bargain. Skirt steak runs just $10.25, while coriander beef kabobs were just $11.95 each. And a cheeseburger runs just $6.35, according to his bill. The burger at another of Pruitt's haunts, French bistro Le Diplomate, runs $17.

Records obtained through a Sierra Club Freedom of Information Act request also show Pruitt often sought to bring friends from Oklahoma to the White House mess.

Five friends from Tulsa — Charlie Polston, Carlyn Mattox, David Mattox, Bob Wagoner and Jerry Dillon — were invited for a September lunch there with him, though it didn't appear in Pruitt's detailed calendar obtained through FOIA.

That lunch came just two weeks after Pruitt made a lunch date there with Bob Funk, a wealthy Oklahoma Republican with whom he bought a major stake in the minor league Oklahoma City RedHawks baseball team back in 2003.

"Please have Mr. Funk arrive at EPA building at 11:40am to ride with Administrator Pruitt to the WH," Lincoln Ferguson, a senior adviser for public affairs, wrote in an email. There was no entry in Pruitt's calendar for the time when the lunch was to have taken place.

Calendars from Pruitt's senior aides show he made frequent use of the space in the month following his February 2017 Senate confirmation. He dined there on Feb. 27, March 2 and met with Ivanka Trump, the president's daughter and West Wing adviser, on March 13. Chief of staff Ryan Jackson's calendar also lists a lunch in the "Mess" on March 16.

Pruitt also hosted representatives from the Oklahoma Farm Bureau on March 29, according to Jackson's calendar. And he returned for lunch with Mike Catanzaro, a senior White House energy aide, and several senior aides on April 7.

Pruitt and his guests also seemed to have a sweet tooth, partaking of a dessert called "Chocolate Freedom" on multiple occasions. As POLITICO reported in January 2017, the dish — a molten cake made with imported French chocolate that must be ordered at the beginning of lunch because of the baking time — was also popular among Obama administration staffers on their way out the door.

Chocolate Freedom has garnered rave reviews online, and once prompted comedian Zach Galifianakis to ask whether it was also the staff's nickname for former President Barack Obama.

Also available to diners: boxes of red, white and blue M&Ms featuring the presidential seal.

Alex Guillén contributed to this report.

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Back

Pruitt wanted to buy 'old mattress' from Trump International Hotel Back

By Anthony Adragna | 06/04/2018 10:43 AM EDT

Two senior House Oversight Democrats are demanding Chairman Trey Gowdy (R-S.C.) subpoena Scott Pruitt for documents after one of his closest aides told congressional investigators the EPA administrator had her book a personal flight to the Rose Bowl, search for housing for him and try to buy him an "old mattress" from the Trump International Hotel.

Ranking member Elijah Cummings (D-Md.) and Gerry Connolly (D-Va.) demanded that Gowdy compel Pruitt to turn over all documents related to the potential mattress purchase, efforts to secure personal flights, and work that agency employees performed on non-EPA tasks for Pruitt that have been withheld from an earlier April Democratic request. That followed a May 18 transcribed interview with Millan Hupp, Pruitt's scheduler.

"If Ms. Hupp's statements to the Committee are accurate, Administrator Pruitt crossed a very clear line and must be held accountable," they wrote. "Federal ethics laws prohibit Administrator Pruitt from using his official position for personal gain and from requesting and accepting services from a subordinate employee that are not part of that employee's official duties."

As part of its investigation into Pruitt, the Oversight Committee said it has conducted several transcribed interviews and obtained 2,350 pages of documents, and a spokeswoman criticized the release of Hupp's testimony.

"Selectively releasing portions of witness interview transcripts damages the credibility of our investigation and discourages future witnesses from coming forward. The Committee will continue conducting a serious, fact-driven investigation, and therefore will wait until the conclusion of our investigation to release our findings," committee spokeswoman Amanda Gonzalez said in a statement.

White House Press Secretary Sarah Huckabee Sanders said Monday the administration is "looking into" the issues in the Democrats' letter, but didn't outline any more specific steps.

"I couldn't comment on the specifics of the furniture use in his apartment and certainly would not attempt to," she said, referring to Pruitt's interest in the mattress.

According to the Democrats' letter, Hupp told Oversight staff she worked with the managing director of the Trump International Hotel in hopes of securing an old mattress. She said Pruitt had told her someone at the hotel indicated he could purchase the mattress, though she did not know why he wished to do so and did not know if he ultimately bought it.

In addition, Hupp said she sent several emails to real estate agents over a period of several months last summer during work hours to help Pruitt find housing after he verbally asked for her help. She said she visited a "probably more than 10" properties during her lunch hour over the course of several months. Hupp said she didn't use work email for the searches and was not paid for her efforts.

Pruitt and his wife ultimately settled on an apartment on 13th and U streets, but left it shortly afterwards because "they were not comfortable in the area," according to Hupp.

Democratic lawmakers have honed in on Pruitt's admission during a May 16 Senate subcommittee hearing that Hupp had searched for housing for him without pay on her own personal time.

"It doesn't cut it that they're a friend or that kind of thing," Sen. Tom Udall (D-N.M.) told Pruitt at the hearing, because having a subordinate staff member voluntarily conduct tasks on personal time would constitute a gift.

"That's in violation of federal law," Udall told Pruitt.

An EPA spokesman said the agency continued to give the information it was seeking.

"We are working diligently with Chairman Gowdy and are in full cooperation in providing the Committee with the necessary documents, travel vouchers, receipts and witnesses to his inquiries." EPA spokesman Jahan Wilcox said in a statement.

According to the Democrats' letter, Hupp said around Christmas she used a personal credit card from Pruitt in her possession to arrange his personal trip to the Rose Bowl in California to watch the Oklahoma Sooners football team play. She did not know why Pruitt, who sent her the details for the trip, and couldn't book the flight on his own.

"He just sent me the flights details and asked me to book for him," Hupp said.

Hupp indicated she considered Pruitt a personal friend, which was why she did these tasks for him. She said the two had met for dinners that were attended by just the two of them.

"We worked very closely together and spent a lot of time together," she said. "I traveled with him, so naturally a friendship developed."

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Back

Republicans losing patience with scandal-scarred Pruitt Back

By Anthony Adragna and Emily Holden | 06/06/2018 05:37 PM EDT

Republicans on Capitol Hill are growing frustrated with EPA Administrator Scott Pruitt — and many are now publicly questioning whether he can hang on to his job amid the unending stream of scandals.

Several GOP lawmakers said their patience was running thin after this week's news that Pruitt sought to buy to buy a used mattress from the Trump Hotel and inquired about securing a Chick-fil-A franchise for his wife. And Pruitt's circle of confidantes inside the agency appeared to be shrinking as well, with two of his closest aides set to depart in the coming days.

"The constant drip needs to stop so the agency can get its footing and focus back," House Energy and Commerce Chairman Greg Walden (R-Ore.) told reporters. "They're doing some really good work in the environmental front, but this needs to stop."

"Sometimes people get tripped up on other things besides the core mission, and I think that's what you're seeing," Sen. Shelley Moore Capito (R-W.Va.) told reporters.

Pruitt's scheduler, Millan Hupp, is resigning following her interview by the House Oversight Committee during which she disclosed that she helped her boss find housing and inquired about purchasing a used mattress for him from the Trump International Hotel.

And his top legal counsel, Sarah Greenwalt, will also depart, according to sources. Both women had worked for Pruitt in the Oklahoma attorney general's office and both were among the staff that received raises that had been rejected by the White House.

"I think it's extremely fair to say her and Millan both are tired of the daily grind here," one EPA official said. "Everybody is painfully aware of that."

While acknowledging that President Donald Trump would ultimately make any decision about Pruitt's job, several Republicans indicated Pruitt's support was waning in their conference.

"I'm not going to come down here, just because he happens to be a nominee of a president I support or a nominee from my party, and try to defend the indefensible," Sen. John Kennedy (R-La.) said. "I thought that Mr. Pruitt would have learned his lesson."

Kennedy added: "I said the same thing about Tom Price," referring to Trump's former HHS secretary who resigned after spending lavishly on military and private jets.

Trump reaffirmed his support for Pruitt on Wednesday when they participated in a briefing on the 2018 hurricane season with several Cabinet officials.

"EPA is doing really, really well," Trump said. "You know, somebody has to say that about you a little bit. You know that, Scott."

But even staunch Pruitt allies like Sen. Jim Inhofe (R-Okla.) said the mounting scandals had them rethinking their support.

"Some are true, some are not true. Whether he can weather the storm, I'm not sure," Inhofe said. "The accusations are all troubling. They are."

A few Republicans stood by Pruitt, arguing he's been targeted by an environmental community and press corps eager to take him down.

"I like him," Sen. Roger Wicker (R-Miss.) said. "He is a target because he's keeping the president's campaign promises."

But a more common view among GOP lawmakers was the collective stream of scandals were taking their toll and making Pruitt's position untenable.

"Take a thousand cuts and [there's] not much energy left," Senate Appropriations Chairman Richard Shelby (R-Ala.) told reporters.

Rep. John Shimkus (R-Ill.), who leads the Energy and Commerce subcommittee overseeing EPA, joked he "can't keep up" with the flood of allegations and said he's concerned they haven't stopped.

"These unforced errors are unforced errors," he said. "I don't like being asked all the time about this."

But he raised a possible reason why Republicans weren't abandoning Pruitt: getting a replacement confirmed by the Senate would be nearly impossible.

"Are you going to promise me we could even get an administrator?" he said. "I think that's another concern."

In a video posted by a Nexstar Wednesday, Pruitt defended his attempts to set his wife up with a Chick-fil-A franchise Wednesday, while the president reaffirmed his support in the administrator.

Pruitt said that his wife is "an entrepreneur herself" and that the pair loved the fast-food franchise. As he has in the past, Pruitt dismissed criticism of his behavior as being driven by opposition to the Trump administration's deregulatory policies.

"With great change comes, I think, opposition," he said in a clip the reporter posted to Twitter.

Pruitt did not directly address whether he had asked an EPA aide to reach out to Chick-fil-A President Dan Cathy to inquire about his wife opening up her own restaurant, as the Washington Post first reported Tuesday.

"Chick-fil-A is a franchise of faith and it's one of the best in the country, so that was something we were very excited about," he told the Nextstar reporter Wednesday. "We need more of them in Tulsa, [Okla.]. We need more of them across the country."

Kelsey Tamborrino contributed to this report.

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Trump's Interior chief 'hopping around from campaign event to campaign event' Back

By Ben Lefebvre and Esther Whieldon | 10/05/2017 05:01 AM EDT

Republican donors paid up to $5,000 per couple for a photo with Interior Secretary Ryan Zinke at a fundraiser held during a taxpayer-funded trip to the U.S. Virgin Islands, according to documents reviewed by POLITICO — raising questions about his habit of mixing official government business with political activism.

The new details about Zinke's March trip to the Caribbean, including the previously undisclosed invitation to the Virgin Islands Republican Party fundraiser, emerged after weeks of scrutiny of the former Montana GOP congressman's travels. The nearly two-hour event was one of more than a half-dozen times Zinke has met with big donors or political groups while on department-paid trips, Interior travel records and other documents show.

Ethics watchdogs say Zinke is combining politics with his Interior duties so frequently that he risks tripping over the prohibitions against using government resources for partisan activity, even though his appearance at the Virgin Islands event seems to have been legal. Democrats have also seized on the issue, including 26 House members who wrote in a letter Tuesday that Zinke's travels "give the appearance that you are mixing political gatherings and personal destinations with official business."

Zinke has said all his actions have obeyed the law, dismissing concerns about his travel as "a little BS."

But some ethics advocates say Zinke's attendance at a fundraiser during his first month as secretary is not in line with past administrations' conduct, even if he crossed no legal red lines.

"It happens on occasion with other Cabinet secretaries, perhaps even a little more often as you get near the election, but it is not a very common practice for Cabinet members to be hopping around from campaign event to campaign event like we're seeing with Zinke," said Craig Holman, government affairs specialist for government watchdog Public Citizen.

The secretary is already under investigation by his department's inspector general over his use of taxpayer-funded private planes for some of the trips, and the Office of Special Counsel is looking into an activist group's allegations that he violated the Hatch Act, the law limiting political activism by federal employees. The White House has cracked down on Cabinet members' travel habits following former HHS Secretary Tom Price's resignation on Friday, which occurred after POLITICO reported on his own expensive flights.

Zinke visited the Virgin Islands from March 30 to April 1 on an official trip related to the Interior Department's role overseeing the U.S. territory. On his first day, following a "veterans meet and greet" and a reception with Gov. Kenneth Mapp, he appeared in his personal capacity at a March fundraiser for the local Republican Party at the patio bar of the Club Comanche Hotel St. Croix, department records show.

Tickets for the fundraiser ranged from $75 per person to as much as $5,000 per couple to be an event "Patron," according to Zinke's official calendar and a copy of the invitation. Patrons and members of the host committee, who paid $1,500 per couple, could get a photo with Zinke at the start of the event, which was attended by local party members and elected officials.

The following day, Zinke took a $3,150 flight on a private plane, paid for by the department, from St. Croix to official functions on St. Thomas and returned later that evening. Interior Department officials said there was no

other way to accommodate his schedule, which included official events on both islands commemorating the 100th anniversary of the Dutch government transferring control of the islands to the United States.

Zinke is allowed to engage in partisan political activity in a "purely personal (not official) capacity," so long as he does not use government resources, according to Interior Department guidelines on the Hatch Act and other federal laws. The invitation to the GOP fundraiser did not identify Zinke by his official title and included a disclaimer that the money is being solicited by the local party and "not by any federal official."

All told, Zinke has spent around $20,000 for three charter flights as secretary, nowhere near the $1 million tab Price racked up on non-commercial trips. But he has on numerous occasions attended political receptions, spoken to influential conservative groups or appeared alongside past campaign donors during trips has taken outside of Washington, D.C., for official department business.

In one instance, Zinke gave a motivational speech for a professional hockey team owned by a major campaign contributor that he said was official business — and which required him to charter a $12,000 flight to Montana for an appearance at the Western Governors Association the next day.

In another case, during a speech to the Western Conservative Summit in Denver, he was introduced via a recorded voice as the Interior secretary and Zinke proceeded to talk about the agency's priorities. The summit was organized by the Centennial Institute, which bills itself as Colorado Christian University's think tank and is a part of the State Policy Network of organizations that collectively push for conservative state-level legislation.

An Interior spokeswoman said Zinke always follows the law but declined to answer specific questions about his appearance at the Virgin Islands fundraiser, nor say whether he would keep raising political money. The agency also has yet to post Zinke's trip expenses involving any of the political events.

"The Interior Department under the Trump Administration has always and will always work to ensure all officials follow appropriate rules and regulations when traveling, including seeking commercial options at all times appropriate and feasible, to ensure the efficient use of government resources," spokeswoman Heather Swift said in a statement.

Swift did not respond to questions about whether the department had gotten reimbursement for the political portion of Zinke's three-day Virgin Islands trip, as the head of one watchdog group says it should have.

"Some of this travel is clearly political and that part of the travel should have been paid for by the RNC, NRCC, state political parties, a campaign committee or Zinke personally," said Daniel Stevens, executive director of the Campaign for Accountability.

No payments to the department are listed in the Virgin Islands Republican Party's FEC records.

Zinke is not the first Interior secretary, or Cabinet member, to have his activities questioned.

In 2012, a watchdog group called Cause of Action urged the Office of Special Counsel to investigate whether President Barack Obama's then- Interior Secretary Ken Salazar had violated the Hatch Act while taking an Obama reelection campaign RV tour of Colorado with a couple of lawmakers and the state lieutenant governor. Local organizers of one stop on that tour had billed Salazar on its online events calendar as attending the political rally in his official role. OSC would not say whether its investigation uncovered any problems, but travel records Interior has posted show that one of Salazar's aides had told the tour's coordinator the schedule "should not refer to (Salazar as) 'secretary.'" Salazar did not respond to a request for comment.

A former Salazar aide, who was not authorized to speak on the record, said the Obama administration generally tried to avoid scheduling political events that coincided with official travel because it was difficult to divvy up what expenses should be reimbursed by a campaign.

The special counsel's office found Obama HHS Secretary Kathleen Sebelius in violation of the Hatch Act in 2012, saying she had made "extemporaneous partisan remarks" by endorsing a candidate for North Carolina governor during a speech she made in her official capacity. Sebelius tried to scrub the violation by reclassifying the appearance as political and reimbursing the Treasury Department for costs associated with the trip.

Sally Jewell, who was Interior secretary during Obama's second term, said Zinke was within his rights to appear at the fundraiser in the Virgin Islands. Jewell said she once appeared at a fundraiser for Democratic Sen. Maria Cantwell while in Obama's Cabinet, though she paid her own way to Washington state and was not identified by her official title.

"If he had legitimate business while he's on the island, to do a political thing on the side, I don't think that is that unusual," Jewell said in an interview.

EPA Administrator Scott Pruitt canceled his scheduled appearance at a fundraiser for the Oklahoma Republican Party in April because an invitation had identified him by his official title and said he would discuss his work at the agency. EPA ethics officials said he would have been cleared to attend the event if not for that language on the invitation.

Watchdog groups say Zinke's behavior fits a pattern for Trump's Cabinet.

"These government resources have been abused by this administration," said Virginia Canter, an executive branch ethics counsel for Citizens for Responsibility and Ethics in Washington who previously worked as an ethics official for Presidents George H.W. Bush, George W. Bush and Obama. "To the extent that some of that supports their political ambitions is inconsistent with the intent of this authority."

The Campaign for Accountability called on Interior's inspector general and the Office of Special Counsel to investigate whether Zinke violated the Hatch Act or department ethics rules with his speech to the hockey team, which the group said appeared to be a favor for a donor. Interior's IG office announced its investigation earlier this week, and OSC told the Campaign for Accountability that it was looking into the group's complaint, according to an email shared with POLITICO. The OSC declined to comment.

Reps. Raúl Grijalva (D-Ariz.) and Donald McEachin (D-Va.) have asked Interior's IG to also look into any trips on which the secretary was accompanied by his wife, Lola Zinke, who is chairing the campaign of Montana Republican Troy Downing, a candidate to unseat Democratic Sen. Jon Tester next year. Swift said Lola Zinke was not in the Virgin Islands and has paid her own way whenever she has traveled with her husband on official trips.

Many who know him see Zinke's travels as an attempt to keep in touch with political contacts as he contemplates what he will do after leaving the Trump administration. Back home, the 55-year-old former Montana congressman is seen as an attractive candidate for the open-seat governor's race in 2020, when Democratic Gov. Steve Bullock will have to step down because of term limits.

"I think he's definitely got political aspirations; that's one of the reasons why he is where he is at right now," said Land Tawney, executive director of Backcountry Hunters and Anglers, a Montana-based sportsman group that supported Zinke's bid for Interior secretary. "You don't go from being a Montana legislator to a first-term congressman to [Interior] secretary without having ambition."

The Virgin Islands trip was Zinke's first interaction with big donors or influential conservative groups during his travel as Interior secretary.

A weeklong trip in May that took Zinke through Montana, Utah and California also offered a chance to squeeze in some political events.

Zinke delivered the keynote speech at the RNC spring meeting on May 11 in Coronado, Calif. Zinke had flown to California the previous night, after several days touring monuments in Utah, and the RNC speech was his only event in the state aside from a meeting earlier that afternoon with Rep. Amata Radewagen, the Republican delegate from American Samoa, and members of the American Tunaboat Association.

The next day, Zinke flew back to Montana, where he joined Sen. Steve Daines (R-Mont.) and Vice President Mike Pence to tour a coal mine on the Crow Indian reservation operated by the Westmoreland Coal Co.

The trip offered Zinke and Pence an opportunity to tout the Trump administration's work to promote new coal mining on federal lands — and it allowed them to make a brief detour to promote Zinke's congressional replacement. That Friday night, Zinke, Pence and Daines attended a political rally for GOP candidate Greg Gianforte, and Zinke attended a get-out-the vote event for the Montana GOP the next day.

Zinke apparently paid for his return trip to Washington out of his own pocket — it was marked "personal travel" on his calendar, a designation not applied to the other flights on that trip.

Gianforte, whose wife is a major political donor in Montana, won the May 25 special election to take over Zinke's House seat.

Greg and Susan Gianforte donated more than $10,000 to Zinke's 2016 congressional campaign and another $10,000 to a joint Zinke-Daines PAC, according to federal records. The couple donated $5,000 for his earlier run for Congress.

Zinke met with big influencers and donors in June as well.

On June 25, he flew from D.C. to Reno, Nev., where his only scheduled event was a meeting of the Rule of Law Defense Fund, a group of Republican attorneys general that has been linked to the Koch brothers, where he spoke and took questions for about 30 minutes, according to his schedule.

After his remarks, he sat at a dinner table with Montana's attorney general, the government relations specialist for the Venetian Resort Hotel Casino and Las Vegas Sands, and Koch Industries lobbyist Allen Richardson, Interior documents show.

The next day, Zinke flew to Las Vegas for an event on public lands in nearby Pahrump, Nev., and a speech that night to the National Hockey League's Vegas Golden Knights. Bill Foley, the team owner and chairman of Fidelity, introduced Zinke. Foley donated $7,800 to Zinke's 2014 campaign, while employees and PACs associated with Fidelity and related companies gave another $180,000. Interior officials said the speech to the NHL team was part of Zinke's official duties, and they pointed to scheduling conflicts it created to justify his use of a $12,000 private plane to get to a Western Governors Association meeting in Montana the next day.

In July, Zinke spoke to several conservative groups in Colorado during a three-day trip that also included tours of Interior Department facilities in the state. He flew into Denver on July 20 so he could appear that evening at a closed-door reception for the American Legislative Exchange Council, a group of conservative state legislators, lobbyists and industry groups that has pushed for more state control over federal lands.

And over the next two days, he was a featured speaker at a Republican committee roundtable and attended the Western Conservative Summit in Denver.

Eric Wolff contributed to this report.

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Back

Zinke's political ties to Virgin Islands improved Interior's hurricane response, party boss says Back

By Ben Lefebvre | 06/07/2018 05:11 AM EDT

The top GOP official in the U.S. Virgin Islands suggested his fundraising group's "behind the scenes" relationship with Interior Secretary Ryan Zinke helped influence the department's response to last year's hurricanes in the island territory.

John Canegata, the head of the Virgin Islands Republican Party, said he had direct access to Interior officials after the storm thanks to money his group raised for Zinke, whom he described as a "close friend." Zinke, a former congressman, has known Canegata since at least 2015, and the secretary was at a fundraiser for the VIGOP, as the group is known, during an official trip to the islands in his first month in President Donald Trump's Cabinet.

Interior officials acknowledged reaching out to Canegata, who also works for a major rum distiller in the territory, although they said it was part of a wider effort to contact business leaders based in the territory and Zinke did not call him personally. However, a representative of the distiller said Canegata was not involved in their relief efforts, and a spokesman for the Virgin Islands' House delegate disputed Canegata's involvement in the hurricane response.

The department expedited reimbursements of rum taxes as part of its response to the hurricanes, although it's unclear whether Canegata's connection influenced that decision. Interior has jurisdiction over U.S. territories including the Virgin Islands but not Puerto Rico, which suffered more extensive devastation.

Disaster response experts say it would be inappropriate for Canegata's political connections to influence Interior's efforts in the Virgin Islands.

"These are processes that are supposed to be transparent and supposed to be above the board," said Eric LeCompte, executive director of Jubilee USA, an anti-poverty group that has been involved in hurricane disaster relief efforts. "So, it would not be something a political party would be part of."

VIGOP is not a typical political party and faces frequent inquiries from the FEC to better explain its fundraising practices and expenses. Some critics, including past Republican clients, say the group bilks conservative donors with promises to fight Democrats while spending the bulk of its money on overhead instead of political advocacy. The group spends the vast majority of its money on a small group of Washington-area political consultants who have also done work for Zinke's campaign and leadership PACs.

Zinke was introduced to the VIGOP in 2015 by a Washington fundraising consultant who also did work for his campaigns, and as a member of Congress he has traveled to at least two political conferences in the Virgin

Islands sponsored by the group, POLITICO reported last year. Zinke and Canegata are seen together during a prior trip in a photo posted to Facebook.

Canegata boasted about his Zinke ties in a televised appearance on WTJX Virgin Islands Public Broadcasting that aired last month but has not received widespread attention outside of the territory.

"We were in direct connection with the Department of Interior," Canegata said in the broadcast.

"Secretary Zinke, happens to be, I wouldn't say a personal friend, but a close friend," Canegata continued. "Prior to him being the secretary of Interior, we spent some time in Washington, we spent some time here in the Virgin Islands. We supported him when he was a congressman and, behold, he becomes the secretary of Interior."

While Canegata credited other officials with their part in aiding the island's response, he said the pre-existing connection to Zinke was key.

"Obviously, we have our congresswoman, our governor doing their job," Canegata continued. "But behind the scenes, trust me, a lot of telephone calls, a lot of maneuvering was going on because, I think, some of the relationships we built."

The Office of Special Counsel on Tuesday closed its investigation into Zinke's appearance at the Virgin Islands fundraiser in March 2017, finding that he had not violated the Hatch Act because he was there in his official capacity and VIGOP reimbursed Interior for its expenses. Interior's inspector general also recently said the appearance at the fundraiser was not inappropriate. It is unclear whether either of those investigations addressed any link between VIGOP and Interior's hurricane response; both offices declined to comment.

Interior's Office of Insular Affairs, which oversees the Virgin Islands, "reached out to dozens of local government employees as well as major private sector employers in the USVI to check their power status and to see how the office could help," Interior spokeswoman Heather Swift said in an email. Canegata "was contacted by those Insular Affairs officials because he works for one of those major private employers, Cruzan Rum."

Canegata, a supply chain specialist at the rum distillery, had no role in the company's disaster relief efforts, according to Cruzan Rum human resources manager Ayanda Daniels.

"He wasn't part of the coordination," Daniels told POLITICO. "Maybe he had a conversation with someone in order to do something, but we had another team for company response."

James Norton, a former Department of Homeland Security Deputy official during the George W. Bush administration, said it is important for disaster response efforts to be handled through the appropriate channels.

"As a matter of proper procedure, it would only be appropriate for all federal actions to be dealt with solely with official authorities at the Department of Defense, Interior, Homeland Security, FEMA, etc., and those local officials on the ground," said Norton, who is now head of the consulting agency Play-Action Strategies. "Anything other than raising awareness and reaching out to get an update on what's happening would be inappropriate, as a political party or other organization doesn't have command and control authority, nor would they be the designated principal federal official on the ground directing rescue operations."

A spokesman for Stacey Plaskett, the Democratic House delegate from the Virgin Islands, disputed Canegata's version of events.

"I cannot honestly remember hearing them or seeing them do anything to that effect," Plaskett's spokesman Mike McQuerry said. "The congresswoman was the person here in D.C. that worked extremely hard during that time to get those funds to the Virgin Islands."

Canegata did not respond to a request for comment this week.

Interior expedited reimbursement of $223 million in taxes on Virgin Islands rum imported into the mainland and provided a $567,500 grant to help with a post-hurricane finance audit. Other hurricane relief funds would have come from FEMA, an Insular Affairs spokesperson said.

Otherwise, Zinke and Insular Affairs head Doug Domenech met with Virgin Islands Gov. Kenneth Mapp to discuss recovery efforts, the Insular Affairs spokesperson said. In November, Domenech also met representatives of Cruzan Rum's parent company, Beam Suntory, to discuss the rum tax reimbursements Interior makes to the territory. Beam Suntory donated $1.5 million to hurricane relief efforts the previous month.

Swift said Zinke did not personally reach out to Canegata. "The only official in the USVI the Secretary called was Governor Mapp," she said.

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Back

Murray had early access to Perry to share coal plan Back

By Eric Wolff | 12/07/2017 04:22 PM EDT

Coal magnate Bob Murray pitched Energy Secretary Rick Perry on his plan to throw an economic lifeline to coal companies less than a month before Perry set in motion plans to aid the industry, according to newly disclosed photographs that show the two meeting.

The liberal magazine In These Times obtained pictures of Murray and Perry from a March 29 meeting at Energy Department headquarters, less than a month after Perry was sworn in. Several other officials were in attendance, including Andrew Wheeler, who at the time was a lobbyist for Murray and has since been nominated as EPA's No. 2 official.

The meeting puts Murray and Perry together at a crucial moment in the timeline of the Trump administration's push to save the struggling coal industry, an effort that would benefit Murray Energy in particular while hiking electricity prices for potentially millions of people. A month before the meeting, one of Murray's biggest customers, FirstEnergy Corp., had told investors it was seriously considering sending its merchant division, FirstEnergy Solutions, into bankruptcy, a move which would likely void its supply contracts with Murray's coal mines.

Three weeks after Murray's visit, Perry would order a grid study that later became part of the justification for a proposed rule to reward coal and nuclear power plants for providing "grid resiliency." FERC, which has jurisdiction over the proposal, must make a decision on it by Monday.

At the time of the meeting, Wheeler was already the leading candidate to become the deputy administrator for EPA. Wheeler, who represented Murray as a lobbyist for Faegre Baker Daniels, would not be officially

nominated for months. Wheeler, who has acknowledged participating in meetings on Murray's coal plan at DOE and on Capitol Hill, cleared committee last week and is awaiting Senate confirmation.

Murray is an outspoken supporter of President Donald Trump and held a fundraiser for him during the 2016 campaign.

DOE did not dispute the validity of the photos.

"Industry stakeholders visit the Department of Energy on a daily basis," DOE spokeswoman Shaylyn Hynes said, when asked about the meeting. "The DOE proposal to FERC was about the future and resiliency of the nation's power supply, an issue much bigger than one industry or company."

The photographs show Perry sitting at the head of a table in the Department of Energy, with Bob Murray, CEO of Murray Energy, to his left, and Wheeler down the table from Murray.

"Enclosed is an Action Plan for achieving reliable and low cost electricity ... and to assist in the survival of our Country's coal industry, which ... power grid reliability and low cost electricity," Murray writes in a cover letter to Perry, parts of which are visible in one photo from the meeting.

Though the document has never been publicly released, DOE critics say Murray's plan appears to have inspired DOE's grid study and the proposed rule Perry sent FERC in September. Copies are visible at the seats of most of the participants, including Perry and Murray. Wheeler, who told members of the Senate Environment Committee he had only seen the memo briefly, is not holding a copy in the photos obtained by In These Times. Murray told Greenwire in November he "didn't have any involvement" in writing the rule.

Murray has acknowledged sharing the plan with Trump.

"I gave Mr. Trump what I called an action plan very early," Murray said in a recent PBS Frontline documentary on EPA. "It's about three-and-a-half pages and — of what he needed to do in his administration. He's wiped out page one."

The meeting appears to have been successful for all. One of the photos shows Perry and Murray in a big bear hug.

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Back

Murray delivered executive orders on coal rules to Trump administration Back

By Darius Dixon | 06/06/2018 07:05 PM EDT

Coal magnate Bob Murray delivered six draft executive orders ready for President Donald Trump to sign to roll back Obama-era environmental regulations in the early weeks of the administration, according to newly released Energy Department documents.

The documents released Wednesday after a Freedom of Information Act request include a letter to Energy Secretary Rick Perry from Murray praising Trump's March 2017 energy independence executive order, which largely aimed to help the coal industry. And to bolster that effort, Murray wrote, "we have developed the

enclosed materials for your review and consideration, consisting of: six (6) Executive Orders further rescinding anti-coal regulations of the Obama administration; and one (1) memorandum outlining the legal rationale for each of these action, and others."

Those executive orders were also sent to EPA Administrator Scott Pruitt, whose agency had jurisdiction over most of the issues they involved, such as ozone rules and regulations on coal ash.

Trump has not signed executive orders resembling Murray's, but the administration has moved to enact the policies, such as pulling U.S. out of the Paris climate agreement. The documents, which were sent to DOE the day Trump signed his energy independence order and one day before Murray met with Perry and DOE chief of staff Brian McCormack, also included concepts about grid security and "resiliency" that Perry later touted as part of his push to stop coal power plants from closing.

"The Department of Energy ("DOE") must issue an emergency directive to have an immediate study done of the security and resiliency of our electric power grids," the document states. "DOE will direct that no power plants having an available fuel supply of at least forty-five (45) days be closed during the study period, or a minimum of two (2) years."

Perry later ordered his staff to write a study about the electric grid that was eventually tied to a regulatory proposal that FERC create financial rewards for power plants with a 90-day supply of fuel on-site. That condition would have overwhelming benefited coal and nuclear generators, but it was shot down by FERC in January.

Critics have said Murray would be the biggest beneficiary of Trump's efforts, since his company supplies coal to many of the power plants at risk of closing because of stiff competition from cheap natural gas and renewable power as well as lagging electricity demand from consumers.

Murray spokesman Gary Broadbent confirmed the company had submitted the documents to Perry "to assist in the reversal of the illegal, job-killing, anti-coal regulations of the Obama Administration."

"Mr. Murray has always sought to secure reliable, low-cost electricity for all Americans, as well as to preserve and protect the jobs and family livelihoods of thousands of coal mining families," he said in a statement. "We applaud the actions taken by President Trump's Administration, to date, to protect these jobs and to advance the energy security of the United States."

Murray has repeatedly called on DOE to issue must-run orders for FirstEnergy power plants that consume his coal, and he blasted the FERC commissioners who opposed the on-site fuel proposal.

On Tuesday, a top DOE official said the agency is still formulating a plan to keep struggling coal and nuclear power plants from closing, and it had no deadline to meet Trump's demand to rescue them.

"We are evaluating options," Energy Undersecretary Mark Menezes told reporters. Last week, Trump called on DOE to take "immediate steps" to stop a wave of coal and nuclear power plant retirements, and like Perry, he cast the shutdowns as a threat to national security.

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House passes WRDA bill Back

By Annie Snider | 06/06/2018 09:42 PM EDT

The House has overwhelmingly approved the Water Resources Development Act of 2018, H.R. 8 (115), the first major infrastructure legislation to move under the Trump administration.

Lawmakers signed off on the measure on a broadly bipartisan vote of 408-2. The bill would authorize six new Army Corps of Engineers projects and enact a suite of policy reforms at the red tape-laden agency. It is significantly narrower than the Senate's measure, which would also make changes to EPA drinking water and wastewater programs.

And it includes a provision that could stir some controversy with the Senate, ordering a study of whether the Army Corps' civilian work should remain within the Department of Defense.

But House leaders dodged provisions that could have derailed the bill by blocking controversial amendments from floor consideration. Those included efforts to repeal the Obama administration's Waters of the U.S. rule, allow firearms at Army Corps recreational sites and exempt pesticide spraying from Clean Water Act permitting requirements.

WHAT'S NEXT: The Senate is expected to consider its version of the WRDA bill, America's Water Infrastructure Act of 2018, S. 2800 (115), this summer.

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Trump calls for coal, nuclear power plant bailout Back

By Eric Wolff | 06/01/2018 02:29 PM EDT

President Donald Trump pressed for a quick regulatory bailout for struggling coal power plants on Friday — a move that would buoy a mining industry that offered him crucial support in 2016, but is riling other energy companies and even some free-market conservatives.

The White House called on Energy Secretary Rick Perry to take immediate steps to keep both coal and nuclear power plants running, backing Perry's claim that plant closures threaten national security. An administration strategy to do that laid out in a memo to the National Security Council circulated widely among industry groups on Friday, but it was not clear that intervention could survive the inevitable political and legal challenges.

It was the latest step in more than a year of efforts by the administration to compel power companies to keep operating the money-losing plants that are suffering from the rise of competing energy sources like natural gas. Those proposals have drawn opposition from most utilities, along with environmentalists, gas producers, power grid operators and conservatives who say it would be an unwarranted intrusion to the energy markets.

The White House statement calling for action came after days of Trump making similarly aggressive moves on international trade, slapping tariffs on the European Union, Canada and Mexico to protect U.S. industries like aluminum and steel. In this case, the president is acting on behalf of what he likes to call "beautiful, clean coal," a once-dominant fuel that still plays a major role in his stump speeches.

Trump "has directed Secretary of Energy Rick Perry to prepare immediate steps to stop the loss of these resources," White House press secretary Sarah Huckabee Sanders said in a statement Friday, referring to coal and nuclear plants.

She added that Trump believes "keeping America's energy grid and infrastructure strong and secure protects our national security... Unfortunately, impending retirements of fuel-secure power facilities are leading to a rapid depletion of a critical part of our nation's energy mix, and impacting the resilience of our power grid."

The statement came five months after federal energy regulators rejected Perry's call that they adopt his proposal to keep the struggling coal and nuclear power plants operating. That proposal would have overwhelmingly benefited mining magnate Bob Murray, an outspoken Trump supporter whose operations supply coal to several endangered plants in the Midwest and Northeast, according to a POLITICO analysis.

Trump's National Security Council gathered Friday to discuss the draft memo that lays out arguments why the administration should use federal authority to keep the money-losing power plants open — despite the assurances from some of the nation's grid operators that no such emergency exists.

"Any federal intervention in the market to order customers to buy electricity from specific power plants would be damaging to the markets and therefore costly to consumers," said the PJM Interconnection, which operates the nation's largest power grid and stretches from the Midwest the Atlantic Coast, in a statement. "There is no need for any such drastic action."

A broad swath of trade associations representing oil and gas, wind and solar power, consumer groups and advanced energy technologies slammed the plan, and they were joined by some congressional Democrats.

"This would be an egregious abuse of power," Sen. Ron Wyden (D-Ore.) said in a statement. "I fought this proposal before, and I will continue to fight this corrupt scheme to prop up the coal industry at the expense of American consumers."

That new 41-page memo, first revealed by Bloomberg News on Thursday evening, says that under the 2015 highway and transit bill known as the FAST Act, DOE must identify critical energy infrastructure, a process the agency is undertaking now with the help of its national labs. But because that is likely to take two years, DOE in the meantime should use the 1950 Defense Production Act and the Federal Power Act to require the plants to keep operating, the memo says.

Power sector experts have said using the two laws to keep specific plants operating would stretch both those measures, and would certainly trigger a major legal fight. Critics of the administration's strategy said the memo appears to signal that the White House is preparing for a fight.

"One way to view the release of this draft is that it is a trial balloon to see how fierce and fast the opposition will be," said Dena Wiggins, CEO of the industry lobby group Natural Gas Supply Association, which opposes the DOE plan. "We've known for some time that all of these federal authorities ... were in play, so the fact that we've now seen it in writing doesn't really change anything. It does, however, underscore how hard it is to cobble together a sound legal rationale to bail out otherwise uneconomic coal and nuclear plants."

And critics say the push to bail out the plants is simply Trump's effort to reward backers like Murray, the coal baron, and live up to his campaign promise to revive coal country. Perry first began work on the power plant issue in March 2017, when he met with Murray at DOE, and Trump himself personally directed Perry to take action on the issue since last summer.

Murray's coal mines have been a major supplier for power plants owned by FirstEnergy Solutions, a unit of Ohio-based utility giant FirstEnergy that sank into bankruptcy this spring. FirstEnergy Solutions has said it plans to close or sell five of its money-losing coal and nuclear power plants.

But the Federal Energy Regulatory Commission and the grid operator have said that even with the planned closures, the region has ample power to supply the market's needs. Stagnant power consumption growth, coupled with the rise of natural gas and renewable power sources like wind, has displaced many of the older coal and nuclear facilities in the markets.

The memo also calls for establishing a new requirement for the electric grid based on "resilience," a term Perry injected into the regulatory conversation last fall with a proposed rule that would have rewarded plants that could keep 90 days of fuel on site. FERC rejected that rule, but it also created a new proceeding to try to define "resilience," which some in the industry say pertains to the grid's ability to withstand and recover from a physical or cyberattack.

The memo largely focuses on the issue of resilience, which it says would suffer if coal and nuclear power plants retire. It specifically targets natural gas as a weakness, because the plants that burn the fuel rely on pipelines that could be disrupted, while coal and nuclear power plants can keep months' worth of fuel on site.

"Natural gas pipelines are increasingly vulnerable to cyber and physical attacks," the memo says. "The incapacitation of certain pipelines through the United States would have severe effects on electric generation necessary to supply critical infrastructure facilities."

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House to vote Thursday on Trump's spending cuts plan Back

By Sarah Ferris | 06/06/2018 05:32 PM EDT

President Donald Trump's prized deficit-reduction package is rolling toward the House floor this week, though its prospects in the Senate remain in doubt — with little time to spare.

House leaders have set a vote Thursday on the Trump administration's roughly $15 billion rescissions bill, according to a GOP aide, nearly a full month after the proposal was first delivered to Capitol Hill.

The House Rules Committee will tee up the bill, H.R. 3 (115), on Wednesday evening, a lightning turnaround that surprised even some GOP lawmakers.

The last-minute scheduling change comes after the White House agreed this week not to slash hundreds of millions of dollars from politically sensitive programs, like Hurricane Sandy aid, which helped secure votes from numerous GOP holdouts.

Even with some of those unpopular cuts reversed, several House Republicans remain anxious about the plan's optics — specifically, cuts to the ultra-popular Children's Health Insurance Program.

At a closed-door meeting of House Republicans Wednesday, several GOP lawmakers stood up to complain that the kids' health cuts could hit hard on the campaign trail, despite assurance from neutral budget experts that the cuts wouldn't harm the program.

In fact, the vast majority of the White House's proposed spending cuts would exist only on paper. The bill would save only $1 billion over a decade, according to the CBO, which is far less than 1 percent of the size of Congress' last spending bill, H.R. 1625 (115).

Next, the White House will have to sell the bill to the Senate, where a single Republican "no" vote could sink the package.

Budget chief Mick Mulvaney has already met with Sen. Lisa Murkowski, an Alaska Republican who has raised issues with the cuts to CHIP. Sen. Susan Collins of Maine, another GOP moderate, has not yet said whether she supports the bill.

If the House clears the bill Thursday, the Senate will have roughly two weeks to send the measure to Trump's desk before its filibuster-proof powers expire June 22.

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Minibus spending package ready for House floor action Back

By Kaitlyn Burton | 06/06/2018 07:46 PM EDT

The House Rules Committee today teed up a three-bill spending bundle for floor consideration as soon as Thursday.

All in all, the panel approved 50 Energy-Water amendments, 22 Military Construction-VA amendments and seven Legislative Branch amendments, setting them up for floor votes.

While the minibus, H.R. 5895 (115), will likely pass, House Democratic leaders threw a wrench in things when they urged lawmakers to oppose the bill, POLITICO reported Tuesday evening.

Votes on the package are expected to come after a separate Thursday vote on the White House's rescissions measure, H.R. 3 (115). Conservatives, including the Republican Study Committee, asked for the spending cuts to be taken up first, according to a House GOP aide. The Rules Committee teed up the rescissions proposal in a 9-3 vote tonight, allowing no amendment votes.

The minibus would be the first House-passed fiscal 2019 funding measure.

Sarah Ferris contributed to this alert.

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House appropriators advance $35B Interior-EPA spending package Back

By Alex Guillén | 06/06/2018 05:04 PM EDT

The House Appropriations Committee today approved its $35 billion Interior-EPA spending bill by a party-line vote of 25-20.

Committee Republicans blocked an effort from Democrats to boost EPA's Office of Inspector General by $12 million, saying the watchdog already has "robust" appropriations. The bill funds the OIG at $12 million less than his request, but higher than the amount requested by the White House.

The committee voted down an amendment that would have required EPA's administrator and deputy administrator to report public details of travel costs within 10 days of a trip, along with various amendments targeting a repeal of the Waters of the U.S. rule and other policy riders, along with EPA's proposed science transparency policy, offshore drilling and other standard policy disputes.

Lawmakers approved an amendment that would change revenue sharing for drilling in the Arctic National Wildlife Refuge. The approved amendment would send 50 percent of revenue to the federal government, 47 percent to the state and 3 percent to the Alaskan Native claims settlement fund.

They also backed a tongue-in-cheek amendment from Rep. Marcy Kaptur (D-Mich.) that would limit EPA from spending more than $50 on any one fountain pen, a response to a recent Washington Post report that Pruitt spent $1,560 for a dozen personalized fountain pens. The amendment passed with no "nay" votes.

WHAT'S NEXT: Lawmakers hope to have the bill before the full House sometime this summer, but it is unclear whether the Senate will act on a similar timeframe. Like most other appropriations bills in recent years, Congress has passed an omnibus rather than conferencing directly.

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GOP blocks funding increase for EPA watchdog probing Pruitt activities Back

By Alex Guillén | 06/06/2018 03:06 PM EDT

House Republicans today blocked a Democratic effort to increase funding for EPA's Office of Inspector General to help the watchdog deal with the increased workload stemming from Administrator Scott Pruitt's spending and ethics scandals.

Rep. Mark Pocan (D-Wis.) and a bloc of Democrats on the House Appropriations Committee pushed an amendment that would have boosted OIG funding for fiscal 2019. It ultimately was voted down on a party-line vote of 21-26.

"It's hard to imagine that there is a more overworked inspector general than at the EPA these days," Pocan said. "This is not a Democrat/Republican thing, this should be a good government thing."

Interior-EPA Appropriations Chairman Ken Calvert (R-Calif.) said the bill "already includes robust support for EPA's inspector general."

The House Interior-EPA spending package would provide the OIG funding of just over $50 million, about flat with 2018's level. Most of that is appropriated directly, though some of it is pulled from the Superfund program for OIG's work on Superfund-specific issues. Pocan's amendment would have drawn the extra $12 million from EPA's "workforce reshaping" account inside the $2.5 billion environmental programs.

In a February letter, EPA Inspector General Arthur Elkins said the president's proposed OIG budget of $46 million would "substantially inhibit the OIG from performing the duties of the office." He asked instead for a budget of $62 million. That request came before an avalanche of congressional requests to review various Pruitt-related issues on spending and ethics.

WHAT'S NEXT: The committee will vote later today on the full spending bill.

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Interior advisory committee recommends streamlining environmental reviews for drilling Back

By Ben Lefebvre | 06/06/2018 06:31 PM EDT

An Interior Department advisory board on Wednesday approved a slew of recommendations aimed at expanding energy lease sales and lowering royalty rates, even as some members questioned whether it had the power to suggest changes to federal environmental reviews.

The Royalty Policy Committee wrapped up its latest meeting in New Mexico after approving nine recommendations for Secretary Ryan Zinke to change how the department collects payments from energy production on federal land. Most of the suggestions would benefit oil and gas companies operating on federal acres, while two recommendations were aimed at boosting renewable energy production.

Two committee members disagreed with a recommendation for the Bureau of Land Management to issue "categorical exclusions" for certain oil and gas projects, allowing those projects to forgo full environmental reviews under the National Environmental Protection Act.

"NEPA is not referred to in the [committee] charter," Rod Eggert, a professor at the Colorado School of Mines, said during the meeting. "The text in the charter refers to royalties and collections of royalties."

Committee member Monte Mills of the University of Montana agreed that recommending categorical exclusions fell outside of the committee's scope.

Western Energy Alliance President Kathleen Sgamma, another member of the committee, defended the recommendation, saying it would increase royalty payments to Interior by making it easier for companies to drill on public land.

"We're trying to increase competitiveness of federal lands," Sgamma said during the meeting. "NEPA is often the aspect of the federal process that takes the longest and decreases the competitiveness of public lands the most."

Ultimately, the committee approved the recommendation and deferred further discussion about the scope of its charter until its next meeting, yet to be scheduled.

The committee also suggested Interior make it easier for companies to pay lower royalty rates for mature oil and gas wells and those "difficult" to operate. And it recommended Zinke ask Congress to amend the Outer Continental Shelf Lands Act with language allowing Interior to hold offshore energy project lease sales in Guam and other U.S. territories.

The committee's two renewable power suggestions were that Interior offer annual lease sales for 2 gigawatts of offshore wind power every year for a decade starting in 2024; and to instruct BLM to reduce fees and streamline permit requirements for solar projects.

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BLM tells field office to expedite drilling permit reviews Back

By Ben Lefebvre | 06/06/2018 08:20 PM EDT

The Bureau of Land Management instructed field offices to prioritize the use of old environmental reviews or categorical exclusions to expedite drilling permit applications for sites where work is already underway, according to a memo released today.

The bulletin posted on the BLM website said those methods will allow officials to process the applications "in the most expeditious and appropriate manner" under the National Environmental Policy Act.

The BLM bulletin directed its field offices that existing environmental analysis for new projects proposed for old sites "should be used to the greatest extent possible" instead of starting a new environmental review process.

If the old analysis isn't sufficient, field offices should determine whether the application falls under an existing categorical exclusion, meaning a new NEPA review would not be required. Criteria to determine whether an exclusion would be available include whether a similar project has already occurred on the same site within the previous five years.

BLM posted its memo soon after Interior's Royalty Policy Committee recommended earlier today that the agency increase its use of categorical exclusions.

WHAT'S NEXT: The environmental review priority list goes into effect immediately.

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White House, EPA headed off chemical pollution study Back

By Annie Snider | 05/14/2018 12:43 PM EDT

Scott Pruitt's EPA and the White House sought to block publication of a federal health study on a nationwide water-contamination crisis, after one Trump administration aide warned it would cause a "public relations nightmare," newly disclosed emails reveal.

The intervention early this year — not previously disclosed — came as HHS' Agency for Toxic Substances and Disease Registry was preparing to publish its assessment of a class of toxic chemicals that has contaminated water supplies near military bases, chemical plants and other sites from New York to Michigan to West Virginia.

The study would show that the chemicals endanger human health at a far lower level than EPA has previously called safe, according to the emails.

"The public, media, and Congressional reaction to these numbers is going to be huge," one unidentified White House aide said in an email forwarded on Jan. 30 by James Herz, a political appointee who oversees environmental issues at the OMB. The email added: "The impact to EPA and [the Defense Department] is going to be extremely painful. We (DoD and EPA) cannot seem to get ATSDR to realize the potential public relations nightmare this is going to be."

More than three months later, the draft study remains unpublished, and the HHS unit says it has no scheduled date to release it for public comment. Critics say the delay shows the Trump administration is placing politics ahead of an urgent public health concern — something they had feared would happen after agency leaders like Pruitt started placing industry advocates in charge of issues like chemical safety.

Sen. Maggie Hassan (D-N.H.) called the delay "deeply troubling" on Monday, urging Pruitt and President Donald Trump "to immediately release this important study."

"Families who have been exposed to emerging contaminants in their drinking water have a right to know about any health impacts, and keeping such information from the public threatens the safety, health, and vitality of communities across our country," Hassan said, citing POLITICO's reporting of the issue.Details of the internal discussions emerged from EPA emails released to the Union of Concerned Scientists under the Freedom of Information Act.

Sen. Jeanne Shaheen, a fellow New Hampshire Democrat, called the delay "an egregious example of politics interfering with the public's right to know. ... [I]t's unconscionable that even the existence of this study has been withheld until now."

The emails portray a "brazenly political" response to the contamination crisis, said Judith Enck, a former EPA official who dealt with the same pollutants during the Obama administration — saying it goes far beyond a normal debate among scientists.

"Scientists always debate each other, but under the law, ATSDR is the agency that's supposed to make health recommendations," she said.

The White House referred questions about the issue to HHS, which confirmed that the study has no scheduled release date.

Pruitt's chief of staff, Ryan Jackson, defended EPA's actions, telling POLITICO the agency was helping "ensure that the federal government is responding in a uniform way to our local, state, and Congressional constituents and partners."

Still, Pruitt has faced steady criticism for his handling of science at the agency, even before the recent spate of ethics investigations into his upscale travels and dealings with lobbyists. In his year leading EPA, he has overhauled several scientific advisory panels to include more industry representatives and recently ordered limits on the kinds of scientific studies the agency will consider on the health effects of pollution.

On the other hand, Pruitt has also called water pollution one of his signature priorities.

The chemicals at issue in the HHS study have long been used in products like Teflon and firefighting foam, and are contaminating water systems around the country. Known as PFOA and PFOS, they have been linked with thyroid defects, problems in pregnancy and certain cancers, even at low levels of exposure.

The problem has already proven to be enormously costly for chemicals manufacturers. The 3M Co., which used them to make Scotchguard, paid more than $1.5 billion to settle lawsuits related to water contamination and personal injury claims.

But some of the biggest liabilities reside with the Defense Department, which used foam containing the chemicals in exercises at bases across the country. In a March report to Congress, the Defense Department listed 126 facilities where tests of nearby water supplies showed the substances exceeded the current safety guidelines.

A government study concluding that the chemicals are more dangerous than previously thought could dramatically increase the cost of cleanups at sites like military bases and chemical manufacturing plants, and force neighboring communities to pour money into treating their drinking water supplies.

The discussions about how to address the HHS study involved Pruitt's chief of staff and other top aides, including a chemical industry official who now oversees EPA's chemical safety office.

Herz, the OMB staffer, forwarded the email warning about the study's "extremely painful" consequences to EPA's top financial officer on Jan. 30. Later that day, Nancy Beck, deputy assistant administrator for EPA's Office of Chemical Safety and Pollution Prevention, suggested elevating the study to OMB's Office of Information and Regulatory Affairs to coordinate an interagency review. Beck, who worked as a toxicologist in that office for 10 years, suggested it would be a "good neutral arbiter" of the dispute.

"OMB/OIRA played this role quite a bit under the Bush Administration, but under Obama they just let each agency do their own thing...," Beck wrote in one email that was released to UCS.

Beck, who started at OMB in 2002, worked on a similar issue involving perchlorate, an ingredient in rocket fuel — linked with thyroid problems and other ailments — that has leached from defense facilities and manufacturing sites into the drinking water of at least 20 million Americans. Beck stayed on at OMB into the Obama administration, leaving the office in January 2012 and going to work for the American Chemistry Council, where she was senior director for regulatory science policy until joining EPA last year.

Yogin Kothari, a lobbyist with the Union of Concerned Scientists, called Beck's January email "extremely troubling because it appears as though the White House is trying to interfere in a science-based risk assessment."

Environmentalists say such interference was routine during the Bush administration.

"It's why the Obama administration issued a call for scientific integrity policies across the federal government," Kothari said in an email to POLITICO. "Dr. Beck should know firsthand that the Bush administration sidelined science at every turn, given that she spent time at OMB during that time."

Soon after the Trump White House raised concerns about the impending study, EPA chief of staff Ryan Jackson reached out to his HHS counterpart, as well as senior officials in charge of the agency overseeing the assessment to discuss coordinating work among HHS, EPA and the Pentagon. Jackson confirmed the outreach last week, saying it is important for the government to speak with a single voice on such a serious issue.

"EPA is eager to participate in and, contribute to a coordinated approach so each federal stakeholder is fully informed on what the other stakeholders' concerns, roles, and expertise can contribute and to ensure that the federal government is responding in a uniform way to our local, state, and Congressional constituents and partners," Jackson told POLITICO via email.

Pruitt has made addressing per- and polyfluoroalkyl substances, or PFAS, a priority for EPA. The unpublished HHS study focused on two specific chemicals from this class, PFOA and PFOS.

States have been pleading with EPA for help, and experts say that contamination is so widespread, the chemicals are found in nearly every water supply that gets tested.

In December, the Trump administration's nominee to head the agency's chemical safety office, industry consultant Michael Dourson, withdrew his nomination after North Carolina's Republican senators said they would not support him, in large part because of their state's struggles with PFAS contamination. Dourson's previous research on the subject has been criticized as too favorable to the chemical industry.

Shortly after Dourson's nomination was dropped, Pruitt announced a "leadership summit" with states to discuss the issue scheduled for next week.

In 2016, the agency published a voluntary health advisory for PFOA and PFOS, warning that exposure to the chemicals at levels above 70 parts per trillion, total, could be dangerous. One part per trillion is roughly the equivalent of a single grain of sand in an Olympic-sized swimming pool.

The updated HHS assessment was poised to find that exposure to the chemicals at less than one-sixth of that level could be dangerous for sensitive populations like infants and breastfeeding mothers, according to the emails.

Dave Andrews, a senior scientist with the Environmental Working Group, said those conclusions line up with recent studies on the health effects of PFAS.

"They are looking at very subtle effects like increased risk of obesity for children exposed in womb, lowered immune response, and childhood vaccines becoming not as effective," Andrews said.

The HHS document at issue is called a toxicological profile, which describes the dangers of a chemical based on a review of previous scientific studies. It would carry no regulatory weight itself, but could factor into cleanup requirements at Superfund sites.

EPA scientists, including career staffers, were already talking with the HHS researchers about the differences in their two approaches to evaluating the chemicals when officials at the White House raised alarm in late January, the emails show. Those differences, according to the correspondence, stemmed from the agencies' use of different scientific studies as a basis, and from taking different approaches to accounting for the harm that the chemicals can do to the immune system — an area of research that has burgeoned in the two years since EPA issued its health advisory.

Enck, the former EPA official, said she sees one troubling gap in the emails: They make "no mention of the people who are exposed to PFOA or PFOS, there's no health concern expressed here."

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Yes, very


Somewhat


Neutral


Not really


Not at all

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 5/7/2018 2:55:51 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Fourth Pruitt Aide Leaving Amid Swirling Controversy at EPA

By Jennifer A. Dlouhy

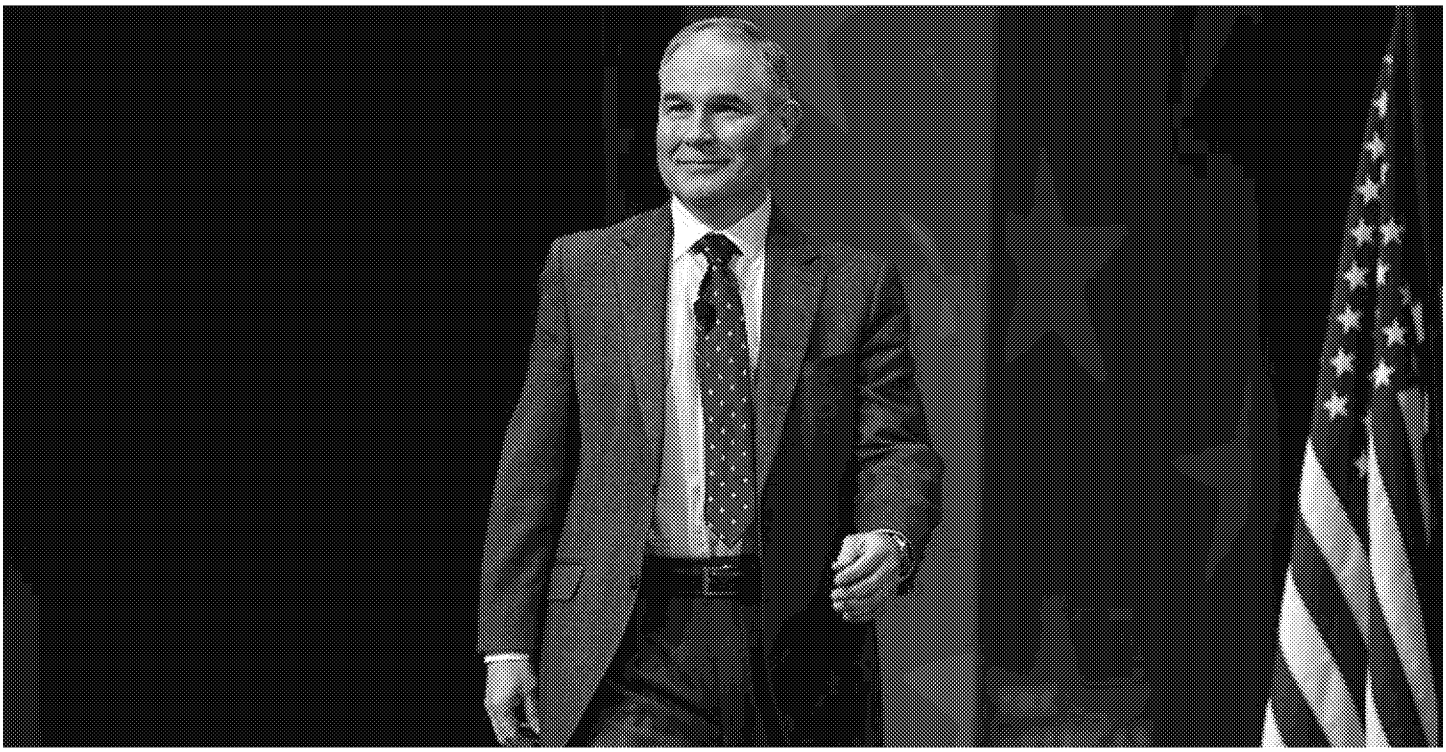
Posted May 4, 2018, 12:46 PM

A fourth departure this week of an Environmental Protection Agency official, announced May 4, may suggest continued fallout from the controversies swirling around Administrator Scott Pruitt.

GREENWIRE ARTICLES

Lobbyist with hand in Pruitt trips tied to gas-rich nation

Kevin Bogardus and Hannah Northey, E&E News reporters Published: Friday, May 4, 2018



EPA Adminstrator Scott Pruitt, shown here in a 2017 file photo. Gage Skidmore/Flickr

The lobbyist who helped arrange EPA Administrator Scott Pruitt's trip to Morocco has another foreign client with natural gas interests, East Timor.

The global law firm DLA Piper hired Richard Smotkin last November as a subcontractor to work on representing the government of the Democratic Republic of Timor-Leste, otherwise known as East Timor, according to Justice Department records.

https://www.eenews.net/greenwire/2018/05/04/stories/1060080879

Press deputy to leave

Kevin Bogardus, E&E News reporter

Published: Friday, May 4, 2018

John Konkus, one of EPA's top press officials, is departing the agency.

Konkus is heading to the Small Business Administration to help lead communications for the agency. As deputy associate administrator in EPA's public affairs shop, his exit marks the fourth high-profile staff departure on Administrator Scott Pruitt's team this week.

Konkus has been involved with EPA from the very beginning of the Trump administration, serving on the president's transition and "beachhead" teams for the agency, as well as helping to guide Pruitt's confirmation in the Senate.

https://www.eenews.net/greenwire/2018/05/04/stories/1060080883

House Dems want more time for comments on 'secret science'

Sean Reilly, E&E News reporter

Published: Friday, May 4, 2018

Democratic Reps. Eddie Bernice Johnson of Texas and Paul Tonko of New York. House/Wikipedia

This article was updated at 2:27 p.m. EDT.

More than 60 House Democrats are urging EPA to allow more time for public feedback on a fiercely disputed proposal to revamp how the agency handles scientific research.

"EPA has the critical mission of protecting human health and the environment," Rep. Paul Tonko (D-N.Y.) and 64 other lawmakers wrote yesterday to EPA Administrator Scott Pruitt. "With this mission in mind, any significant change should go through a serious discussion, a series of public hearings and a robust comment period."

In the proposed rule published Monday, EPA set a 30-day comment period that ends May 30.

The Democrats are asking Pruitt to extend the comment period to at least three months.

https://www.eenews.net/greenwire/2018/05/04/stories/1060080881

South Korea proposes universal chemical tracking system

Overseas manufacturers would submit details through appointed representatives

3 May 2018 / Confidentiality & right-to-know, Enforcement, K-REACH, Labelling, South Korea

South Korea's Ministry of Environment (MOE) has proposed a mandatory system of tracking chemicals from their import and manufacture to end use.

It would introduce a unique government-allocated "checking number" for all manufactured or imported chemical substances. These could then be tracked, regardless of how they are subsequently used or if some information is inaccurate or changes, for example, product name.

Companies must currently check whether substances are toxic and report on them if the case. This would be replaced with a mandatory reporting system for all substances.

The number would follow substances to downstream producers. Companies handling hazardous substances would have to use it on packaging and products.

The overall aim is to bring transparency to distribution and, in the case of accidents, allow the identification of a substance and distribution routes.

The ministry says it will also address problems of obtaining hazard information for the 8,000 under one tonne substances, exempted from registration under K-REACH.

Overseas manufacturers would have also have to submit details of substances for the Korean market. To allay CBI concerns, they will be able to appoint a domestic representative to act on their behalf.

The representative would provide full ingredient disclosure through the reporting system, which would be managed confidentially in the government's internal database.

The MOE says the new system would be implemented two years after legislation is passed. In the future, it expects barcodes/QR codes with the tracking identifier to become mandatory.

The proposal was published on 3 May.

More details available on CW+AsiaHub

Sunny Lee

Asia editor

Related Articles

- South Korea proposes universal chemical tracking system

Further Information:

- MOE press release (in Korean)

UK's ability to keep pace with REACH changes threatened by Bill amendment

If passed, Lords' amendment to EU Withdrawal Bill would hamper ongoing adoption of authorisations, restrictions

3 May 2018 / Europe, REACH

As the UK government prepares for the end of the House of Lords review of its EU Withdrawal Bill, sources close to the process have warned that one of the amendments adopted by the Lords would, if included in the final text of the Bill, make it extremely difficult for the UK to adopt updates to REACH post Brexit.

During its passage through the Lords, a number of amendments were adopted including Amendment 11, which relates to enhanced protection for certain areas of EU law, including environmental standards and protection.

On the day the UK leaves, the amendment would ensure government ministers cannot change or repeal EU law – other than for technical changes – except by an Act of Parliament or by secondary legislation that must undergo greater parliamentary scrutiny than is usually the case.

Sources say this could mean that changes to a transposed REACH Regulation, such as adding chemicals to a UK authorisation list or introducing new restrictions, would therefore require an Act of Parliament or enhanced scrutiny.

'Not convinced'

The technical changes mentioned in Amendment 11 link to clause 7 of the EU Withdrawal Bill. This contains the power to make corrections to retained EU law in order to deal with deficiencies that arise as a consequence of the UK's exit.

Elizabeth Shepherd, partner at law firm Eversheds Sutherland, said "we are not convinced that the addition of more chemicals to a UK authorisation list, or to introduce new restrictions would fall within either of these provisions."

However, she added, even if they did and could – according to Amendment 11– be dealt with by secondary legislation, "this would not necessarily guarantee that UK legislation, including UK REACH, will remain the same as the EU".

The government has previously said that "certain areas of health and safety legislation, such as chemical regulation will require more fundamental review to ensure operability". And that these "will be dealt with in separate legislation which will also be made under EU Withdrawal Bill powers; these policy areas are cross-cutting and require a specific regime approach".

If Britain established a new environmental regulator "there will need to be a new set of delineated statutory powers and functions for that regulator", Ms Shepherd said.

Lord Whitty, a member of the House or Lords, who proposed an amendment concerning chemicals, said without an agreement on continued membership of REACH and Echa "there is no automatic reflection of new REACH provisions in UK law".

He added that amendment 11 "reflects the Lords' concern at the so called 'Henry VIII powers' that the bill would otherwise give to ministers in future to vary legislation with minimum or no parliamentary scrutiny – particularly in the areas designated. It does not prohibit changes being made under secondary legislation – it simply requires greater scrutiny."

Government response

When questioned on the potential problem for future chemicals management, a government spokesperson told Chemical Watch: "We are disappointed that Parliament voted for this amendment in spite of the assurances we provided.

"We will review this decision when the Bill returns to the House of Commons to ensure we deliver a workable piece of legislation that provides certainty as we leave.

"The purpose of this Bill," the spokesperson added "is to provide a functioning statute book on exit day and this amendment would prevent us from doing that. It would risk legislation in key areas not working after exit day."

Progress of Bill

The Bill started in the House of Commons where it underwent five stages before being passed to the House of Lords for scrutiny – first and second readings followed by a committee stage, a report stage and then a final reading.

It is currently completing its report stage - when amendments are voted on and adopted or rejected - in the House of Lords. After final reading it will be returned to MPs in the House of Commons for consideration of amendments and the two chambers will send final changes back and forth - a process known in Parliament as 'ping pong'. Once all differences between them have been solved, the Bill will receive royal assent from the Queen and become law.

Further Information:

- House debate transcript
- Progress of bill

Stockholm Convention factsheet lists POPs exemptions

4 May 2018 / Global, Persistent organic pollutants

The Stockholm Convention on persistent organic pollutants (POPs) has published a factsheet on exempted uses for perfluorooctane sulfonate (PFOS), its salts and perfluorooctanoic acid (PFOA).

The factsheet puts these in three categories:

- acceptable purposes, such as photo-imaging, medical devices, semiconductors and firefighting foam;
- time-limited exempted uses for SCCPs, such as rubber industry transmission belts, lubricant additives and adhesives; and
- time-limited exempted uses for synthetic substance c-deca-BDE, such as aircraft and vehicle parts, textiles and polyurethane foam.

The convention aims to eliminate or restrict the production and use of POPs.

Further Information:

- Factsheet

Industry criticises 'misleading' baby products guide

NGO coalition advises avoiding items containing toxic chemicals

4 May 2018 / Children's products, Food & drink, Retail, United States

US children's products trade associations have criticised an NGO report that advises parents to avoid buying baby items containing a number of chemicals including certain plastics, flame retardants and solvents.

The Getting Ready for Baby coalition's *Safe baby guide* gives detailed guidelines for avoiding chemicals in baby products. It also recommends consumers buy items carrying the Made Safe independent labelling certification.

However, Kelly Mariotti, executive director of the Juvenile Products Manufacturers Association (JPMA), called the guide "misleading", and said children's products are already subject to stringent federal safety requirements.

"Simply put, hazardous substances cannot be accessible to a child so as to present either an acute or chronic hazard," she told Chemical Watch. If that were the case the product would already be banned, she said.

The coalition comprises more than 95 organisations that campaign for retailers to avoid selling baby products containing toxic chemicals. Other recommendations in the guide include avoiding:

- flame retardants, perfluoroalkyl and polyfluoroalkyl substances (PFASs), polyvinyl chloride (PVC) and microbial substances in mattresses;
- formaldehyde in baby furniture such as cots, changing tables and highchairs;
- bisphenol A (BPA) and bisphenol S (BPS) in baby bottles;
- PVC in teethers;
- flame retardants in baby changing mats;
- solvents and PVC in strollers; and
- flame retardants in car seats

Toy concern

The guide also provides guidance on purchasing toys and puzzles for babies.

It recommends consumers avoid giving their babies toys made before 2008, when the Consumer Product Safety Improvement Act set stricter limits on lead and certain phthalates. And it also advises that:

- clear hard plastic toys may contain bisphenols;
- plastic dolls may be made of PVC; and
- metal products may include cadmium, mercury and antimony.

But Alan Kaufman, senior vice president of technical affairs at the Toy Association, told Chemical Watch the advice was "needlessly frightening to new parents and not based on any credible underlying science".

All toys sold in the US must comply with strict toy safety regulations, tests, and requirements which "make it illegal to sell toys or children's products containing substances harmful to children and to which they might be exposed," he said.

Responding to the criticisms, Bobbi Wilding, deputy director of the NGO Clean and Healthy New York, which is a partner in the campaign, said: "All of the chemicals we highlight have scientific evidence of contributing to negative health problems. We have released a technical document that provides the rationale for our choices, and parents can, if they're interested, easily access this information on every page of our guide."

Tammy Lovell

Business reporter

Related Articles

- US children's product line first to achieve NGO safety certification

Further Information:

- Safe Baby Products Guide
- Children's Safe Products Reporting Rule
- Made Safe

OTHER ARTICLES

Popular Black Hair Products Are Filled With Toxic Chemicals Linked To Disease, Study Finds

Vibe

A new study claims that the most popular hair products for black women and children contain "multiple chemicals" linked to cancer, weight gain, asthma, and fertility issues, among other things. Silent Springs Institute found that 80 percent of the 18 tested products (chosen based on customer surveys) ...

'Poison Papers': US and Canadian Regulators Colluded with Manufacturers of Highly Toxic ...

The Real News Network

The **poison** papers were analyzed **and** published by the Center for Media **and** Democracy **and** Dr. Jonathan Latham. They are a compilation of over 20000 documents obtained from federal agencies **and chemical** manufacturers via open records requests **and** public interest litigation. They include ...

House falls short of veto override on protecting kids from chemicals

Stowe Today

Last week the House failed to override the governor's veto of the **toxic chemicals** bill. I voted to override. This bill would have kept **toxic chemicals** out of children's toys and held companies liable for introducing these chemicals into the environment. With new chemicals always coming onto the market, this ...

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 4/24/2018 9:57:47 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: RE: SIGNED: Strengthening Transparency in Regulatory Science

Of course. Should be on our website now.

From: Beck, Nancy
Sent: Tuesday, April 24, 2018 3:38 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: RE: SIGNED: Strengthening Transparency in Regulatory Science

Thanks. Can I share with my staff?

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
P: 202-564-1273
M: 202-731-9910
beck.nancy@epa.gov

From: Bolen, Brittany
Sent: Tuesday, April 24, 2018 3:20 PM
To: Schwab, Justin <Schwab.Justin@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
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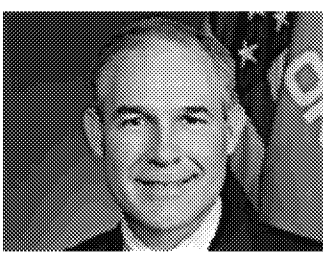
Subject: News Articles (For EPA Distribution Only)

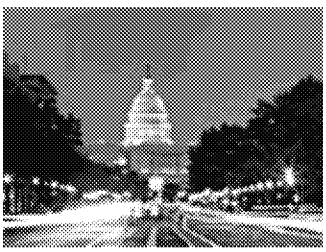
BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt Met With Lobbyist Tied to Condo Rental (1)



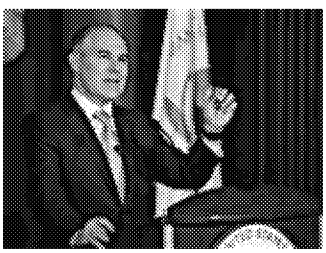
The lobbyist whose wife rented a bedroom in a Capitol Hill condo to EPA Administrator Scott Pruitt met with him in July along with the director of the charitable arm of Smithfield Foods Inc., a pork processing company that was regulated by the agency.

Lobbyist Steps Down Amid Fallout Over Pruitt Condo Controversy



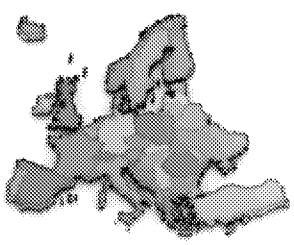
The lobbyist whose wife rented a bedroom in a Capitol Hill condo to EPA Administrator Scott Pruitt is leaving his job as chairman of high-powered lobbying firm Williams & Jensen.

White House Said to Deter Republicans from Defending EPA Chief



White House officials are cautioning Republican lawmakers and other conservative allies to temper their defense of Scott Pruitt, according to two people familiar with the discussions, in a sign that administration support for the embattled EPA chief may be waning.

EU Enforcers Find Toxic Chemical Products Sold With No Warnings



Most European Union online vendors of cleaning agents, glues, insect sprays, and other products containing hazardous chemicals are failing to comply with the bloc's labeling rules.

INSIDEEPA.COM ARTICLES

EPA Floats 'Secret Science' Ban Rule, Signaling Possible Internal Fixes

EPA has sent for White House review a proposed rule to increase the transparency of regulatory science, advancing Administrator Scott Pruitt's controversial efforts to ban the use of "secret science" in a move that suggests officials have addressed at least some internal concerns that such a policy could violate statutory protections of medical privacy and trade secrets.

Environmentalists Launch Suit Challenging EPA's TSCA Framework Rules

Environmentalists have filed their opening brief in their suit challenging EPA's "framework" rules for prioritizing and assessing existing chemicals for possible regulation under the revised Toxic Substances Control Act (TSCA), arguing the rules violate a requirement to conduct a holistic review that considers all of a chemical's uses.

Agencies Wrestle With Lead Exposure Goals Ahead Of Strategy's Release

Two months before the planned release of a federal strategy for reducing children's lead exposures, EPA and other agencies are wrestling with key policy goals, including a planned schedule for eliminating exposures, whether the strategy will complement pending EPA rules and if EPA plans to account for stricter federal health standards that are slated to be adopted later this year.

EPA Sees TSCA Fee Increase If It Adopts New 'Small Business' Metric

EPA says it might have to hike the fees it charges companies for approving new and existing chemicals under the revised toxics law if it adopts one of two employee-based size metrics it is considering for defining “small businesses” that are charged lower fees.

Pruitt Scandals Prompt Agency Staff Anger At Ethics 'Double Standard'

EPA Administrator Scott Pruitt's mounting ethics problems are prompting an angry reaction from many agency staff who fear they would be reprimanded, suspended or even removed for conduct similar to Pruitt's, citing in part warnings in annual ethics trainings to avoid even the appearance of improper actions and to not waste government resources.

GREENWIRE ARTICLES

'Shocked' by noncompliance, enforcement chief warns industry

Sean Reilly, E&E News reporter

Published: Monday, April 23, 2018

With an expression of surprise at the continuing lack of compliance with environmental laws, EPA enforcement chief Susan Bodine warned businesses Friday against cutting corners to save money.

While that's bad for the environment and public health, it's also bad for the company, Bodine said at the EarthX festival in Dallas, "because you're going to lose whatever those savings were in penalties, lost reputation, even debarment from getting federal government contracts."

https://www.eenews.net/greenwire/2018/04/23/stories/1060079817

Senator linked to Pruitt condo fundraisers

Geof Koss and Kevin Bogardus, E&E News reporters

Published: Monday, April 23, 2018

EPA administrator Scott Pruitt has faced controversy for his use of this condo, rented for $50 a night from the wife of a lobbyist whose firm has clients that lobby the agency. Sen. Mike Crapo (R-Idaho) is also facing heat for allegedly not reporting paying for the use of the condo for fundraisers on campaign filings. Kevin Bogardus/E&E News

The environmentalists who blanketed Capitol Hill with posters mocking EPA Administrator Scott Pruitt's deal living in a lobbyist-owned condo are back, this time taking Senate Banking Chairman Mike Crapo (R-Idaho) to task for holding fundraisers at the now-infamous property.

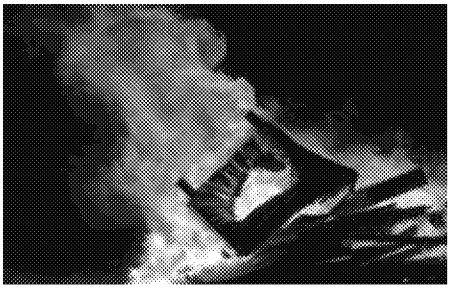
https://www.eenews.net/greenwire/2018/04/23/stories/1060079829

CHEMICAL WATCH ARTICLES

US body abandons plans for new flammability standard

NFPA hears concerns over flame retardants in furniture

24 April 2018 / Built environment, Halocarbons, United States



The National Fire Protection Association in the US has voted to halt development of a new flammability standard for residential upholstered furniture. The vote came amid stakeholder concern around the toxicity of the flame retardant chemicals that may have been needed to meet it.

Since 2014, a technical committee and two task groups at the NFPA have been working to develop a method to evaluate upholstered residential furniture subjected to a flaming ignition source. They were responding to a "significant fire issue" posed by burning upholstered furniture, according to Christian Dubay, NFPA vice president and chief engineer.

But the organisation received "numerous comments in opposition" to the draft – NFPA 277. Among these, many raised concerns that its implementation could increase the use of flame retardant chemicals in the furniture.

The NFPA's Standards Council voted to end development of the standard, citing a "fundamental lack of consensus on how to test and evaluate residential upholstered furniture flammability, exposed to a flaming ignition source."

Standards driving flame retardant use

The NFPA develops codes and standards through an open, consensus-based process. Although its standards are voluntary, many are adopted by local governments or firms.

Its work on standard 277 came though there has been a move away from 'open flame' flammability standards in favour of 'smoulder' tests in recent years.

Prior to 2014, California had in place an open-flame test for upholstered furniture. Many manufacturers used added chemical flame retardants in furniture sold nationwide to meet this.

Amid concerns of the possible harmful effects to human health and the environment of exposure to the substances, Governor Jerry Brown approved a new standard in November 2013 – Technical Bulletin (TB) 117-2013. This replaced the open-flame test in the original TB 113 with a smoulder test, which could more readily be met without added flame retardants.

Following that change, many foam suppliers and furniture manufacturers began removing flame retardants from products. Several US states have since acted to ban or restrict the substances' use in those applications.

Stakeholder opposition

The Polyurethane Foam Association is opposed to the standard. In comments to the NFPA, it said that, among other concerns, furniture assemblies would probably include the use of flame retardants to "score" well with NFPA 277.

And because some jurisdictions have restricted or prohibited them in furniture, "without the availability of such substances (either ethically or legally), it may be impossible for many furniture designs to achieve acceptable NFPA 277 performance," it said.

Dr Donald Lucas, a retired Lawrence Berkeley National Laboratory scientist who served on the NFPA 277 secondary task group, welcomed the decision to halt the standard's development. "Too many questions remain about [...] the health and environmental effects surrounding how flammability standards would be met to develop a meaningful method at this time," he said.

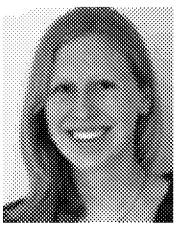
And Bifma, a trade group for commercial furniture, said it supports existing 'smoulder test' flammability standards as "appropriate regulation".

The Green Science Policy Institute (GPSI) – a longtime critic of flame retardant usage – also welcomed the decision.

But the NGO's executive director, Arlene Blum, told Chemical Watch she is concerned that the Consumer Product Safety Commission (CPSC) may be considering adopting a similar standard.

"Historically, the largest driver of the addition of flame retardant chemicals to furniture in the US was the open-flame flammability testing required by California's Technical Bulletin 117," said Dr Blum. "I question why the [CPSC] is still considering such a standard."

The CPSC is set to meet on 16 May to discuss furniture fire standards. The GSPI agrees with a coalition of petitioning furniture trade groups that the agency should adopt California's updated TB 117-13 as the national standard.



Kelly Franklin

North America editor

Related Articles

- California approves new upholstered furniture flammability standards
- Rhode Island bans sale of organohalogen flame-retardant treated furniture
- Maine bans all flame retardants in upholstered furniture
- Flame retardants debate sparked by IEC flammability specification
- US furniture industry calls for national flammability standard

Further Information:

- NFPA blog
- Press release

US EPA asked to extend consultation on alternative tests strategy

NGO advocates publication and review of 'robust and extensive' stakeholder analysis

24 April 2018 / Test methods, TSCA, United States

The Environmental Defense Fund has requested that the US EPA extend the public comment period for its draft plan to promote the development of alternative test methods under TSCA.

The EDF's call comes after it was revealed that the agency has yet to release a stakeholder analysis that could "significantly influence" its consideration of issues raised in the plan.

The EPA published its *Strategic plan to promote the development and implementation of alternative test methods* in early March. It outlines the move towards making TSCA determinations with new approach methodologies (NAMs) in place of vertebrate animal testing.

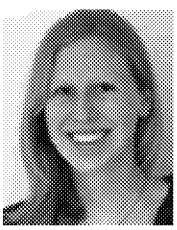
But, at a 10 April hearing, Nancy Beck, deputy assistant administrator for the Office of Chemical Safety and Pollution Prevention at the EPA, "prominently highlighted" the stakeholder-submitted analysis it is yet to release. The former American Chemistry Council staffer reportedly described the analysis as "robust and extensive".

The EPA said it would release it in the public docket, according to the EDF. But this has yet to happen.

The organisation has requested the agency make the document public and then extend the consultation by 30 days from this date.

"Given the importance that EPA itself publicly attributed to the analysis it received from a stakeholder, EPA should provide the public with sufficient opportunity to review and comment on that analysis," it says.

The comment period is currently set to close on 26 April.



Kelly Franklin

North America editor

Related Articles

- US EPA publishes draft strategy to promote alternative tests

Further Information:

- Extension request
- Public docket

OTHER ARTICLES

Brian Shupe: In veto of toxics bill, Scott put the interests of industry before children

vtdigger.org

Editor's note: This commentary is by Brian Shupe, who is executive director of the Vermont Natural Resources Council. Last week Governor Scott surprised the Legislature **and** public health **and** environmental advocates by vetoing S.103, a bill that would do two simple **and** important things: Ensure ...

Lowe's: Time to spring into action for safer chemicals

Safer Chemicals, Healthy Families (press release) (blog)

With the federal government asleep at the wheel when it comes to protecting consumers from **toxic chemicals** like methylene chloride, retailers like Lowe's must act. Because of Lowe's inaction, we have launched a national campaign calling on Lowe's to ban products containing these **toxic chemicals**.

Message

From: Hewitt, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41B19DD598D340BB8032923D902D4BD1-HEWITT, JAM]
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Subject: EPA News Highlights 4.24.18

Attachments: EPA News Highlights 4.24.18.docx

EPA News Highlights 4.24.18

The Washington Post: Pruitt to unveil controversial 'transparency' rule limiting what research EPA can use

Environmental Protection Agency Administrator Scott Pruitt is expected to propose a rule Tuesday that would establish new standards for what science could be used in writing agency regulations, according to individuals briefed on the plan. It is a sweeping change long sought by conservatives. The rule, which Pruitt has described in interviews with select media over the past month, would only allow EPA to consider studies for which the underlying data are made available publicly. Advocates describe this approach as an advance for transparency, but critics say it would effectively block the agency from relying on long-standing, landmark studies linking air pollution and pesticide exposure to harmful health effects.

Inside EPA: EPA's Ross Eyes Greater Water Policy 'Engagement,' Incremental Changes

EPA water chief David Ross is looking for ways to replicate in other rulemakings the type of engagement the agency used with states to discuss changes to the Obama-era Clean Water Act (CWA) jurisdiction rule, while stressing the need for incremental progress with water policies rather than trying to accomplish everything at once. Speaking at the National Water Policy Fly-In April 17 in Washington, D.C., Ross outlined his priorities as assistant administrator of the Office of Water, and said his overarching goal is to be proactive instead of reactive. The fly-in was sponsored by the National Association of Clean Water Agencies, the Water Environment Federation, the Water Research Foundation and WateReuse. One example of how Ross wants to change the way EPA does business is to change the process of consultation with state and local governments and the regulated community into one of "engagement," he said, pointing to the process used with the jurisdiction rule.

The Daily Caller: SOURCES: Most Of What EPA's Leaker Told Dems About Scott Pruitt Is 'False'

A former Environmental Protection Agency (EPA) official likely behind negative media stories about Administrator Scott Pruitt doesn't have all his facts straight, according to sources familiar with EPA's inner-workings. Former Trump campaign official Kevin Chmielewski, who's also former EPA deputy chief of staff operations, gave congressional Democrats a list of accusations against Pruitt, detailing the administrator's alleged "wasteful spending" and "disregard for ethical and legal requirements." Chmielewski is the likely source for media reports surrounding Pruitt's spending habits and alleged ethical lapses. Chmielewski was allegedly removed from his position at EPA for challenging Pruitt, but that hasn't been confirmed, reports said.

The Washington Examiner: EPA's Scott Pruitt says burning wood is renewable energy

The Environmental Protection Agency will begin treating energy created by burning trees as renewable, the same as wind and solar. Biomass from burning wood to produce electricity will be considered carbon-neutral, the EPA announced Monday. "Today's announcement grants America's foresters much-needed certainty and clarity with respect to the carbon neutrality of forest biomass," Administrator Scott Pruitt said Monday after meeting with forest industry representatives during a visit to a school in Georgia. "Managed forests improve air and water quality, while creating valuable jobs and thousands of products that improve our daily lives. This is environmental stewardship in action." The recent spending bill passed by Congress had directed the EPA, Energy Department and Agriculture Department to "reflect the carbon-neutrality of forest bioenergy and recognize biomass as a renewable energy source."

National News Highlights 4.24.18

Reuters: Senate committee paves way for Pompeo to become top U.S. diplomat

A U.S. Senate committee approved the nomination of President Donald Trump's choice for secretary of state, Mike Pompeo, on Monday after a Republican senator who had been opposed threw his support behind the CIA director in the face of party pressure. The Senate Foreign Relations Committee approved the nomination on a party-line vote, with all 11 Republicans backing him, nine Democrats opposed and one Democrat, Chris Coons, voting "present" because one Republican was at a funeral out of town. Majority Leader Mitch McConnell said there were enough votes in the full Senate to confirm Pompeo this week. That would allow Pompeo to attend a NATO summit on Friday. Pompeo became one of Trump's closest advisers during his 15 months as CIA director. He most recently has been deeply involved in preparations for Trump's summit with North Korean leader Kim Jong Un, including meeting with him three weeks ago

The Wall Street Journal: Driver Plows Van Into Toronto Pedestrians, Kills 10

A man in his mid-20s plowed a rented van into people walking along a busy Toronto thoroughfare on Monday, killing 10 and injuring 15, and rattled one of North America's safest major cities. Police said they arrested the driver, Alek Minassian, 25 years old, of Ontario. Authorities said Monday evening that they were still trying to determine his motive. "We cannot come to any firm conclusions at this stage," said Canada's Public Safety Minister Ralph Goodale. But he said there was "no national security connection" to the attack, based on the evidence police have seen so far. Toronto Chief of Police Mark Saunders said the attack "looks intentional." The casualties occurred on one of the city's first warm spring days, along Toronto's main artery, Yonge Street. Mass killings have been much rarer in Canada than in the U.S. and Europe, and many said they were stunned.

Politico: Ronny Jackson's VA nomination on the rocks

Rear Adm. Ronny Jackson's nomination to be Veterans Affairs secretary may be in trouble, according to senators and aides in both parties. Republicans are considering postponing his confirmation hearing this week as senators pore over potentially new negative information that committee members have received, according to GOP sources familiar with the matter. And Senate Democrats are digging into his record after being made aware of potential new problems with the nomination. On Monday evening, committee Democrats huddled in the Capitol office of Sen. Jon Tester of Montana, the top committee Democrat, to plot strategy. "There's a need for very exacting and close scrutiny and vetting," said Sen. Richard Blumenthal (D-Conn.) after the meeting. "And some questions that need to be answered. I'm not going to comment on any of the specifics, except to say we're going to be doing very close and careful scrutiny."

The Washington Post

https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/?utm_term=.ef6bdbd6cb3f

Pruitt to unveil controversial 'transparency' rule limiting what research EPA can use

By Juliet Eilperin and Brady Dennis, 4/24/18

Environmental Protection Agency Administrator Scott Pruitt is expected to propose a rule Tuesday that would establish new standards for what science could be used in writing agency regulations, according to individuals briefed on the plan. It is a sweeping change long sought by conservatives.

The rule, which Pruitt has described in interviews with select media over the past month, would only allow EPA to consider studies for which the underlying data are made available publicly. Advocates describe this approach as an advance for transparency, but critics say it would effectively block the agency from relying on long-standing, landmark studies linking air pollution and pesticide exposure to harmful health effects.

In an interview Sunday with radio host John Catsimatidis on 970 AM in New York, Pruitt described the change as a way to let the public judge "the data, the methodology, the analytics" behind any scientific analysis presented to the EPA as it drafts regulations.

"That's transparency," he told Catsimatidis. "It gives people the opportunity in real time to peer review. It goes to the heart of what we should be about as an agency."

The individuals briefed on the rule, which will be subject to a 30-day comment period, spoke on the condition of anonymity in advance of the announcement.

Many scientists argue that applying a standard to public health and environmental studies that is not currently required by peer-reviewed journals would limit the information the EPA could take into account when crafting federal limits on everything from power-plant emissions to which chemicals can be used in agriculture and in homes. Some researchers collect personal data from subjects but pledge to keep it confidential — as was the case in a major 1993 study by Harvard University that established the link between fine-particle air pollution and premature deaths. That practice would not be allowed under the new rule.

House Science Committee Chairman Lamar Smith (R-Tex.) sought to establish a requirement similar to the one Pruitt will propose through legislation, but it failed to pass both chambers.

On Monday, 985 scientists signed a letter organized by the Union of Concerned Scientists urging Pruitt not to forge ahead with the policy change.

"There are ways to improve transparency in the decision-making process, but restricting the use of science would improve neither transparency nor the quality of EPA decision-making," they wrote. "If fully implemented, this proposal would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health studies."

Under the proposed rule, third parties would be able to test and try to replicate the findings of studies submitted to EPA. But, the scientists wrote, "many public health studies cannot be replicated, as doing so would require intentionally and unethically exposing people and the environment to harmful contaminants or recreating one-time events."

Andrew Rosenberg, director of the Union of Concerned Scientists' Center for Science and Democracy, said in an email that Pruitt's move would expand on his earlier decision to change the standards for who can serve on EPA's advisory committees. Last year, Pruitt barred any scientists from serving if they received EPA grants for their work. Researchers funded by industries regulated by the agency to continue serving, however.

"First, they came after the agency's independent science advisers, and now, they're going after the science itself," Rosenberg said. "What is transparent is the unabashed takeover of EPA leadership by individuals who have demonstrated disinterest in helping communities combat pollution by using the best available science."

Inside EPA

http://insideepa.com/daily-news/epas-ross-eyes-greater-water-policy-engagement-incremental-changes

EPA's Ross Eyes Greater Water Policy 'Engagement,' Incremental Changes

By Laura Beaven, 4/23/18

EPA water chief David Ross is looking for ways to replicate in other rulemakings the type of engagement the agency used with states to discuss changes to the Obama-era Clean Water Act (CWA) jurisdiction rule, while stressing the need for incremental progress with water policies rather than trying to accomplish everything at once.

Speaking at the National Water Policy Fly-In April 17 in Washington, D.C., Ross outlined his priorities as assistant administrator of the Office of Water, and said his overarching goal is to be proactive instead of reactive. The fly-in was sponsored by the National Association of Clean Water Agencies, the Water Environment Federation, the Water Research Foundation and WateReuse.

One example of how Ross wants to change the way EPA does business is to change the process of consultation with state and local governments and the regulated community into one of "engagement," he said, pointing to the process used with the jurisdiction rule. In that case, EPA invited nine states to each bring three representatives, including state agriculture directors, for two days of talks with the agency, he said.

"We got really close to the vision I have for engagement," Ross said, adding that the challenge now is figuring out "how do I replicate that to other rulemakings."

In terms of other areas of focus, Ross said "aging infrastructure is priority 1, 2 and 3" and is part of Administrator Scott Pruitt's focus on "back to basics."

"Infrastructure at a high level is what I was focused on coming in," with a goal of making "incremental improvements on an annual basis," Ross said.

Using a baseball analogy, Ross said he prefers to "take the safe singles" rather than take bigger risks that may not work.

One aspect of aging infrastructure that has received great attention from Pruitt is the need to replace lead drinking water service lines, something that could be addressed in the agency's upcoming proposal to revise the Safe Drinking Water Act lead and copper rule (LCR).

Recommendations from the agency's National Drinking Water Advisory Council (NDWAC) in 2015 on how to change the LCR included a call for drinking water utilities to conduct full lead service line replacements (LSLRs), rather than partial replacements.

But legal and financial questions over how to accomplish this remain unanswered, and drinking water utilities recently urged EPA to focus on "financially prudent" ways to reduce human health risks when revising the LCR, noting that it may be impossible to include all of NDWAC's recommendation in the proposed rule.

Ross said EPA is "working hard to balance the competing needs" within the LCR revisions and that "you'll see some action this year."

During a panel discussion after Ross' speech, Peter Grevatt, director of the Office of Ground Water and Drinking Water, said Pruitt is very focused on LSLR and noted the administrator's recent visit to Cincinnati to meet with local water utilities and tour two LSLR construction sites.

Grevatt said he suggested the April 16 Cincinnati trip, in part because the city is proactively working to remove its lead pipes rather than doing so because of elevated levels of lead in its drinking water.

Lead Programs

In an April 16 EPA press release, Cathy Bailey, director of the Greater Cincinnati Water Works, said Pruitt's "visit gave us a chance to explain our enhanced lead program that includes education, outreach and removal of lead service lines. Our program wasn't mandated by regulations, but implemented because it is the right thing to do for our community, and we believe it can serve as a model across the country."

Grevatt echoed the agency's emphasis on helping utilities find a way to conduct LSLRs. "It's not just that we'll order you to do that," he said.

Ross also suggested that the Water Infrastructure Finance and Innovation Act (WIFIA) program could provide funding for LSLRs. EPA is prioritizing projects that reduce lead for its next round of WIFIA loans.

Another area Ross highlighted as a priority is nutrient pollution. "I want to aggressively go after it, but holistically," he said, adding that EPA has previously "missed the opportunity to engage with state agriculture directors" on ways to prevent nutrient runoff.

Ross said he wants EPA research to be focused on how to solve the problem. Later, during a question-and-answer session, he said that to date much of the agency's research has been focused on measuring nutrients downstream but he wants it to tackle the question of "how do you get source reduction?"

A water utility representative from Bowling Green, OH, asked Ross if there is any way to leverage WIFIA funds for agriculture projects.

Ross, after consulting with Office of Wastewater Management Director Andrew Sawyers, said, yes. "WIFIA is a very flexible program," Ross said. If a bunch of rural communities wanted to get together and develop a WIFIA proposal, they could, he said.

"Farmers are willing to do the work" to reduce nutrient runoff, especially if they can see the results, Ross said.

Ross also said he wants to "take a long hard look at trading," saying that it "hasn't been utilized enough" and that he likes the idea of utilizing nature to treat agricultural runoff.

Water Trading

During a second question-and-answer period, other EPA water officials reiterated Ross' interest in trading.

John Goodin, acting director of the Office of Wetlands, Oceans and Watersheds, said Ross is particularly interested in figuring out how to remove current hindrances to water quality trading.

And Sawyers said there are "some real opportunities around watershed permitting," adding that some states are looking how to enhance or retool their trading programs.

While water quality trading programs can be developed to address any number of pollutants, most have focused on nutrients. Nutrient credit trading programs are designed to allow a point source to purchase pollutant reduction credits from another point source or a nonpoint source in the same watershed with the intent of meeting the discharge limits established in a Clean Water Act discharge permit

The Government Accountability Office last year found that states with the greatest number of nutrient water quality trades are those with discharge limits dictated by a regulatory cleanup plan, and that without such a driver, trading is unlikely to occur. -- Lara Beaven (lbeaven@iwpnews.com)

The Daily Caller

http://dailycaller.com/2018/04/23/sources-epa-leaker-dems-scott-pruitt-false/

SOURCES: Most Of What EPA's Leaker Told Dems About Scott Pruitt Is 'False'

By Michael Bastasch, 4/23/18

A former Environmental Protection Agency (EPA) official likely behind negative media stories about Administrator Scott Pruitt doesn't have all his facts straight, according to sources familiar with EPA's inner-workings.

Former Trump campaign official Kevin Chmielewski, who's also former EPA deputy chief of staff operations, gave congressional Democrats a list of accusations against Pruitt, detailing the administrator's alleged "wasteful spending" and "disregard for ethical and legal requirements."

Chmielewski is the likely source for media reports surrounding Pruitt's spending habits and alleged ethical lapses. Chmielewski was allegedly removed from his position at EPA for challenging Pruitt, but that hasn't been confirmed, reports said.

But many of Chmielewski's claims have been called into question by two sources familiar with EPA's inner-workings. One source told The Daily Caller News Foundation of Chmielewski's claims that "more than 60 percent is false, the other 40 percent is information he distorted."

In one instance Chmielewski alleged "a $30,000 contract with private Italian security personnel entered into by Mr. [Pasquele] Nino Perrotta," ahead of Pruitt's attendance of a G7 summit in Italy.

However, two sources familiar with Pruitt's security said that never happened, adding Perrotta, the special agent in charge of Pruitt's security detail, would have had no authority to enter into such a contract on his own.

The "special agent in charge has no authority to make purchase agreements or authorize people to make purchases," one source told TheDCNF. Perrotta would need approval from higher-ups in the Office of Criminal Enforcement and Forensic Training, the source said.

Perrotta did communicate with contacts in Italy but only to get an idea of what sort of security would be typical for a U.S. official of Pruitt's stature, not to negotiate a five-figure security contract, a second source said.

Before joining EPA in 2004, Perrotta joined the Secret Service in 1995. Before that, Perrotta served as an Army intelligence officer for three years and did tours in Italy, Bulgaria and Romania.

Like his boss, Perrotta's become the focus of intense media scrutiny, including a New York Times article that referred to the special agent as Pruitt's "sheriff." NYT's April 12 article, published the same day as Democrats' letter, repeated many of Chmielewski's accusations.

"Perrotta, has clashed — at least once physically — with top EPA officials who challenged Mr. Pruitt's spending, and has steered at least one EPA security contract to a business associate," current and former officials told NYT.

Likewise, "at least one security-related contract was awarded to an individual who works at Mr. Perrotta's private security firm, and he believes that other contracts may also have been awarded to friends or associates of Mr. Perrotta's," Chmielewski told Democrats.

It's true EPA hired Edwin Steinmetz to conduct a security sweep of Pruitt's office in 2017, costing the agency $3,000. Steinmetz is listed on the management team of Perrotta's security firm he operates on the side named Sequoia Security Group.

"It was an emergency; they needed it right away," Steinmetz told NYT. "I dropped everything and took care of it." None of the money Steinmetz was paid went to Sequoia Security Group, and there's no evidence Perrotta played a role in any other security contracts.

Both DCNF sources confirmed Steinmetz's security sweep but contested NYT's characterization Perrotta "steered" the contract toward them. EPA hadn't conducted a security sweep in years and asked Perrotta for a recommendation, the sources said.

EPA contracting officials took the ball from there, the source said. Steinmetz got the $3,000 job through an official agency process, both sources said.

"Very few people are qualified in that specific field and EPA had a hard time finding a vendor," one source said.

Perrotta got permission from EPA to operate a side business in 2013, during the Obama administration. As for "physically" clashing with an EPA official, as NYT alleged, that never happened, one source told TheDCNF.

"Things got so heated that a scuffle broke out during a meeting last summer of the agency's top security and administrative staff" where "Perrotta traded expletives with Mario Caraballo, who until recently served as the deputy

associate administrator of the homeland security office, and that the two men had to be physically separated," NYT reported.

The discussion between Caraballo and Perrotta got heated, but no physical altercation broke out, a source, who spoke with officials present at the meeting, said. Caraballo has since been removed from his position at EPA.

The Washington Examiner

https://www.washingtonexaminer.com/policy/energy/epas-scott-pruitt-says-burning-wood-is-renewable-energy

EPA's Scott Pruitt says burning wood is renewable energy

By Josh Siegel 4/23/18

The Environmental Protection Agency will begin treating energy created by burning trees as renewable, the same as wind and solar.

Biomass from burning wood to produce electricity will be considered carbon-neutral, the EPA announced Monday.

"Today's announcement grants America's foresters much-needed certainty and clarity with respect to the carbon neutrality of forest biomass," Administrator Scott Pruitt said Monday after meeting with forest industry representatives during a visit to a school in Georgia. "Managed forests improve air and water quality, while creating valuable jobs and thousands of products that improve our daily lives. This is environmental stewardship in action."

The recent spending bill passed by Congress had directed the EPA, Energy Department and Agriculture Department to "reflect the carbon-neutrality of forest bioenergy and recognize biomass as a renewable energy source."

Georgia and other large timber states had lobbied the EPA to consider biomass carbon-neutral when the states were facing limits on carbon emissions from power plants required by the Obama administration's Clean Power Plan, one of its key climate change initiatives. Pruitt has begun a process for repealing and replacing the Clean Power Plan, which was never implemented because of court challenges.

The EPA says it will consider biomass as carbon neutral when devising regulatory actions on energy production from power plants, such as a potentially revised, more modest Clean Power Plan.

"The use of biomass from managed forests can bolster domestic energy production, provide jobs to rural communities, and promote environmental stewardship by improving soil and water quality, reducing wildfire risk, and helping to ensure our forests continue to remove carbon from the atmosphere," the EPA said in a policy document explaining the move.

Despite Pruitt's action, EPA's science advisers haven't come to a consensus on whether biomass is carbon-neutral. Many scientists say that while biomass is a renewable resource, it is not carbon-neutral because burning wood for energy releases large amounts of carbon all at once, faster than what is absorbed by newly planted forests.

The EPA's policy statement contends that U.S. forests absorb more carbon from the air than burning wood releases. In 2015, forests offset about 11.2 percent of gross U.S. greenhouse gas emissions, the agency says.
The EPA said it will continue to enforce current air pollution regulations against power generation from biomass as it normally would, not treating it as carbon-neutral.

"This statement of agency policy is not a scientific determination and does not revise or amend any scientific determinations that EPA has previously made," the EPA document says. "Although this policy announcement does not itself alter sources' obligations with regard to [greenhouse gases] and CO2 in any particular regulatory program, the agency is committed to addressing regulatory uncertainty about how it treats biogenic CO2 emissions in forthcoming actions under various EPA programs."

Reuters
https://www.reuters.com/article/us-usa-trump-pompeo/senate-committee-paves-way-for-pompeo-to-become-top-u-s-diplomat-idUSKBN1HU26X

Senate committee paves way for Pompeo to become top U.S. diplomat

By Patricia Zengerle, 4/23/18

A U.S. Senate committee approved the nomination of President Donald Trump's choice for secretary of state, Mike Pompeo, on Monday after a Republican senator who had been opposed threw his support behind the CIA director in the face of party pressure.

The Senate Foreign Relations Committee approved the nomination on a party-line vote, with all 11 Republicans backing him, nine Democrats opposed and one Democrat, Chris Coons, voting "present" because one Republican was at a funeral out of town.

Majority Leader Mitch McConnell said there were enough votes in the full Senate to confirm Pompeo this week. That would allow Pompeo to attend a NATO summit on Friday.

Pompeo became one of Trump's closest advisers during his 15 months as CIA director. He most recently has been deeply involved in preparations for Trump's summit with North Korean leader Kim Jong Un, including meeting with him three weeks ago.

While many Democrats consider Pompeo too hawkish and worry about past harsh statements on homosexuality and Islam, he has the support of at least three Democratic senators not on the committee who are running for re-election in states Trump won easily in 2016. That all but assures Pompeo will be confirmed.

"I do not believe Director Pompeo is someone who will always prioritize diplomacy over conflict, particularly in the context of the aggressive foreign policy voices growing around him," said Senator Robert Menendez, the top Democrat on the Foreign Relations Committee, citing Pompeo's past openness to regime change in North Korea and Iran.

No Republican besides Senator Rand Paul, who changed his vote on Monday, had announced opposition.

Paul's late switch meant Pompeo avoided the embarrassment of being the first nominee for secretary of state to fail to secure the committee's endorsement since it began considering them in the late 19th century.

That would have weakened Pompeo's reputation internationally and cast a cloud over Trump's push to overhaul his national security team after firing Secretary of State Rex Tillerson and replacing his national security adviser, H.R. McMaster, with John Bolton, also known as a hawk.

The White House and Republican Party had thrown their weight behind the nomination, with unceasing attacks on Democrats for opposing Trump's pick.

Paul had opposed Pompeo for weeks, holding a news conference to announce his opposition to him, as well as Trump's pick to replace him at the CIA, Deputy CIA Director Gina Haspel.

Haspel, whose Senate confirmation hearing is next month, also faces a tough confirmation fight. Democrats, and some Republicans, are concerned about her links to the CIA's past use of "harsh interrogation techniques," widely seen as torture.

Paul has repeatedly threatened opposition on policy positions staked out by Trump, before changing his mind at the last minute. Trump recently predicted he would come around again on Pompeo, calling Paul "a good man" who has "never let us down."

The Wall Street Journal
https://www.wsj.com/articles/van-strikes-pedestrians-in-toronto-1524508659

Driver Plows Van Into Toronto Pedestrians, Kills 10

By Vipal Monga and Jacquie McNish, 4/24/18

A man in his mid-20s plowed a rented van into people walking along a busy Toronto thoroughfare on Monday, killing 10 and injuring 15, and rattled one of North America's safest major cities.

Police said they arrested the driver, Alek Minassian, 25 years old, of Ontario. Authorities said Monday evening that they were still trying to determine his motive.

"We cannot come to any firm conclusions at this stage," said Canada's Public Safety Minister Ralph Goodale. But he said there was "no national security connection" to the attack, based on the evidence police have seen so far.

Toronto Chief of Police Mark Saunders said the attack "looks intentional."

The casualties occurred on one of the city's first warm spring days, along Toronto's main artery, Yonge Street. Mass killings have been much rarer in Canada than in the U.S. and Europe, and many said they were stunned.

"I'm at a loss for words. I can't believe that this has happened here. Things like this don't happen in Canada," said, Melissa Phillips, a nurse who was walking her dog Monday evening just steps away from where pedestrians were hit earlier.

The van jumped up onto the sidewalk around 1:30 p.m. Monday, hitting pedestrians as it headed south for about a mile. Police said 26 minutes lapsed between the first 911 call and the driver's arrest.

The area where the incident occurred is home to people of many ethnic backgrounds, said John Filion, a city councilor representing the area where the incident took place, but is predominantly home to immigrants from Iran, Iraq, Korea and elsewhere in Asia. Businesses in the area include banks, pensions, and government buildings, as well as retail shops.

"This is the kind of community where you rarely even encounter angry people, let alone something like this," said Mr. Filion. "It's a such a shock."

Toronto resident Reza Bahramian said he was out enjoying the nice weather when he saw a van "cut everything." He and some other neighbors started chasing after the van and yelling for it to stop. They saw about four people get hit.

He said he helped one woman who was struck, with CPR, for about half-hour before paramedics arrived. "Blood flowed on the sidewalk," he said, referring to the numerous injuries of people who were hit.

Another witness said in an interview he saw two responders trying to give CPR to two people lying in the street, but eventually the responders covered their bodies with tarps.

Witness Alex Shaker told CTV news that the van was moving at high speed along the sidewalk, striking everything in its way.

"People just with a stroller, with their baby, everything was flying down one by one. And he was going really fast," Mr. Shaker told the network.

The CP24 channel aired witnesses' videos that showed a black-clad man by the white van appearing to point something at a police officer before he drops it and is forced to the ground and handcuffed.

In Canada, mass-casualty events are relatively rare, but when they happen, they loom large: The country reeled after 14 women were killed by gunman at the Universite du Montreal's Ecole Polytechnique in 1989, and again in 2016 after four people were killed in a shooting in La Loche, Saskatchewan.

On Monday afternoon, over a mile of Yonge Street was cordoned off with yellow police tape and the area was swarming with cars from both the Toronto police and the Ontario provincial police. Police were interviewing passersby and asking if they had witnessed the incident.

"I ask everyone to await the results of the police investigation and avoid speculation," Toronto Mayor John Tory said.

"It was with great sadness that I heard about the tragic and senseless attack that took place in Toronto," Canadian Prime Minister Justin Trudeau said in a statement Monday night. He said officials were monitoring events closely, and would work with law-enforcement agencies across the country to ensure Canadians' security.

"As of now, #ISIS channels are not promoting the #Toronto vehicular attack, which contains staples of ISIS-inspired events," said Rita Katz, executive director at SITE Intel Group, which monitors jihadist activity online, on Twitter. ISIS channels typically share images and statements celebrating jihadist attacks on the encrypted messaging app Telegram, and the terror group has previously used vehicles in attacks on the streets of major cities such as London and New York.

Attacks involving either a van or truck striking pedestrians have also unfolded in New York City and some of Europe's urban centers.

Sayfullo Saipov, a 29-year-old Uzbek man, was charged with killing eight people and injuring 12 others last October after driving a rented truck down a crowded Manhattan bike path. Law-enforcement officials say the deadly drive had been planned for weeks and was done in the name of Islamic State. Mr. Saipov has pleaded not guilty to the charges.

In Europe over the past two years, 86 people were killed after a truck drove through crowds watching Bastille Day fireworks in Nice, France; 12 people died after a rejected Tunisian asylum seeker rammed a stolen truck into a busy Christmas market in Berlin; and in Barcelona, 13 died and over 100 were injured after a van mowed down pedestrians on city's most famous central thoroughfare, Las Ramblas.

Politico

https://www.politico.com/story/2018/04/23/ronny-jackson-veterans-affairs-nomination-hearing-546408

Ronny Jackson's VA nomination on the rocks

By Burgess Everett and Elana Schor, 4/23/18

Rear Adm. Ronny Jackson's nomination to be Veterans Affairs secretary may be in trouble, according to senators and aides in both parties.

Republicans are considering postponing his confirmation hearing this week as senators pore over potentially new negative information that committee members have received, according to GOP sources familiar with the matter. And Senate Democrats are digging into his record after being made aware of potential new problems with the nomination.

On Monday evening, committee Democrats huddled in the Capitol office of Sen. Jon Tester of Montana, the top committee Democrat, to plot strategy.

"There's a need for very exacting and close scrutiny and vetting," said Sen. Richard Blumenthal (D-Conn.) after the meeting. "And some questions that need to be answered. I'm not going to comment on any of the specifics, except to say we're going to be doing very close and careful scrutiny."

Republicans and Democrats alike have been talking over the weekend, and in person on Monday, about the potential for allegations to derail Jackson's nomination, senators said. But the nature of discussions now going on about the material is "conversational," said Sen. Thom Tillis (R-N.C.).

Tillis suggested that the Jackson confirmation hearing scheduled for Wednesday may be "pushed back pending a review of some of this stuff that, like I said, I've only heard on a conversational basis. I think that's where we'll spend our time this week."

Jackson is President Donald Trump's physician at the White House and is already facing major questions from Republicans over his lack of experience managing an agency as large as the VA. If he faces additional problems, his nomination could be derailed entirely.

"I would like to hear what he has to say about that. I'm not sure anybody can run the VA. It's so big," said Senate Majority Whip John Cornyn (R-Texas). "But I'm willing to give him the benefit of the doubt and listen to him and hear what he has in mind."

Axios was first to report that new information about Jackson's "professional conduct" was taken to Tester earlier this month.

Democrats declined to comment on the severity of the allegations that have been presented to the committee about Jackson.

"We're going to vet him. The Trump administration doesn't do a particularly good job," said Sen. Sherrod Brown (D-Ohio), another committee member. "That's all I'm going to say."

Spokespeople for the committee did not comment on whether Jackson's hearing has been postponed. But a Republican working on the nomination said it was unlikely the hearing would take place pending review of the new information, though that source cautioned that few have seen the documents rattling the nomination.

"You have to be concerned about any nomination" in a closely divided Senate, the Republican said.

Republicans currently hold just 51 seats and Sen. John McCain (R-Ariz.) is recovering from cancer treatment, leaving them no margin for error if Democrats unify to oppose the nomination.

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Environmental Protection Agency
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EPA News Highlights 4.23.18

The Washington Post: Pruitt to unveil controversial 'transparency' rule limiting what research EPA can use

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The Washington Examiner: EPA's Scott Pruitt says burning wood is renewable energy

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National News Highlights 4.23.18

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one of Trump's closest advisers during his 15 months as CIA director. He most recently has been deeply involved in preparations for Trump's summit with North Korean leader Kim Jong Un, including meeting with him three weeks ago

The Wall Street Journal: Driver Plows Van Into Toronto Pedestrians, Kills 10

A man in his mid-20s plowed a rented van into people walking along a busy Toronto thoroughfare on Monday, killing 10 and injuring 15, and rattled one of North America's safest major cities. Police said they arrested the driver, Alek Minassian, 25 years old, of Ontario. Authorities said Monday evening that they were still trying to determine his motive. "We cannot come to any firm conclusions at this stage," said Canada's Public Safety Minister Ralph Goodale. But he said there was "no national security connection" to the attack, based on the evidence police have seen so far. Toronto Chief of Police Mark Saunders said the attack "looks intentional." The casualties occurred on one of the city's first warm spring days, along Toronto's main artery, Yonge Street. Mass killings have been much rarer in Canada than in the U.S. and Europe, and many said they were stunned.

Politico: Ronny Jackson's VA nomination on the rocks

Rear Adm. Ronny Jackson's nomination to be Veterans Affairs secretary may be in trouble, according to senators and aides in both parties. Republicans are considering postponing his confirmation hearing this week as senators pore over potentially new negative information that committee members have received, according to GOP sources familiar with the matter. And Senate Democrats are digging into his record after being made aware of potential new problems with the nomination. On Monday evening, committee Democrats huddled in the Capitol office of Sen. Jon Tester of Montana, the top committee Democrat, to plot strategy. "There's a need for very exacting and close scrutiny and vetting," said Sen. Richard Blumenthal (D-Conn.) after the meeting. "And some questions that need to be answered. I'm not going to comment on any of the specifics, except to say we're going to be doing very close and careful scrutiny."

The Washington Post

https://www.washingtonpost.com/news/energy-environment/wp/2018/04/24/pruitt-to-unveil-controversial-transparency-rule-limiting-what-research-epa-can-use/?utm_term=.ef6bdbd6cb3f

Pruitt to unveil controversial 'transparency' rule limiting what research EPA can use

By Juliet Eilperin and Brady Dennis, 4/24/18

Environmental Protection Agency Administrator Scott Pruitt is expected to propose a rule Tuesday that would establish new standards for what science could be used in writing agency regulations, according to individuals briefed on the plan. It is a sweeping change long sought by conservatives.

The rule, which Pruitt has described in interviews with select media over the past month, would only allow EPA to consider studies for which the underlying data are made available publicly. Advocates describe this approach as an advance for transparency, but critics say it would effectively block the agency from relying on long-standing, landmark studies linking air pollution and pesticide exposure to harmful health effects.

In an interview Sunday with radio host John Catsimatidis on 970 AM in New York, Pruitt described the change as a way to let the public judge "the data, the methodology, the analytics" behind any scientific analysis presented to the EPA as it drafts regulations.

"That's transparency," he told Catsimatidis. "It gives people the opportunity in real time to peer review. It goes to the heart of what we should be about as an agency."

The individuals briefed on the rule, which will be subject to a 30-day comment period, spoke on the condition of anonymity in advance of the announcement.

Many scientists argue that applying a standard to public health and environmental studies that is not currently required by peer-reviewed journals would limit the information the EPA could take into account when crafting federal limits on everything from power-plant emissions to which chemicals can be used in agriculture and in homes. Some researchers

collect personal data from subjects but pledge to keep it confidential — as was the case in a major 1993 study by Harvard University that established the link between fine-particle air pollution and premature deaths. That practice would not be allowed under the new rule.

House Science Committee Chairman Lamar Smith (R-Tex.) sought to establish a requirement similar to the one Pruitt will propose through legislation, but it failed to pass both chambers.

On Monday, 985 scientists signed a letter organized by the Union of Concerned Scientists urging Pruitt not to forge ahead with the policy change.

"There are ways to improve transparency in the decision-making process, but restricting the use of science would improve neither transparency nor the quality of EPA decision-making," they wrote. "If fully implemented, this proposal would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health studies."

Under the proposed rule, third parties would be able to test and try to replicate the findings of studies submitted to EPA. But, the scientists wrote, "many public health studies cannot be replicated, as doing so would require intentionally and unethically exposing people and the environment to harmful contaminants or recreating one-time events."

Andrew Rosenberg, director of the Union of Concerned Scientists' Center for Science and Democracy, said in an email that Pruitt's move would expand on his earlier decision to change the standards for who can serve on EPA's advisory committees. Last year, Pruitt barred any scientists from serving if they received EPA grants for their work. Researchers funded by industries regulated by the agency to continue serving, however.

"First, they came after the agency's independent science advisers, and now, they're going after the science itself," Rosenberg said. "What is transparent is the unabashed takeover of EPA leadership by individuals who have demonstrated disinterest in helping communities combat pollution by using the best available science."

Inside EPA

http://insideepa.com/daily-news/epas-ross-eyes-greater-water-policy-engagement-incremental-changes

EPA's Ross Eyes Greater Water Policy 'Engagement,' Incremental Changes

By Laura Beaven, 4/23/18

EPA water chief David Ross is looking for ways to replicate in other rulemakings the type of engagement the agency used with states to discuss changes to the Obama-era Clean Water Act (CWA) jurisdiction rule, while stressing the need for incremental progress with water policies rather than trying to accomplish everything at once.

Speaking at the National Water Policy Fly-In April 17 in Washington, D.C., Ross outlined his priorities as assistant administrator of the Office of Water, and said his overarching goal is to be proactive instead of reactive. The fly-in was sponsored by the National Association of Clean Water Agencies, the Water Environment Federation, the Water Research Foundation and WateReuse.

One example of how Ross wants to change the way EPA does business is to change the process of consultation with state and local governments and the regulated community into one of "engagement," he said, pointing to the process used with the jurisdiction rule. In that case, EPA invited nine states to each bring three representatives, including state agriculture directors, for two days of talks with the agency, he said.

"We got really close to the vision I have for engagement," Ross said, adding that the challenge now is figuring out "how do I replicate that to other rulemakings."

In terms of other areas of focus, Ross said "aging infrastructure is priority 1, 2 and 3" and is part of Administrator Scott Pruitt's focus on "back to basics."

"Infrastructure at a high level is what I was focused on coming in," with a goal of making "incremental improvements on an annual basis," Ross said.

Using a baseball analogy, Ross said he prefers to "take the safe singles" rather than take bigger risks that may not work.

One aspect of aging infrastructure that has received great attention from Pruitt is the need to replace lead drinking water service lines, something that could be addressed in the agency's upcoming proposal to revise the Safe Drinking Water Act lead and copper rule (LCR).

Recommendations from the agency's National Drinking Water Advisory Council (NDWAC) in 2015 on how to change the LCR included a call for drinking water utilities to conduct full lead service line replacements (LSLRs), rather than partial replacements.

But legal and financial questions over how to accomplish this remain unanswered, and drinking water utilities recently urged EPA to focus on "financially prudent" ways to reduce human health risks when revising the LCR, noting that it may be impossible to include all of NDWAC's recommendation in the proposed rule.

Ross said EPA is "working hard to balance the competing needs" within the LCR revisions and that "you'll see some action this year."

During a panel discussion after Ross' speech, Peter Grevatt, director of the Office of Ground Water and Drinking Water, said Pruitt is very focused on LSLR and noted the administrator's recent visit to Cincinnati to meet with local water utilities and tour two LSLR construction sites.

Grevatt said he suggested the April 16 Cincinnati trip, in part because the city is proactively working to remove its lead pipes rather than doing so because of elevated levels of lead in its drinking water.

Lead Programs

In an April 16 EPA press release, Cathy Bailey, director of the Greater Cincinnati Water Works, said Pruitt's "visit gave us a chance to explain our enhanced lead program that includes education, outreach and removal of lead service lines. Our program wasn't mandated by regulations, but implemented because it is the right thing to do for our community, and we believe it can serve as a model across the country."

Grevatt echoed the agency's emphasis on helping utilities find a way to conduct LSLRs. "It's not just that we'll order you to do that," he said.

Ross also suggested that the Water Infrastructure Finance and Innovation Act (WIFIA) program could provide funding for LSLRs. EPA is prioritizing projects that reduce lead for its next round of WIFIA loans.

Another area Ross highlighted as a priority is nutrient pollution. "I want to aggressively go after it, but holistically," he said, adding that EPA has previously "missed the opportunity to engage with state agriculture directors" on ways to prevent nutrient runoff.

Ross said he wants EPA research to be focused on how to solve the problem. Later, during a question-and-answer session, he said that to date much of the agency's research has been focused on measuring nutrients downstream but he wants it to tackle the question of "how do you get source reduction?"

A water utility representative from Bowling Green, OH, asked Ross if there is any way to leverage WIFIA funds for agriculture projects.

Ross, after consulting with Office of Wastewater Management Director Andrew Sawyers, said, yes. "WIFIA is a very flexible program," Ross said. If a bunch of rural communities wanted to get together and develop a WIFIA proposal, they could, he said.

"Farmers are willing to do the work" to reduce nutrient runoff, especially if they can see the results, Ross said.

Ross also said he wants to "take a long hard look at trading," saying that it "hasn't been utilized enough" and that he likes the idea of utilizing nature to treat agricultural runoff.

Water Trading

During a second question-and-answer period, other EPA water officials reiterated Ross' interest in trading.

John Goodin, acting director of the Office of Wetlands, Oceans and Watersheds, said Ross is particularly interested in figuring out how to remove current hindrances to water quality trading.

And Sawyers said there are "some real opportunities around watershed permitting," adding that some states are looking how to enhance or retool their trading programs.

While water quality trading programs can be developed to address any number of pollutants, most have focused on nutrients. Nutrient credit trading programs are designed to allow a point source to purchase pollutant reduction credits from another point source or a nonpoint source in the same watershed with the intent of meeting the discharge limits established in a Clean Water Act discharge permit

The Government Accountability Office last year found that states with the greatest number of nutrient water quality trades are those with discharge limits dictated by a regulatory cleanup plan, and that without such a driver, trading is unlikely to occur. -- Lara Beaven (lbeaven@iwpnews.com)

The Daily Caller

http://dailycaller.com/2018/04/23/sources-epa-leaker-dems-scott-pruitt-false/

SOURCES: Most Of What EPA's Leaker Told Dems About Scott Pruitt Is 'False'

By Michael Bastasch, 4/23/18

A former Environmental Protection Agency (EPA) official likely behind negative media stories about Administrator Scott Pruitt doesn't have all his facts straight, according to sources familiar with EPA's inner-workings.

Former Trump campaign official Kevin Chmielewski, who's also former EPA deputy chief of staff operations, gave congressional Democrats a list of accusations against Pruitt, detailing the administrator's alleged "wasteful spending" and "disregard for ethical and legal requirements."

Chmielewski is the likely source for media reports surrounding Pruitt's spending habits and alleged ethical lapses. Chmielewski was allegedly removed from his position at EPA for challenging Pruitt, but that hasn't been confirmed, reports said.

But many of Chmielewski's claims have been called into question by two sources familiar with EPA's inner-workings. One source told The Daily Caller News Foundation of Chmielewski's claims that "more than 60 percent is false, the other 40 percent is information he distorted."

In one instance Chmielewski alleged "a $30,000 contract with private Italian security personnel entered into by Mr. [Pasquele] Nino Perrotta," ahead of Pruitt's attendance of a G7 summit in Italy.

However, two sources familiar with Pruitt's security said that never happened, adding Perrotta, the special agent in charge of Pruitt's security detail, would have had no authority to enter into such a contract on his own.

The "special agent in charge has no authority to make purchase agreements or authorize people to make purchases," one source told TheDCNF. Perrotta would need approval from higher-ups in the Office of Criminal Enforcement and Forensic Training, the source said.

Perrotta did communicate with contacts in Italy but only to get an idea of what sort of security would be typical for a U.S. official of Pruitt's stature, not to negotiate a five-figure security contract, a second source said.

Before joining EPA in 2004, Perrotta joined the Secret Service in 1995. Before that, Perrotta served as an Army intelligence officer for three years and did tours in Italy, Bulgaria and Romania.

Like his boss, Perrotta's become the focus of intense media scrutiny, including a New York Times article that referred to the special agent as Pruitt's "sheriff." NYT's April 12 article, published the same day as Democrats' letter, repeated many of Chmielewski's accusations.

"Perrotta, has clashed — at least once physically — with top EPA officials who challenged Mr. Pruitt's spending, and has steered at least one EPA security contract to a business associate," current and former officials told NYT.

Likewise, "at least one security-related contract was awarded to an individual who works at Mr. Perrotta's private security firm, and he believes that other contracts may also have been awarded to friends or associates of Mr. Perrotta's," Chmielewski told Democrats.

It's true EPA hired Edwin Steinmetz to conduct a security sweep of Pruitt's office in 2017, costing the agency $3,000. Steinmetz is listed on the management team of Perrotta's security firm he operates on the side named Sequoia Security Group.

"It was an emergency; they needed it right away," Steinmetz told NYT. "I dropped everything and took care of it." None of the money Steinmetz was paid went to Sequoia Security Group, and there's no evidence Perrotta played a role in any other security contracts.

Both DCNF sources confirmed Steinmetz's security sweep but contested NYT's characterization Perrotta "steered" the contract toward them. EPA hadn't conducted a security sweep in years and asked Perrotta for a recommendation, the sources said.

EPA contracting officials took the ball from there, the source said. Steinmetz got the $3,000 job through an official agency process, both sources said.

"Very few people are qualified in that specific field and EPA had a hard time finding a vendor," one source said.

Perrotta got permission from EPA to operate a side business in 2013, during the Obama administration. As for "physically" clashing with an EPA official, as NYT alleged, that never happened, one source told TheDCNF.

"Things got so heated that a scuffle broke out during a meeting last summer of the agency's top security and administrative staff" where "Perrotta traded expletives with Mario Caraballo, who until recently served as the deputy

associate administrator of the homeland security office, and that the two men had to be physically separated," NYT reported.

The discussion between Caraballo and Perrotta got heated, but no physical altercation broke out, a source, who spoke with officials present at the meeting, said. Caraballo has since been removed from his position at EPA.

The Washington Examiner

https://www.washingtonexaminer.com/policy/energy/epas-scott-pruitt-says-burning-wood-is-renewable-energy

EPA's Scott Pruitt says burning wood is renewable energy

By Josh Siegel 4/23/18

The Environmental Protection Agency will begin treating energy created by burning trees as renewable, the same as wind and solar.

Biomass from burning wood to produce electricity will be considered carbon-neutral, the EPA announced Monday.

"Today's announcement grants America's foresters much-needed certainty and clarity with respect to the carbon neutrality of forest biomass," Administrator Scott Pruitt said Monday after meeting with forest industry representatives during a visit to a school in Georgia. "Managed forests improve air and water quality, while creating valuable jobs and thousands of products that improve our daily lives. This is environmental stewardship in action."

The recent spending bill passed by Congress had directed the EPA, Energy Department and Agriculture Department to "reflect the carbon-neutrality of forest bioenergy and recognize biomass as a renewable energy source."

Georgia and other large timber states had lobbied the EPA to consider biomass carbon-neutral when the states were facing limits on carbon emissions from power plants required by the Obama administration's Clean Power Plan, one of its key climate change initiatives. Pruitt has begun a process for repealing and replacing the Clean Power Plan, which was never implemented because of court challenges.

The EPA says it will consider biomass as carbon neutral when devising regulatory actions on energy production from power plants, such as a potentially revised, more modest Clean Power Plan.

"The use of biomass from managed forests can bolster domestic energy production, provide jobs to rural communities, and promote environmental stewardship by improving soil and water quality, reducing wildfire risk, and helping to ensure our forests continue to remove carbon from the atmosphere," the EPA said in a policy document explaining the move.

Despite Pruitt's action, EPA's science advisers haven't come to a consensus on whether biomass is carbon-neutral. Many scientists say that while biomass is a renewable resource, it is not carbon-neutral because burning wood for energy releases large amounts of carbon all at once, faster than what is absorbed by newly planted forests.

The EPA's policy statement contends that U.S. forests absorb more carbon from the air than burning wood releases. In 2015, forests offset about 11.2 percent of gross U.S. greenhouse gas emissions, the agency says.
The EPA said it will continue to enforce current air pollution regulations against power generation from biomass as it normally would, not treating it as carbon-neutral.

"This statement of agency policy is not a scientific determination and does not revise or amend any scientific determinations that EPA has previously made," the EPA document says. "Although this policy announcement does not itself alter sources' obligations with regard to [greenhouse gases] and CO2 in any particular regulatory program, the

agency is committed to addressing regulatory uncertainty about how it treats biogenic CO2 emissions in forthcoming actions under various EPA programs."

Reuters

https://www.reuters.com/article/us-usa-trump-pompeo/senate-committee-paves-way-for-pompeo-to-become-top-u-s-diplomat-idUSKBN1HU26X

Senate committee paves way for Pompeo to become top U.S. diplomat

By Patricia Zengerle, 4/23/18

A U.S. Senate committee approved the nomination of President Donald Trump's choice for secretary of state, Mike Pompeo, on Monday after a Republican senator who had been opposed threw his support behind the CIA director in the face of party pressure.

The Senate Foreign Relations Committee approved the nomination on a party-line vote, with all 11 Republicans backing him, nine Democrats opposed and one Democrat, Chris Coons, voting "present" because one Republican was at a funeral out of town.

Majority Leader Mitch McConnell said there were enough votes in the full Senate to confirm Pompeo this week. That would allow Pompeo to attend a NATO summit on Friday.

Pompeo became one of Trump's closest advisers during his 15 months as CIA director. He most recently has been deeply involved in preparations for Trump's summit with North Korean leader Kim Jong Un, including meeting with him three weeks ago.

While many Democrats consider Pompeo too hawkish and worry about past harsh statements on homosexuality and Islam, he has the support of at least three Democratic senators not on the committee who are running for re-election in states Trump won easily in 2016. That all but assures Pompeo will be confirmed.

"I do not believe Director Pompeo is someone who will always prioritize diplomacy over conflict, particularly in the context of the aggressive foreign policy voices growing around him," said Senator Robert Menendez, the top Democrat on the Foreign Relations Committee, citing Pompeo's past openness to regime change in North Korea and Iran.

No Republican besides Senator Rand Paul, who changed his vote on Monday, had announced opposition.

Paul's late switch meant Pompeo avoided the embarrassment of being the first nominee for secretary of state to fail to secure the committee's endorsement since it began considering them in the late 19th century.

That would have weakened Pompeo's reputation internationally and cast a cloud over Trump's push to overhaul his national security team after firing Secretary of State Rex Tillerson and replacing his national security adviser, H.R. McMaster, with John Bolton, also known as a hawk.

The White House and Republican Party had thrown their weight behind the nomination, with unceasing attacks on Democrats for opposing Trump's pick.

Paul had opposed Pompeo for weeks, holding a news conference to announce his opposition to him, as well as Trump's pick to replace him at the CIA, Deputy CIA Director Gina Haspel.

Haspel, whose Senate confirmation hearing is next month, also faces a tough confirmation fight. Democrats, and some Republicans, are concerned about her links to the CIA's past use of "harsh interrogation techniques," widely seen as torture.

Paul has repeatedly threatened opposition on policy positions staked out by Trump, before changing his mind at the last minute. Trump recently predicted he would come around again on Pompeo, calling Paul "a good man" who has "never let us down."

The Wall Street Journal

https://www.wsj.com/articles/van-strikes-pedestrians-in-toronto-1524508659

Driver Plows Van Into Toronto Pedestrians, Kills 10

By Vipal Monga and Jacquie McNish, 4/24/18

A man in his mid-20s plowed a rented van into people walking along a busy Toronto thoroughfare on Monday, killing 10 and injuring 15, and rattled one of North America's safest major cities.

Police said they arrested the driver, Alek Minassian, 25 years old, of Ontario. Authorities said Monday evening that they were still trying to determine his motive.

"We cannot come to any firm conclusions at this stage," said Canada's Public Safety Minister Ralph Goodale. But he said there was "no national security connection" to the attack, based on the evidence police have seen so far.

Toronto Chief of Police Mark Saunders said the attack "looks intentional."

The casualties occurred on one of the city's first warm spring days, along Toronto's main artery, Yonge Street. Mass killings have been much rarer in Canada than in the U.S. and Europe, and many said they were stunned.

"I'm at a loss for words. I can't believe that this has happened here. Things like this don't happen in Canada," said, Melissa Phillips, a nurse who was walking her dog Monday evening just steps away from where pedestrians were hit earlier.

The van jumped up onto the sidewalk around 1:30 p.m. Monday, hitting pedestrians as it headed south for about a mile. Police said 26 minutes lapsed between the first 911 call and the driver's arrest.

The area where the incident occurred is home to people of many ethnic backgrounds, said John Filion, a city councilor representing the area where the incident took place, but is predominantly home to immigrants from Iran, Iraq, Korea and elsewhere in Asia. Businesses in the area include banks, pensions, and government buildings, as well as retail shops.

"This is the kind of community where you rarely even encounter angry people, let alone something like this," said Mr. Filion. "It's a such a shock."

Toronto resident Reza Bahramian said he was out enjoying the nice weather when he saw a van "cut everything." He and some other neighbors started chasing after the van and yelling for it to stop. They saw about four people get hit.

He said he helped one woman who was struck, with CPR, for about half-hour before paramedics arrived. "Blood flowed on the sidewalk," he said, referring to the numerous injuries of people who were hit.

Another witness said in an interview he saw two responders trying to give CPR to two people lying in the street, but eventually the responders covered their bodies with tarps.

Witness Alex Shaker told CTV news that the van was moving at high speed along the sidewalk, striking everything in its way.

"People just with a stroller, with their baby, everything was flying down one by one. And he was going really fast," Mr. Shaker told the network.

The CP24 channel aired witnesses' videos that showed a black-clad man by the white van appearing to point something at a police officer before he drops it and is forced to the ground and handcuffed.

In Canada, mass-casualty events are relatively rare, but when they happen, they loom large: The country reeled after 14 women were killed by gunman at the Universite du Montreal's Ecole Polytechnique in 1989, and again in 2016 after four people were killed in a shooting in La Loche, Saskatchewan.

On Monday afternoon, over a mile of Yonge Street was cordoned off with yellow police tape and the area was swarming with cars from both the Toronto police and the Ontario provincial police. Police were interviewing passersby and asking if they had witnessed the incident.

"I ask everyone to await the results of the police investigation and avoid speculation," Toronto Mayor John Tory said.

"It was with great sadness that I heard about the tragic and senseless attack that took place in Toronto," Canadian Prime Minister Justin Trudeau said in a statement Monday night. He said officials were monitoring events closely, and would work with law-enforcement agencies across the country to ensure Canadians' security.

"As of now, #ISIS channels are not promoting the #Toronto vehicular attack, which contains staples of ISIS-inspired events," said Rita Katz, executive director at SITE Intel Group, which monitors jihadist activity online, on Twitter. ISIS channels typically share images and statements celebrating jihadist attacks on the encrypted messaging app Telegram, and the terror group has previously used vehicles in attacks on the streets of major cities such as London and New York.

Attacks involving either a van or truck striking pedestrians have also unfolded in New York City and some of Europe's urban centers.

Sayfullo Saipov, a 29-year-old Uzbek man, was charged with killing eight people and injuring 12 others last October after driving a rented truck down a crowded Manhattan bike path. Law-enforcement officials say the deadly drive had been planned for weeks and was done in the name of Islamic State. Mr. Saipov has pleaded not guilty to the charges.

In Europe over the past two years, 86 people were killed after a truck drove through crowds watching Bastille Day fireworks in Nice, France; 12 people died after a rejected Tunisian asylum seeker rammed a stolen truck into a busy Christmas market in Berlin; and in Barcelona, 13 died and over 100 were injured after a van mowed down pedestrians on city's most famous central thoroughfare, Las Ramblas.

Politico

https://www.politico.com/story/2018/04/23/ronny-jackson-veterans-affairs-nomination-hearing-546408

Ronny Jackson's VA nomination on the rocks

By Burgess Everett and Elana Schor, 4/23/18

Rear Adm. Ronny Jackson's nomination to be Veterans Affairs secretary may be in trouble, according to senators and aides in both parties.

Republicans are considering postponing his confirmation hearing this week as senators pore over potentially new negative information that committee members have received, according to GOP sources familiar with the matter. And Senate Democrats are digging into his record after being made aware of potential new problems with the nomination.

On Monday evening, committee Democrats huddled in the Capitol office of Sen. Jon Tester of Montana, the top committee Democrat, to plot strategy.

"There's a need for very exacting and close scrutiny and vetting," said Sen. Richard Blumenthal (D-Conn.) after the meeting. "And some questions that need to be answered. I'm not going to comment on any of the specifics, except to say we're going to be doing very close and careful scrutiny."

Republicans and Democrats alike have been talking over the weekend, and in person on Monday, about the potential for allegations to derail Jackson's nomination, senators said. But the nature of discussions now going on about the material is "conversational," said Sen. Thom Tillis (R-N.C.).

Tillis suggested that the Jackson confirmation hearing scheduled for Wednesday may be "pushed back pending a review of some of this stuff that, like I said, I've only heard on a conversational basis. I think that's where we'll spend our time this week."

Jackson is President Donald Trump's physician at the White House and is already facing major questions from Republicans over his lack of experience managing an agency as large as the VA. If he faces additional problems, his nomination could be derailed entirely.

"I would like to hear what he has to say about that. I'm not sure anybody can run the VA. It's so big," said Senate Majority Whip John Cornyn (R-Texas). "But I'm willing to give him the benefit of the doubt and listen to him and hear what he has in mind."

Axios was first to report that new information about Jackson's "professional conduct" was taken to Tester earlier this month.

Democrats declined to comment on the severity of the allegations that have been presented to the committee about Jackson.

"We're going to vet him. The Trump administration doesn't do a particularly good job," said Sen. Sherrod Brown (D-Ohio), another committee member. "That's all I'm going to say."

Spokespeople for the committee did not comment on whether Jackson's hearing has been postponed. But a Republican working on the nomination said it was unlikely the hearing would take place pending review of the new information, though that source cautioned that few have seen the documents rattling the nomination.

"You have to be concerned about any nomination" in a closely divided Senate, the Republican said.

Republicans currently hold just 51 seats and Sen. John McCain (R-Ariz.) is recovering from cancer treatment, leaving them no margin for error if Democrats unify to oppose the nomination.

Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 8/8/2018 9:40:09 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy: Trump wildfire tweets renew spending fight — Several API staffers head for exit — City goes to court over PFAS

By Kelsey Tamborrino | 08/08/2018 05:38 AM EDT

With help from Annie Snider and Eric Wolff

MAKING WAVES: In attempting to blame California's devastating wildfires on environmental laws and Democratic Gov. Jerry Brown, President Donald Trump may have upped the stakes for one of the many spending fights Congress will have to resolve this fall. No serious expert has endorsed the president's view that allowing some water to follow its natural course to the Pacific Ocean has complicated efforts to battle the blaze, and the president offered more measured comments late Tuesday night. But Trump's earlier series of tweets this week echoed arguments that agricultural interests have been making for years in long-running wars over how the thirsty state's scant supplies get used.

In Congress, California Republicans are trying to block the state from diverting less water to central and southern California farms and cities to preserve more for endangered fish, a plan that has won support from local green groups like the San Francisco chapter of the Sierra Club. The State Water Resources Control Board, whose members were appointed by Brown, is set to vote this month on the plan, and while agricultural interests and their allies are largely powerless to stop him in Sacramento they have had better luck in Washington. GOP Rep. Jeff Denham, whose Central California district would feel some of the deepest cuts under the state's plan, successfully attached an amendment to the House Interior-EPA appropriations bill to block federal funding related to implementation of the plan.

The policy rider faces an uphill battle as appropriators attempt to conference the House measure with the Senate's companion bill, H.R. 6147 (115), which contains no such language. Sen. Dianne Feinstein , the California Democrat who was key to a 2016 California drought deal, hasn't taken a public position on the issue, but has historically opposed legislative efforts to override California law. And the provision is sure to draw the ire of Northern California Democrats who have called Denham's provision a water grab.

Denham hosted Interior Secretary Ryan Zinke at the New Melones Dam late last month, and shortly thereafter the Interior Department formally weighed in with comments opposing the state's plan, saying it would "essentially elevate the Project's fish and wildlife purposes over the Project's irrigation and domestic purposes contrary to the prioritization scheme carefully established by Congress."

Don't forget: Zinke's No. 2, David Bernhardt, was previously the long-time lobbyist for the powerhouse Westlands Water District, battling to send more water to the district's massive farms.

That's not all: The president presented a subdued response to the California wildfires during remarks Tuesday night, where he told reporters he was "monitoring the situation very close," adding that his administration "is in constant contact with everything going out in the state and with the local authorities and with the state authorities." Trump applauded the firefighters and first responders and said his administration would hold meetings about the wildfires, "because there are reasons and there are things you can do to mitigate what's happening," per a pool report.

WELCOME TO WEDNESDAY! I'm your host, Kelsey Tamborrino. Bracewell's Frank Maisano is back with the win for knowing the island country of Tokelau is powered entirely by solar. For today: What is the name of the only one-word country whose first and last letter starts with the same consonant? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

SEE IT: Greenhouse gas emissions in 2017 hit levels never seen before, marking the warmest year on record in a non-El Niño year. Pro's DataPoint team dives into the numbers from the American Meteorological Society's latest "State of the Climate" report here. Want to add DataPoint to your Pro account? Learn more.

SEVERAL API STAFFERS HEAD FOR EXIT: The oil and gas industry's top trade association is losing several staffers after hiring a new chief executive , according to sources and social media posts. At least six officials at the American Petroleum Institute, including one of its top lobbyists, have left in recent months, an association spokesman confirmed to Pro's Ben Lefebvre and Marianne LeVine. API's former senior director of federal affairs, Khary Cauthen, is among those who've exited. Cauthen is now vice president of federal affairs at LNG supplier Cheniere, according to a Cheniere spokesperson. Additional senior officials at API are expected to leave in the coming weeks, sources said. Read more here.

DINNER GUESTS: Trump dined last night with business executives at the White House, including Continental Resources CEO Harold Hamm, according to a pool report. The dinner follows news this week that Hamm's company gave $25,000 in May to the legal defense fund created for Trump aides caught up in special counsel Robert Mueller's Russia investigation.

VOTERS SELECT MICHIGAN GOV. CONTENDERS: Come November, Democrat Gretchen Whitmer will face off against Republican state Attorney General Bill Schuette for Gov. Rick Snyder's term-limited seat amid the still-unresolved drinking water crisis in Flint and PFAS contamination elsewhere. Whitmer won the Democratic nomination Tuesday, turning back a primary challenge from progressive outsider candidate Abdul El-Sayed. Schuette, who leads the state's investigation into the Flint water crisis, also handily won his race. Read the recap of last night's primary winners and losers here.

Detroit-area voters faced power outages in at least 14 polling sites due to thunderstorms that struck the area Monday night, electric and gas company DTE Energy said Tuesday morning. The outages caused some poll workers to rely on flashlights and small generators to keep things running for voters, according to tweets sent by Rashida Tlaib, a Democratic candidate in the 13th District. Power was eventually restored to all 14 polling places by around 4:30 p.m., the electric company said.

CITY GOES TO COURT OVER PFAS: The toxic nonstick chemicals known as PFAS that have been popping up in water supplies across the country will be the focus of a lawsuit sought by the New York city of Newburgh. The city filed a federal lawsuit Monday over the contamination in its own water supply in the U.S. District Court of the Southern District of New York. The suit, the city said, seeks to require 23 defendants to clean up the watershed contamination and pay for the supply of clean water needed until the contamination is gone. The defendants range from those who have manufactured or sold the chemicals to those who owned and operated the Stewart Air National Guard Base and Stewart International Airport, where the contamination originated. The lawsuit alleges the defendants' use of the "aqueous film forming foam" resulted in the spread of 12 different types of PFAS chemicals within Washington Lake, the city's primary water supply.

EDF FILES 'SECRET SCIENCE' FOIA SUIT: The Environmental Defense Fund is suing EPA over its failure to release documents requested under the Freedom of Information Act pertaining to EPA's proposed "secret science" rule to ban the use of studies that don't publicly disclose all their data. Earthjustice is representing EDF in the lawsuit, which was filed Tuesday in the District Court for the Southern District of New York. The suit comes as a slate of experts at Harvard University also submitted a comment letter on the transparency rule Tuesday, ahead of the Aug. 16 comment deadline.

SECRET KEEPERS: The Trump administration won't have to turn over documents to a law firm related to its legal arguments for the decision to shrink national monuments, U.S. District Judge David Nye said Monday. The law firm, Advocates for the West, sued for 12 documents withheld from a public records request related to the move to downsize the Bears Ears and Grand-Staircase Escalante national monuments, The Associated Press reports . Instead the federal judge said the records are protected presidential communications. The Advocates for the West's lawyer told the AP the group hasn't decided whether to appeal the decision to the 9th U.S. Circuit Court of Appeals, but said the decision "shows how difficult it is to force sunlight on a government that flourishes in secrecy."

PRIVATE PRACTICE: Tesla CEO Elon Musk took to Twitter on Tuesday to say he's considering taking the electric car company private, jolting the company's stock. The tweet came after a Financial Times report that said Saudi Arabia's sovereign wealth fund has acquired an undisclosed stake of between 3 percent and 5 percent of Tesla's shares this year. In a vague tweet, Musk said he was considering taking the company private at $420 a share and already has secured funding.

Shortly after, the company posted an email Musk sent to staff explaining the potential move. Musk wrote that the intention is not to merge SpaceX and Tesla, but to instead emulate SpaceX's structure. Tesla shares were at about $342 in morning trading, Pro's Patrick Temple-West reports, but shortly after 2 p.m., trading was halted on the Nasdaq market at $367.09, up 7 percent from the start of the day. When trading resumed, Tesla shares bid higher to close at $379.44.

HAPPY BIRTHDAY, RFS: The Renewable Fuel Standard turns 13 today, making it old enough to have its bar or bat mitzvah. Ethanol producers are filled with naches over the program's expansion of domestic biofuel production, but they want presents. What they'd really like is a Clean Air Act waiver allowing year-round sales of E15, something Trump promised Iowans last week was "very close" (though acting EPA Administrator Andrew Wheeler was skeptical). "President Trump vowed to protect the engine of economic growth that has delivered for 13 years," Kyle Gilley, a spokesman for ethanol producer POET, said in a statement. "It is time to allow year-round E15 access for America's drivers."

BLM SEEKS COMMENT ON ALASKA PROSPECT: The Bureau of Land Management announced Tuesday it is taking comment until Sept. 6 on scoping for an environmental impact statement for the Willow oil and gas prospect within the Bear Tooth Unit of Alaska's National Petroleum Reserve. ConocoPhillips Alaska initiated discussions with the agency regarding the potential development of the prospect, BLM said, which is located within federal leases held by ConocoPhillips.

The proposed project includes the construction of a central processing facility, roadways, an infrastructure pad, drill pads with up to 50 wells on each, an airstrip, pipelines, and a gravel mine on the BLM-managed lands within the reserve, which makes up 23 million acres. Already environmentalists are targeting the project's potential adverse effects. "It will scar the land, harm wildlife and worsen climate change," said Kristen Monsell, senior attorney at the Center for Biological Diversity, in a statement.

POWER BACK FOR MOST: The Puerto Rico Electric Power Authority said this week that just 25 customers — or .002 percent — remain without electricity in the aftermath of Hurricane Maria, which first hit the island 11 months ago. That number is out of the close to 1.4 million customers who initially lost power from the hurricane.

CLIMATE SUMMIT IN SIGHTS: The Peoples Climate Movement will host a press conference in San Francisco today announcing its "Rise for Climate, Jobs and Justice" day of action on Sept. 8 — one week before the Global Climate Action Summit takes place in the city. Today's press conference will involve a street mural drawn in real-time by artists using materials from areas affected by the California wildfires.

MAIL CALL! NUCLEAR REACTIONS: Four senators are expressing concern over a draft proposed rule to decommission nuclear power plants. In a letter to Nuclear Regulatory Commission Chairwoman Kristine Svinicki, the lawmakers question the rule's changes to environmental considerations and financial protection requirements, among other issues, and write that the proposal would make it easier for nuclear power plants to be exempt from safety, security and emergency planning regulations. The letter was signed by Sens. Ed Markey , Bernie Sanders, Kirsten Gillibrand and Kamala Harris.

QUICK HITS

— "Trump tariffs could nix savings that car buyers might see from environmental rollbacks," McClatchy.

— "Official: Pennsylvania 'clearly behind' in pollution goals," The Associated Press.

— "Florida gutted water quality monitoring — as killer algae increased," Tampa Bay Times.

— "Welcome to the 'Man Camps' of West Texas," Bloomberg.

— "Oil pipeline inspection industry 'going wrong' as surveys fail to prevent spills," Climate Home News.

HAPPENING TODAY

8:30 a.m. — American Legislative Exchange Council annual meeting, New Orleans.

7 p.m. — The Politics and Prose Bookstore discussion on "We're Doomed. Now What?: Essays on War and Climate Change," 5015 Connecticut Avenue NW.

THAT'S ALL FOR ME!

To view online:
https://subscriber.politicopro.com/newsletters/morning-energy/2018/08/trump-wildfire-tweets-renew-spending-fight-309001

Stories from POLITICO Pro

Trump wildfire tweets spark bewilderment about California water Back

By Annie Snider, Carla Marinucci and Jeremy B. White | 08/06/2018 03:10 PM EDT

OAKLAND, Calif. — Californians are stunned at President Donald's Trump's latest tweets on the state's catastrophic wildfires — and his insistence that the state is burning because leaders are letting too much fresh water flow into the Pacific Ocean.

Trump tweeted Monday that California "Governor Jerry Brown must allow the Free Flow of the vast amounts of water coming from the North and foolishly being diverted into the Pacific Ocean. Can be used for fires, farming and everything else. Think of California with plenty of Water - Nice! Fast Federal govt. approvals."

That tweet — on the heels of a Sunday tweet that referenced California's "bad environmental laws" as a cause of the state's current raging wildfires — drew an immediate reaction from veteran California GOP strategist Rob Stutzman, who responded via Twitter: "This is nuts" and also "low water IQ." Stutzman has advised former Gov. Arnold Schwarzenegger and a host of national and state GOP candidates.

Trump's comments may be referencing an unrelated dispute between Brown's administration and California Republicans over how much of the state's water can be diverted to Southern California farms and cities and how much must be allowed to flow naturally to benefit endangered and threatened fish species.

Wildfires around California have killed nine people, but firefighters have not raised concerns about the available water supplies.

"The notion that somehow more water would be mitigating or better in fighting these fires is just mind-boggling," Stutzman told POLITICO on Monday. "I don't watch 'Fox & Friends,' but it would seem that someone has put the idea in his head. It doesn't even show an elementary understanding of water policy."

Fox & Friends had aired a segment about the California fires nearly five hours before Trump's Monday tweet but didn't discuss water issues as part of the segment.

Stutzman called the president's recent tweets on California fires and water policy "frightening," saying that "water has nothing to do with why these places are tinder boxes. It's very exasperating. ... It's a statement from the president that shows no understanding of hydrology."

He said he would advise Brown, a Democrat, to "not take the bait" and react to such uninformed views.

Indeed, Evan Westrup, the spokesman for Brown, told POLITICO that "this does not merit a response." But he also added via email: "It's a sad state of affairs when journalism is reduced to chasing the uninformed, unsupervised tweets of the president."

Some Democrats seized on the latest tweet. Rhys Williams, spokesman for Democratic gubernatorial candidate Gavin Newsom, tweeted: "Has anybody seen the baby's pacifier? He dropped it again."

In a purely political sense, Trump's tweets reflected his alignment with California Republicans who have long complained that the state unfairly prioritizes environmental uses for water over the state's sprawling agricultural industry. Putting "fish over farms" is a popular formulation that has been invoked by Trump allies from California's agricultural heartland, such as Reps. Devin Nunes and Kevin McCarthy.

"Forests should be managed properly and water should be allowed for farmers to grow food to feed people," Nunes wrote on Twitter in response to Trump's Sunday tweet, cheering the president "for bringing much needed attention to our flawed environmental policies!"

Trump has courted the Republican-leaning Farm Bureau heavily. California's water wars are a huge issue for the group. Trump addressed the annual Farm Bureau convention in January, becoming the first president in more than two decades to do so. He also raised the issue during a campaign stop in Fresno in 2016.

But experts who make their living studying California's water system reacted for the second consecutive day with a communal groan of exasperation. Peter Gleick of the Pacific Institute, one of the state's foremost experts on how the state manages its water, issued a tweet calling Trump's latest missive "nuts" after labeling the president's initial tweet "gobbledygook bullsh--."

In an email to POLITICO, Gleick noted that the water that flows from California's rivers into the ocean is what remains after cities and farms take their gulp — and that those flows are critical to shoring up ecosystems that, in some parts of the state, are teetering on the brink of collapse.

"Trump's tweets last night and today show a profound misunderstanding about water, fires, California environmental policy, and of course, climate change," Gleick said, adding that the "idea that somehow state water policies are leading to a shortage of water for fighting the fires is too stupid to rebut."

Stutzman said that even more potentially damaging is that the president's Twitter pronouncement is "even somewhat offensive, given that he's trying to make a point on the backs of these fires."

He noted the president on Twitter to date has shown "no sympathy" and expressed no personal concern for the 18 active and raging blazes around the state, which have to date been responsible for the destruction of more than 1,000 homes and billions of dollars in damage.

Ironically, Stutzman said, Trump has stepped on what could have been his own positive message to California — that the White House "has been quick to approve funds and the emergency declarations have come without any complications."

In July, the State Water Resources Control Board proposed major changes to the state's water allocations, preserving more for ailing fish populations. The changes are slated for a vote later this month. That announcement drew the ire of the state's agricultural groups, and state Republicans have turned to their allies in Congress, who have voted to block federal funding related to the allocation plan.

—Rebecca Morin contributed to this report.

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Back

API sees staff departures as new chief settles in Back

By Ben Lefebvre and Marianne LeVine | 08/07/2018 06:04 PM EDT

The American Petroleum Institute, the oil and gas industry's top trade association, is losing several staffers as its new chief executive settles in, according to sources and social media.

At least six API officials, including one of its top lobbyists, have left in recent months, an association spokesman confirmed. Additional senior officials are expected to leave in the coming weeks, according to two other sources familiar with the moves.

The departures come as Mike Sommers, a former chief of staff to then-House Speaker John Boehner, formally takes over API from former president and chief executive Jack Gerard. The industry is negotiating a host of issues with Congress and the White House, including a new offshore drilling plan, renewable fuel standards and steel tariffs.

API's former senior director of federal affairs Khary Cauthen has left to become vice president of federal affairs at LNG supplier Cheniere, according to a Cheniere spokesperson. Former API policy adviser Heidi Keller joined oil company BP as associate director in July, according to her LinkedIn account. Former API Senior Director for External Mobilization Deryck Spooner joined e-cigarette company JUUL Labs, according to a JUUL spokesman. Tyra Metoyer, who worked in API's Houston office, also decamped for JUUL in July, according to her LinkedIn profile.

Former Chief Financial Officer John Robertson left in June, according his LinkedIn page. Vice President of Global Industry Services Lisa Salley has also left the association, the API spokesperson confirmed. Their current activities are unknown.

The former API staffers did not immediately reply to requests for comment sent via social media.

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Business executives come back to Trump a year after Charlottesville Back

By Andrew Restuccia, Christopher Cadelago and Stephanie Murray | 08/07/2018 01:52 PM EDT

Business executives who distanced themselves from President Donald Trump a year ago in the wake of the deadly clashes in Charlottesville are back to finding common cause with the administration.

The guest list for a Tuesday night dinner at the president's Bedminster, New Jersey, country club includes 15 top executives of some of the country's largest companies. Of the guests, one publicly resigned from a Trump outside advisory council after the president's refusal to condemn white supremacists and neo-Nazis. And two others were reportedly close to stepping down from another advisory council before Trump abruptly dissolved the councils himself amid the backlash.

The dinner offers Trump a high-profile opportunity to show his critics that at least some in the business community have set aside their previous criticism of him.

"They feel that they can associate with [Trump] now because his policies have been such an amazing success," said Stephen Moore, an economic adviser to Trump during the 2016 presidential campaign.

Moore added that he was surprised the president, infamous for blocking those he believes have betrayed him, invited some executives back into the fold: "I don't understand why President Trump would invite anyone who ran for the high grass when there was the first signs of trouble."

One of the attendees slated to attend Tuesday's dinner, Johnson & Johnson CEO Alex Gorsky, released a statement last year criticizing Trump and announcing his decision to step down from Trump's advisory council on manufacturing.

Though Gorsky had initially insisted he would remain on the council, he changed his mind after Trump gave a press conference at Trump Tower in which he drew an equivalence between white supremacists and the protesters who rallied in Charlottesville against their racist views. "[T]he president's remarks yesterday — equating those who are motivated by race-based hate with those who stand up against hatred — were unacceptable," Gorsky said in the statement at the time. A Johnson & Johnson spokesperson did not immediately respond to a request for comment about why Gorsky decided to attend the Bedminster dinner.

At least two other attendees - PepsiCo CEO Indra Nooyi and Ernst & Young CEO Mark Weinberger - were reportedly weighing stepping down from a separate outside policy advisory group before the president announced that he was disbanding the councils.

Several Trump loyalists are also among the invitees to the dinner, including Continental Resources CEO Harold Hamm, Red Apple Group CEO John Catsimatidis and LeFrak CEO Richard LeFrak. Hamm, a vocal defender of Trump who has advised him on energy policy, donated $25,000 in May to a legal defense fund created for the benefit of White House aides.

Another attendee, FedEx CEO Fred Smith, also has close ties to Trump, even though he has criticized Trump's trade policies. Smith was among the business executives who attended a "Pledge to America's Workers" event last month at the White House, where he received repeated shoutouts from Trump.

Boeing CEO Dennis Muilenburg, who will also attend the dinner, has also courted Trump since he took office and regularly speaks with the president.

Though Nooyi was among the executives who were angry about Trump's remarks about Charlottesville, she also has close ties to the White House. Ivanka Trump, Trump's daughter and adviser, called Nooyi a "mentor" to her in a tweet Tuesday morning amid news that Nooyi would step down as Pepsi's CEO.

International Paper CEO Mark Sutton, another of the participants scheduled to attend Tuesday's dinner, condemned the violence that took place in Charlottesville in a statement at the time, but said he was remaining on Trump's manufacturing council.

Other attendees scheduled to attend Tuesday's dinner include Fiat Chrysler CEO Michael Manley, Mastercard CEO Ajaypal Banga, Boston Beer Company chairman Jim Koch, Honeywell CEO Darius Adamczyk, Newsmax CEO Christopher Ruddy and DocuSign chairman Keith Krach.

The dinner comes during Trump's working vacation in Bedminster, which White House spokesman Hogan Gidley said Monday is taking place while the "White House undergoes needed renovations to the Oval Office and other areas in the West Wing."

White House aides have organized several meetings with the president throughout the week.

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Trump allies back fund for aides' legal defense in Mueller probe Back

By Kyle Cheney and Lorraine Woellert | 08/06/2018 01:54 PM EDT

A legal defense fund created for the benefit of White House aides has largely relied on contributions from a handful of President Donald Trump's longtime friends and political allies in the first five months of its existence.

Phillip Ruffin, a billionaire casino mogul who has worked with Trump and accompanied him to Moscow for the Miss Universe Pageant in 2013, contributed $50,000 in April, the documents show. Continental Resources, an oil shale company whose CEO, Harold Hamm, has advised Trump on policy, kicked in $25,000 in May.

The largest donation in the most recent quarter came from Geoffrey Palmer, a Los Angeles developer who has been a large political contributor of Trump's. He contributed $100,000 in late June.

The contributions are being collected by the Patriot Legal Expense Fund Trust, a vehicle established by Trump allies in February and managed by former New York GOP Congresswoman Nan Hayworth. It is designed to pay for legal fees for Trump aides who are roped into special counsel Robert Mueller's investigation of Russian interference in the 2016 presidential election. Aides to former President Bill Clinton had a similar arrangement for congressional and special counsel probes during his administration.

The only money raised in the fund's first quarter, which ended March 31, came from a Virginia-based consulting firm called ProActive Communications, which chipped in $22,000. The firm is owned by Mark Serrano, a onetime consultant to Trump's presidential campaign who is also the spokesman for the legal defense fund.

In all, the fund raised about $200,000 from February to the end of June. It released its required first- and second-quarter paperwork Monday, after watchdog groups filed complaints with the IRS that the fund had missed a July filing deadline.

"I expected to see millions of dollars raised already," said Craig Holman, a lobbyist with the nonprofit Public Citizen, which filed a complaint with the IRS. "Clearly, there has not yet been a comprehensive effort to raise funds and support the legal costs of administration officials."

Clinton's first fund, established in 1994 to help pay for his personal legal defense amid inquiries into a land deal and a sexual harassment lawsuit, raised more than $608,000 in the first six months of its existence. The Trump defense fund was designed to pay for his aides' expenses, not for the president's own legal fees.

The Republican National Committee also has been paying legal fees for Trump family members and others under investigation for activities related to the 2016 campaign.

Hayworth did not respond to requests for comment. A lawyer for the fund referred questions to Serrano, who also did not respond.

The Trump team's fund does not accept donations from lobbyists, and anyone giving at least $200 over a calendar year must have their donations disclosed.

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Ocasio-Cortez and Sanders work to elect first Muslim governor Back

By Daniel Strauss | 08/04/2018 06:42 AM EDT

Bernie Sanders and Alexandria Ocasio-Cortez are joining forces to elect an underdog but potentially history-making candidate on the ballot in Michigan next week: Abdul El-Sayed, a 33-year-old physician who would be the nation's first Muslim governor.

Sanders is spending the final weekend of the race in the state, and Ocasio-Cortez was there last week to campaign with El-Sayed ahead of Tuesday's Democratic primary. He also has a constellation of hard-left groups in his corner, including MoveOn.org, Justice Democrats and Our Revolution, the offshoot of Sanders' failed presidential campaign.

After a July lull in primary season, the race in Michigan represents the first opportunity for insurgent liberals to shove Democrats leftward since Ocasio-Cortez's upset victory over Rep. Joe Crowley (D-N.Y.) six weeks ago. Tuesday is also the first real test of the burgeoning alliance between Sanders and Ocasio-Cortez, who have also campaigned for two congressional candidates on the ballot next week in Kansas.

El-Sayed, a first-time candidate who's trailed in public polls, has emerged as a threat to the front-runner, former state Sen. Gretchen Whitmer. Whitmer is a favorite of most elected Democrats as well as organized labor and women's groups such as EMILY's List, which backs Democratic women who support abortion rights.

Every public poll of the primary has shown Whitmer leading El-Sayed and entrepreneur Shri Thanedar, a self-funder who has blanketed the airwaves with television ads but hasn't caught fire. But with Sanders parachuting into Michigan this weekend, El-Sayed backers and Sanders allies see a parallel in recent history.

"Bernie was written off" going into the 2016 presidential primary in Michigan, said Democratic strategist Julian Mulvey, whose firm worked for Sanders on that campaign. "I think Nate Silver predicted that Hillary Clinton had a 99 percent chance of winning in Michigan, and Bernie was able to pull it out. So the best thing you can do is have Bernie going in there to help try to close."

Attorney General Bill Schuette is the favorite to win the Republican primary and has been endorsed by President Donald Trump. Schuette has worked to distance himself from unpopular term-limited Gov. Rick Snyder, a Republican. The state is seen as a prime pickup opportunity for Democrats.

According to a Democrat close to her campaign, Whitmer's most recent internal polling showed her with a 16-point lead in the primary. She has raised more money than El-Sayed, and she has more institutional support: In addition to local politicians, unions and EMILY's List, Whitmer was just endorsed by Sen. Kirsten Gillibrand (D-N.Y.).

But El-Sayed, a former executive director of the Detroit Health Department and a public-health expert, has built a significant support base by presenting himself as a Sanders-aligned progressive alternative to the more mainstream Whitmer. Some of the same outside groups that backed Sanders in 2016 are behind El-Sayed, as are Rep. Ro Khanna (D-Calif.) and grass-roots favorites like Ocasio-Cortez and activist Michael Moore. El-Sayed has also received donations from Ben Affleck and received praise from the hosts of the liberal podcast Pod Save America.

Sanders endorsed the candidate only this week, even though El-Sayed had embraced the Vermont senator and many of his core issues, like a $15 minimum wage, single-payer health care and tuition-free college for families making less than $150,000 a year. Sanders is planning to appear at two El-Sayed rallies on Sunday, in Detroit and Ypsilanti.

"Abdul has run a campaign — win or lose — that speaks explicitly to the policies that Bernie talked about during the 2016 campaign and continues to talk about in the Senate," said Ari Rabin-Havt, a senior adviser to Sanders. "Abdul lines up so perfectly on these values that the endorsement is a testament to running a campaign based on that."

El-Sayed hasn't shied from his religion in the campaign, even as he's had to swat away rumors that he's a George Soros plant sympathetic to the Muslim Brotherhood. He's happily described the immigrant story of his father moving to the United States from Egypt and spending time with his stepmother, whose family history in Michigan goes back to before the Civil War.

But foremost, El-Sayed and his liberal supporters are betting that campaigning on a Sanders-style platform isn't just good politics in a primary: They're trying to prove that a candidate can tout these issues and win one of the three states that Trump flipped in 2016.

"Michigan is ground zero for the debate over how you win back power from Trump and Trumpism," said Ben Wikler, the Washington director of MoveOn.org, which is backing El-Sayed. "And Abdul El-Sayed is the living avatar of the idea that to defeat Trump you don't move right."

In addition to El-Sayed, Sanders and Ocasio-Cortez are backing two congressional candidates on the ballot Tuesday in Kansas. The two New York natives traveled last month to the state to stump with two candidates: Brent Welder, a former Sanders campaign staffer running for a battleground seat in the Kansas City suburbs, and James Thompson, a repeat, liberal challenger for a more solidly Republican seat.

Welder is running in a crowded, six-candidate Democratic primary for the right to take on Rep. Kevin Yoder (R-Kan.) in a district Clinton narrowly won in 2016. But in a sign that Republicans see Welder's ties to Sanders as a liability, a conservative group began running last-minute ads on Friday that appear designed to boost Welder in the Democratic primary, meddling that Welder's opponents decried, blaming Yoder and the GOP.

Back in Michigan, while El-Sayed is rallying with Sanders, Whitmer will be campaigning with prominent Michigan Democratic politicians, including Detroit Mayor Mike Duggan and Rep. Brenda Lawrence.

Whitmer's surrogates and supporters remain bullish about her chances but also are familiar with their state's history of upsets in gubernatorial races. Democrat Jennifer Granholm wasn't the front-runner when she ran for governor in 2002.

"There's polling data, but primaries are tough to poll," said former Gov. Jim Blanchard, a Whitmer supporter, adding that he still expects Whitmer to win.

EMILY's List President Stephanie Schriock painted the primary as an ultimately constructive argument about how to win a general election fight in a battleground state. The differences between Whitmer and El-Sayed, Schriock said, pale in comparison to the contrast between either of them and Schuette, the front-runner in the Republican primary.

"The values all these Democrats share is the same," Schriock said. "What we're having is a very active debate on how to get there. I'll take that. That's what we're talking about there. You've got Schuette on the other side, who wants to tear it all down."

El-Sayed echoed that sentiment on Friday, promising that Democrats will come together, despite the intraparty battle playing out in the final days before the primary.

"Four days out, things can get heated," El-Sayed tweeted Friday. "I admire [Whitmer and] the vigorous debate we share. While I deeply disagree on health care [and] corporate money in politics, I admire her work [and] commitment to serve. We will walk in lockstep, whoever wins, to a blue wave in November."

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Chaotic day for Tesla shares amid Musk's tweeting Back

By Patrick Temple-West | 08/07/2018 05:59 PM EDT

Trading in shares of electric vehicle maker Tesla Inc. was halted today after founder and CEO Elon Musk said on Twitter that his company could be taken private.

Musk stunned the stock market with a message from his personal Twitter account: "Am considering taking Tesla private at $420. Funding secured."

Tesla shares were at about $342 in morning trading. Shortly after 2 p.m., trading was halted on the Nasdaq market at $367.09, up 7 percent from the start of the day. When trading resumed, Tesla shares bid higher to close at $379.44.

Tesla's shares have been attacked by short-sellers this year, and Musk has taunted them on Twitter before.

"It is possible that he wants to hurt short sellers of Tesla now [and] he has been very vocal against them recently." analysts for Morningstar wrote today.

WHAT'S NEXT: In a blog posting on Tesla's website, Musk said no final decision has been made and he did not elaborate about funding for the deal.

To view online click here.

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Message

From: E&E News [ealerts@eenews.net]
Sent: 5/24/2018 5:45:59 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: May 24 -- Greenwire is ready

Read today's Greenwire on the web

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Sent: 4/24/2018 12:02:08 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: April 24 -- Climatewire is ready

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CLIMATEWIRE

AN E&E NEWS PUBLICATION

CLIMATEWIRE — Tue., April 24, 2018

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1. POLITICS:

Lamar Smith visited the Galápagos, where warming is visible

Rep. Lamar Smith, the Texas Republican who chairs the House Science, Space and Technology Committee, led a bipartisan delegation to the Galápagos Islands earlier this month, where they were told that climate change is transforming the Ecuadorean nature preserve.

TOP STORIES

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Pruitt to unveil 'secret science' effort today — sources

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Ex-con's campaign has 1 donor (other than him)

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Pruitt says biomass plants are carbon neutral. Greens gape

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Skepticism drops when people are told of scientific consensus — study

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Trees might cool things down more than scientists thought

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More drought, deluges coming — study

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ADAPTATION

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'Climate gentrification' drives middle class inland

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Message

From: POLITICO Pro Energy [politicoemail@politicopro.com]
Sent: 4/24/2018 9:44:24 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: Morning Energy: Pruitt's watershed moment — 'Secret science' policy coming — Blankenship slipping

By Kelsey Tamborrino | 04/24/2018 05:42 AM EDT

With help from Emily Holden

PRUITT'S WATERSHED MOMENT: EPA Administrator Scott Pruitt is approaching his two separate House committee hearings this week with sagging support on the hill. The make-or-break moment is approaching as once-stalwart backers begin to express concern about the controversies that have swirled in recent weeks. Republican Sen. Jim Inhofe (Okla.) — perhaps Pruitt's staunchest ally in Congress — told Pro's Anthony Adragna he thinks it's "appropriate to have a hearing in so far as any accusation having to do with his office is concerned," and he cited a report in The New York Times detailing a sweetheart deal Pruitt received on an Oklahoma City home previously owned by a lobbyist.

Sen. Shelley Moore Capito (R-W.Va.) also thought Thursday's hearings before the House Energy and Commerce and Appropriations committees would prove pivotal for Pruitt's long-term future in the administration. "It's really important," Capito said. "He's going to have to answer some tough questions. I'm sure they'll be put to him by both sides and we'll see what his response is."

And Sen. John Boozman joined his two Republican colleagues in supporting hearings by the Environment and Public Works Committee. Meanwhile, sources told Bloomberg that administration officials privately cautioned lawmakers and other conservative allies to pump the brakes on their defenses of Pruitt.

Publicly, however, the White House stands firm in its commitment to Pruitt. Press secretary Sarah Huckabee Sanders told reporters the administration is "continuing to review a number of the reports" about Pruitt, but noted the EPA chief "has done a good job of implementing the president's policies," particularly on deregulation and energy dominance. White House legislative affairs director Marc Short was more direct earlier Monday: "I think Scott Pruitt is doing a great job and we look forward to keeping him there as EPA administrator," he told MSNBC.

More to come? Earlier Monday, five senior congressional Democrats asked House Oversight Chairman Trey Gowdy to obtain further documents and hold hearings after obtaining new records they say raise "troubling" new questions about Pruitt's security expenditures. EPW ranking member Tom Carper told Anthony he had a good conversation with Gowdy regarding Pruitt, but said there was no formal bipartisan agreement to work together on an investigation. "I just gave him plenty of encouragement that he's doing the right thing," Carper said. Read more.

WELCOME TO TUESDAY! I'm your host Kelsey Tamborrino. Congrats to the Nuclear Energy Institute's Robert Powers, who was first to correctly guess Mary Walker was the first woman to receive the Medal of Honor. For today: Who is the last former senator to appear on a U.S. postage stamp? Send your tips, energy gossip and comments to ktamborrino@politico.com, or follow us on Twitter @kelseytam, @Morning_Energy and @POLITICOPro.

POLITICO's Ben White is bringing Morning Money to the Milken Institute Global Conference to provide coverage of the day's events and evening happenings. The newsletter will run April 29 - May 2. **Sign up to keep up with your daily conference coverage.**

BLINDED WITH SCIENCE: EPA's Pruitt is expected to unveil his new science policy that restricts the agency from relying on research that doesn't make public all its available data, a source briefed on the announcement tells Pro's Emily Holden. The proposed rule, which the agency submitted to the White House for review last week, will mirror legislation from House Science Chairman Lamar Smith (R-Texas).

Pruitt argues the change will bolster transparency, but scientists and health advocates say it is an effort to constrain rulemaking. The rollout has been delayed as agency officials tried to determine how to treat industry research used to evaluate the safety of pesticides and toxic chemicals, as Pro's Annie Snider reported last week. While academic studies often can't disclose data that includes personal health records, corporations can't reveal proprietary information either.

SCIENTISTS REACT: Close to 1,000 scientists signed onto a letter to Pruitt Monday, calling on the administrator to reverse course on his plans to revise how the agency considers outside research. "EPA can only adequately protect our air and water and keep us safe from harmful chemicals if it takes full advantage of the wealth of scientific research that is available to the agency," write the scientists, including some former EPA career staffers. Read it here.

A BLANK SLIP: GOP establishment attacks on former coal baron Don Blankenship seem to be taking hold, POLITICO's Alex Isenstadt reports via new polling. With the West Virginia Senate primary a mere two weeks away, a poll out Monday found Blankenship falling behind his more mainstream rivals, GOP Rep. Evan Jenkins and state Attorney General Patrick Morrisey. The poll found Morrisey leading with 24 percent, followed by Jenkins with 20 percent, and Blankenship trailing with 12 percent.

National Republicans have scrambled to intervene in the race, concerned that a Blankenship primary win would destroy their prospects of defeating Democratic Sen. Joe Manchin in November. Blankenship, who spent a year in jail following the deadly 2010 explosion at his Upper Big Branch Mine, has poured nearly $2 million of his own money into a slash-and-burn style campaign savaging Jenkins and Morrisey as pawns of the establishment, Alex writes. Blankenship has also used the Senate run as a path to clear his name. So far, much of his campaign has been geared toward portraying himself as the casualty of the Obama-era Justice Department, which he says was bent on locking him up.

The new survey, which was conducted April 17-April 19 and has a margin of error of 4.9 percentage points, precedes a GOP debate today, and another that will be hosted by Fox News next week for a nationally televised audience. Read more.

SPECIAL ELECTION TODAY: Arizona voters will decide today who will pick up the seat left vacant by Rep. Trent Franks' departure in the state's 8th District. While neither candidate highlights specific environmental issues on her campaign website, Republican Debbie Lesko and Democrat Hiral Tipirneni have markedly different takes on climate change. Tipirneni's site says she believes "climate change is real and that we need to reduce carbon emissions." Meanwhile, Lesko said during a debate earlier this year that "certainly not the majority" of climate change is human-caused. "I think it just goes through cycles and it has to do a lot with the sun. So no, I'm not a global warming proponent," she said.

RULES TO MEET ON COLUMBIA RIVER BILL: The House Rules Committee will meet at 5 p.m. to formulate a rule on H.R. 3144 (115), which would void the environmental impact statement process for altering the hydropower system along the Columbia and Snake rivers. Earlier this month , the 9th Circuit Court of Appeals sided with the state of Oregon, the Nez Perce tribe and conservation groups, ruling that dam operations on the Columbia and Snake rivers must forgo hydropower production during key times of the year to protect

endangered salmon. An environmental impact statement for the system has been the subject of congressional fights, with Rep. Cathy McMorris Rodgers filing the legislation to void that process.

COAL ASH HEARING TODAY: EPA holds a public hearing today on its proposal to roll back the Obama-era regulation for the cleanup and disposal of coal ash. The hearing will begin at 9 a.m. in Arlington, Va., where there will be three sessions: 9 a.m. until noon; another beginning at 1 p.m. and ending at 4 p.m.; and a final session beginning at 5 p.m. and ending at 8 p.m.

PROMISES, PROMISES: Senate spending leaders vowed to restore chamber-wide debate on amendments to individual appropriations bills, Pro's Sarah Ferris and Kaitlyn Burton report. It's a risky move, ME readers may recall, considering how Democrats blocked a largely noncontroversial Energy and Water bill in 2016 because of a proposed amendment on Iran, and in 2015, House Republicans' Interior-Environment bill was tripped up by an unrelated rider on the Confederate flag. But Senate Appropriations Chairman Richard Shelby and his Democratic counterpart Patrick Leahy told committee members in a closed-door meeting Monday that leadership has agreed to allow amendments on the Senate floor for every individual spending bill. And the two have met with Majority Leader Mitch McConnell and Minority Leader Chuck Schumer in recent days about opening up the floor for debate on spending bills.

JUDGE: ENBRIDGE PIPELINE SHOULD STICK TO PLAN : An administrative law judge recommended on Monday that Minnesota regulators approve Enbridge Energy's proposal for replacing its Line 3 crude oil pipeline. But the court stipulated that the pipeline should follow the existing route, not the company's preferred route, which would carry Canadian tar sands crude from Alberta across areas in the Mississippi River, the Associated Press reports. Administrative Law Judge Ann O'Reilly's recommendation to the Public Utilities Commission sets up further disputes, "because the existing line crosses two Ojibwe reservations where tribal governments have made it clear that they won't consent and want the old line removed altogether." Read more.

A METHANE TO THE MADNESS: The comment period on the Bureau of Land Management's proposal to reverse the Methane Waste Prevention Rule ended Monday, drawing thousands of far-reaching comments. The left-leaning Center for Western Priorities analyzed a random sample of 2,000 comments, it said, finding 99.8 percent of them were opposed to the proposal. The Independent Petroleum Association of America and Western Energy Alliance meanwhile submitted joint comments applauding the move. "We were pleased to see workable changes are being considered to the rule that more accurately represent the scope of power and authority given to the BLM for regulating this type of activity," IPAA's Dan Naatz said in a statement. And, E2, an affiliate of the Natural Resources Defense Council, sent a letter to Interior Secretary Ryan Zinke on Monday, expressing its opposition to BLM's proposal. Close to 400 businesses signed onto that letter, which calls BLM's proposal "a net negative for the American public." Read it here.

MAIL CALL! IN HONOR OF NATIONAL PARKS WEEK: League of Conservation Voters organized 122 groups — including the American Civil Liberties Union and the Human Rights Campaign — in a letter to members of Congress opposing the administration's moves on public lands. National monuments "have helped make our public lands more inclusive," the letter states, before calling on lawmakers to "reject any legislation that would limit the president's authority under the Antiquities Act or codify any unlawful rollbacks of existing national monuments." Read it here.

FOR YOUR RADAR: The House will vote to overhaul the 1988 Stafford Act this week, Pro's Budget & Appropriations team reports. The three-decade-old bill is the main piece of legislation overseeing federal disaster-relief efforts, with proposed tweaks that include new incentives to build "smarter and stronger to better withstand disasters in the future," according to GOP Majority Leader Kevin McCarthy's office. That could equate to big changes on how states spend disaster relief money.

ICYMI: ZINKE DRAWS OLIVER'S IRE: The Interior secretary got the full treatment from HBO host John Oliver on "Last Week Tonight" on Sunday. Oliver hit Zinke for referring to himself as a geologist and said he

"has a real flair for creative license." Of course, Zinke is not the first to draw scrutiny from the HBO host. A judge recently dismissed a defamation lawsuit brought by coal magnate Bob Murray against Oliver, who referred to Murray as a "geriatric Dr. Evil." Watch the Zinke video here.

STATE NEWS — CUOMO INTRODUCES PLASTIC BAG BILL: New York Gov. Andrew Cuomo introduced a bill Monday to ban the use of plastic bags throughout the state, Pro New York's Danielle Muoio reports. The legislation — a long-sought promise from Cuomo — would give the state Department of Environmental Conservation jurisdiction over all matters concerning plastic bags and recycling, but comes with caveats that left some environmental advocates saying it isn't far-reaching enough. Read more.

QUICK HITS

— Trump administration official says it's a "top priority" to improve American weather forecasting model, The Washington Post.

— Sources: Arrested Chevron workers could face treason charge in Venezuela, Reuters.

— Trump likes coal, but that doesn't mean he's hostile to wind, Associated Press.

— Halliburton writes off investment in crisis-hit Venezuela, Financial Times.

— U.S. coal bailout review slows after Trump faces pushback, Bloomberg.

HAPPENING TODAY

8:00 a.m. — American Fuel & Petrochemical Manufacturers holds security conference, New Orleans

10:00 a.m. — Senate Energy and Natural Resources Committee hearing on the president's proposed budget request for FY 2019 for the Forest Service, 366 Dirksen

10:00 a.m. — Senate Foreign Relations Committee hearing on nominations, including Jackie Wolcott to be representative to the International Atomic Energy Agency, 419 Dirksen

10:00 a.m. — The Bipartisan Policy Center webcast on "Can America's Infrastructure Withstand the Next Natural Disasters? Lessons Learned from Previous Disasters."

3:00 p.m. — Woodrow Wilson Center book launch discussion on "Can We Price Carbon?" 1300 Pennsylvania Ave NW

5:00 p.m. — Johns Hopkins University's Energy, Resources and Environment presentation on "Cities as Innovation Centers: Investing in Resilient Infrastructure," 1619 Massachusetts Avenue NW

THAT'S ALL FOR ME!

To view online:
https://www.politicopro.com/newsletters/morning-energy/2018/04/pruitts-watershed-moment-180878

Stories from POLITICO Pro

White House reiterates support for Pruitt Back

By Anthony Adragna | 04/23/2018 02:30 PM EDT

The White House says it is still standing behind EPA's Scott Pruitt, voicing support for the embattled administrator two days after it was revealed that a Washington lobbyist whose wife rented a condo to him personally lobbied Pruitt despite weeks of denying they had held any meetings.

"We're reviewing some of those allegations, however Administrator Pruitt has done a good job of implementing the president's policies, particularly on deregulation," press secretary Sarah Huckabee Sanders said at the White House briefing.

She added the administration continues its look into Pruitt's conduct, including his lavish spending, first-class travel arrangements, pay raises for political appointees and use of security personnel. White House budget director Mick Mulvaney told a congressional subcommittee last week he'd investigate the EPA chief's spending $43,000 on a privacy booth for his office.

Pruitt is scheduled to testify at two House hearings on Thursday.

What's next: Sanders said the White House is "monitoring" additional reports about Pruitt.

To view online click here.

Back

White House stands behind Pruitt despite new lobbying disclosure Back

By Anthony Adragna | 04/23/2018 01:54 PM EDT

The White House said Monday it still stands behind EPA Administrator Scott Pruitt, praising him for enacting President Donald Trump's environmental and energy policies even as it looked into reports of ethical lapses.

It was the first statement from the White House since POLITICO first reported that despite his denials, Pruitt had met with a lobbyist whose wife rented the Environmental Protection Agency chief his $50-per-night condo. A disclosure form filled late Friday said J. Steven Hart had lobbied the EPA, although both the agency and the lobbyist contend the meeting, held last July, did not constitute formal lobbying.

"We're reviewing some of those allegations. H however, Administrator Pruitt has done a good job of implementing the president's policies, particularly on deregulation," press secretary Sarah Huckabee Sanders said at the White House briefing.

The White House has been looking into Pruitt's lavish spending on first-class travel arrangements, pay raises for political appointees and use of security personnel. Budget director Mick Mulvaney told a congressional subcommittee last week he'd investigate the EPA chief's spending of $43,000 on a privacy booth for his office.

That's on top of several ongoing probes by the EPA's own watchdog and three by congressional committees, including the House Committee on Oversight and Government Reform.

Pruitt is scheduled to testify at two House hearings on Thursday.

Sanders' comments come as five senior congressional Democrats asked House Oversight Chairman Trey Gowdy (R-S.C.) to seek new documents and hold hearings regarding "troubling" new questions about Pruitt's security expenditures.

According to nonpublic documents cited in the Democrats' letter, Pruitt's office was not cleared for classified communications as of March 2017. EPA previously said Pruitt's need to handle such information justified the installation of the privacy booth. The Government Accountability Office concluded last week the agency violated federal law by not informing Congress of the purchase.

The letter also alleges that a security sweep of Pruitt's office — the contract for which went to a business partner of Pruitt's security chief, Pasquale "Nino" Perrotta — went outside federal contracting norms without proper pre-approval.

"Given the latest developments and these new documents, we believe these and related matters are ripe for additional document requests to EPA and that Administrator Pruitt should testify about all of these matters immediately," the lawmakers wrote. Sens. Tom Carper of Delaware and Sheldon Whitehouse of Rhode Island and Reps. Elijah Cummings of Maryland and Gerry Connolly and Don Beyer, both of Virginia, signed the letter.

To view online click here.

Back

Pruitt support in Senate erodes as GOP lawmakers seek hearings Back

By Anthony Adragna | 04/23/2018 08:32 PM EDT

Scott Pruitt's wall of GOP support developed some new cracks on Monday, with three key Senate defenders calling for hearings into the embattled EPA administrator's recent controversies.

The three, including staunch Pruitt ally Sen. Jim Inhofe (R-Okla), all said they supported hearings by the Senate Environment and Public Works Committee to look into the former Oklahoma attorney general's actions.

"I think that a couple of us on the committee think it's appropriate to have a hearing in so far as any accusation having to do with his office is concerned," Inhofe told POLITICO.

Inhofe said he was troubled by a report over the weekend in The New York Times detailing a sweetheart deal Pruitt received on an Oklahoma City home previously owned by a lobbyist while serving in a state government. The Oklahoma Republican declined to discuss which allegations he found disturbing, but said "there are some things in there that I'd like to check out and see."

Joining his call for a Senate hearing were two other senior GOP members of the EPW panel, Sens. Shelley Moore Capito (W.Va.) and John Boozman (Ark.).

"Most people have concerns about some of the allegations," Boozman said. "At some point he'll be before the committee and we'll dig deeper and see exactly what's going on."

EPW Chairman John Barrasso (R-Wyo.) told reporters he expected Pruitt would come to testify at some point, but he stopped short of providing a specific timeframe or stating his intention to call a hearing.

To date, four House Republicans have called on Pruitt to resign, along with scores of elected Democrats. And Sen. Susan Collins (R-Maine), has said Pruitt was "the wrong person" to lead the agency based on his policies.

Pruitt has drawn criticism about his ethics and lavish spending in recent months. Three Congressional committees, the White House and EPA's inspector general are all probing his behavior, ranging from his security expenses, high pay raises for aides, first-class travel and meetings with a coal group.

The House Oversight Committee has requested interviews with five senior agency aides and the White House said it would formally investigate Pruitt's expenses after the Government Accountability Office last week found EPA broke the law by failing to notify Congress about a $43,000 privacy booth Pruitt had built in his office.

Pruitt will go to the Hill on Thursday to testify before a House Energy and Commerce subcommittee in the morning and at a House Appropriations subpanel in the afternoon. Those appearances will mark his first time before Congress since the recent allegations broke.

Both Inhofe and Capito said they thought those House hearings would prove pivotal for Pruitt's long-term future in the administration.

"It's really important," Capito said. "He's going to have to answer some tough questions. I'm sure they'll be put to him by both sides and we'll see what his response is."

Meanwhile, EPW ranking member Tom Carper (D-Del.) said he had a good conversation with House Oversight Chairman Trey Gowdy (R-S.C.) regarding Pruitt, but he said there was no formal bipartisan agreement to work together on an investigation.

"I just gave him plenty of encouragement that he's doing the right thing," he said.

But the mounting public criticism from Republicans suggests GOP lawmakers' patience in defending the EPA chief's behavior is waning.

"Some of the things that he's done and that he's been alleged to do are just indefensible," Sen. John Kennedy (R-La.) said. "You just can't put lipstick on those pigs. You can't."

To view online click here.

Back

EPA emails show industry worries slowed new science policy Back

By Annie Snider | 04/19/2018 05:01 PM EDT

EPA's rollout of a controversial new transparency policy that would severely restrict the scientific research the agency can rely on when drafting new regulations has been slowed down by political officials' fears that it could have major unintended consequences for chemical makers, according to newly released EPA documents.

The issue of scientific transparency has been high on the agenda of House Science Chairman Lamar Smith (R-Texas), who has found strong support from EPA Administrator Scott Pruitt — much to the consternation of public health advocates and green groups, who view the effort as backdoor attack on the agency's ability to enact environmental regulations.

Since Pruitt announced plans for the new policy last month, researchers and public health proponents have raised alarms that it could restrict the agency's ability to consider a broad swath of data about the effects of pollution on human health. But documents released under the Freedom of Information Act show that top EPA officials are more worried the new restrictions would prevent the agency from considering industry studies that frequently support their efforts to justify less stringent regulations.

Emails between EPA officials obtained by the Union of Concerned Scientists show that Nancy Beck, the top political official in the agency's chemicals office who came to the agency after serving as a key expert for the chemical industry's lead lobbying group, voiced major concerns after she received a draft of the not-yet-released policy on Jan. 31.

The new scientific transparency directive is expected to require that the raw data for all studies EPA relies on be publicly available, and that the studies be peer-reviewed. But Beck said these requirements would exclude a great deal of industry data about pesticides and toxic chemicals that her office considers when determining whether a substance is safe or must be restricted.

It costs companies "millions of dollars to do these studies," Beck wrote in an email to Richard Yamada, the political official in EPA's office of research and development who is spearheading work on the new scientific policy and is also a former staffer for the House Science Committee chairman.

"These data will be extremely valuable, extremely high quality, and NOT published," Beck wrote. "The directive needs to be revised."

Moreover, much of this data, Beck noted, is considered proprietary by companies. It is dubbed confidential business information, and even though EPA can consider it as part of its regulatory review, the data cannot legally be made public.

Yamada replied to thank Beck for the heads up. "Yes, thanks this is helpful - didn't know about the intricacies of CBI," he wrote. "We will need to thread this one real tight!"

The term "confidential business information" primarily applies to industry information. That data is separate from the personal medical information that public health researchers worry could block consideration of their work.

Yogin Kothari, a lobbyist for the Union of Concerned Scientists, said the emails show the Trump administration's EPA has been "trying to stack the deck in favor of the industries they're supposed to be regulating."

"They want to potentially create exemptions for industry, but if you look at this entire set of documents ... you will see that there's not a single consideration for the impacts on public health data, on long-term health studies, on studies that EPA does after public health disasters like the BP oil spill," he said.

EPA spokeswoman Liz Bowman emphasized the policy is not yet finalized.

"These discussions are part of the deliberative process; the policy is still being developed. It's important to understand; however, that any standards for protecting [confidential business information] would be the same for all stakeholders," she said in a statement.

The emails indicate Pruitt wanted the new science policy rolled out at the end of February, and teased his plans in an interview with conservative outlet The Daily Caller in mid-March. But the agency has yet to finalize the policy.

The transparency directive has its origins in legislation introduced by Smith during the Obama administration, that had the backing of a number of industry groups, including the American Chemistry Council. The House Science Committee chairman frequently charged that the Obama EPA used "secret science" to justify "costly new regulations."

Although versions of the measure were approved by the House multiple times, the Senate never took it up. CBO estimated that one version of Smith's legislation would cost EPA $250 million a year, at least in the initial years, and a leaked staff response to questions from the budget office said a later version would be even more costly, would endanger confidential medical and business information, and "would prevent EPA from using the best available science."

But Smith found an ally in Pruitt. The emails indicate that Smith met with Pruitt in early January and show that Pruitt's staff quickly began working on a directive to "internally implement" the legislation.

Industry's backing for the new scientific approach began to waiver under the Trump administration, though. When a top American Chemistry Council scientist testified before Smith's committee in February 2017, she emphasized the need to protect industry information if the transparency initiative moved forward.

"One of the things that we do need to take into consideration as making that data publicly available is that there are adequate protections for confidential business information to ensure that we keep innovation and competitiveness available for the marketplace," Kimberly White told the committee.

Industry has historically claimed that a wide range of information about chemicals, ranging from the processes by which they are produced, to the locations of manufacturing plants, to their very identities, must be kept confidential in order to keep competitors from learning trade secrets. Environmental and public health advocates argue that industry claims this exemption in many cases where it's not necessary and that it often keeps important health and safety information from public view.

The issue was a key point of debate when Congress considered a major overhaul of the nation's primary chemical safety law passed 2016 and has reemerged as Pruitt's EPA sets about implementing the law.

Asked for comment on EPA's new effort to implement the scientific transparency approach internally, American Chemistry Council spokesman Scott Openshaw said the group looks forward to reviewing the directive once it's finalized.

"It is critical that any final directive properly protect confidential business information and competitive intelligence," he said in a statement.

The internal emails show that EPA political staff were particularly attuned to this concern. In a Feb. 23 email to colleagues, Beck forwarded language from a 2005 White House document that laid out narrow exemptions from its requirement that all "important scientific information" disseminated by the federal government go through peer review.

"[Y]ou may need to tweak but hopefully there is something helpful here that can be borrowed/adopted," she wrote.

Richard Denison, lead senior scientist for the Environmental Defense Fund, said that EPA's access to industry data is indeed important to its ability to review the safety of new chemicals and pesticides, but said the internal EPA communications show that Pruitt's EPA wants to "have their cake and eat it too" with the new directive.

"They're trying to force peer review studies done by academic scientists to disclose every last detail, while at the same time allowing industry studies to be kept private or aspects of those to still be kept private," he said.

He pointed out that the concerns Beck raised about the burden the new policy would place on industry are the very same ones that the CBO report said the policy would place on EPA.

To view online click here.

Back

Poll: Coal baron Blankenship fading in W.Va. Senate primary Back

By Alex Isenstadt | 04/23/2018 07:26 PM EDT

WHEELING, W.Va. — A new poll out Monday evening shows recently imprisoned coal baron and Senate hopeful Don Blankenship fading in the Republican primary, amid an avalanche of establishment attacks aimed at stopping him from winning the nomination.

With the primary two weeks away, the survey shows Blankenship, who spent a year in jail following the deadly 2010 explosion at his Upper Big Branch Mine, falling far behind his more mainstream rivals, GOP Rep. Evan Jenkins and state Attorney General Patrick Morrisey. The poll found Morrisey leading with 24 percent, followed by Jenkins with 20 percent, and Blankenship trailing with 12 percent. Thirty-nine percent were undecided.

The survey, which was conducted April 17-19 and has a margin of error of 4.9 percentage points, came as Blankenship squared off against his rivals in a 90-minute debate held at Wheeling Jesuit University. The candidates spent much of the evening aligning themselves with President Donald Trump, and beating up on Democratic Sen. Joe Manchin.

They will also meet on Tuesday, and again next week for a nationally televised debate hosted by Fox News.

The survey of 411 primary voters was commissioned by GOPAC, an organization that promotes state Republican legislators, and was conducted by National Research Inc., a polling firm that worked on Trump's 2016 campaign. Neither has taken sides in the primary.

National Republicans have scrambled to intervene in the contest, fearing that a Blankenship primary win would destroy their prospects of unseating Manchin. The 68-year-old former coal executive has spent nearly $2 million of his own to fund a slash-and-burn style campaign savaging Jenkins and Morrisey as establishment pawns.

He has also sought to clear his name. Much of Blankenship's campaign has been geared toward portraying himself as the casualty of an Obama Justice Department bent on locking him up.

Fearful that Blankenship was gaining traction, Mountain Families PAC, a super PAC overseen by strategists close to Senate Majority Leader Mitch McConnell's political operation, swung back — airing around $700,000 worth of TV ads in recent days accusing Blankenship of contaminating drinking water.

The effort to defeat Blankenship has gone further. Earlier this month, Trump flew to West Virginia to hold an event aimed at selling his tax reform legislation. The president was seated next to Jenkins and Morrisey, a clear attempt to promote their candidacies over Blankenship, who was not in attendance.

For national Republicans, the move was not without risk. Last year, a McConnell-aligned super PAC spent millions to stop Alabama Senate candidate Roy Moore from winning the nomination, only to see it backfire. Moore used it to cast himself as the victim of the establishment, and went on to win the primary before losing the general election in a stunning upset.

Blankenship is taking a similar approach. With the contest hurtling into the final stretch, he has begun airing commercials calling McConnell a "swamp creature."

And during a news conference on Monday morning, Blankenship pledged not to support McConnell as Senate GOP leader if he's elected.

"He needs to understand that if I'm there I will not vote for him for majority leader, and so the rest of the senators should understand that they should not put him up if they need my vote," he told reporters.

The candidates largely avoided attacking each other at Monday's debate, perhaps because three lesser-known contenders were also included onstage, a setup that limited the amount of speaking time.

Blankenship used the debate to further his argument against the establishment. He called the 2010 mine explosion "heart-wrenching," and called it "one of the worst days of my life."

But he blamed the disaster on the government, saying it had taken steps to limit the amount of airflow available to the miners.

During his closing remarks, Blankenship referred to Washington as the "district of corruption," and argued that politicians there often tried to make themselves look like they were fighting over ideals when they were merely posturing.

"When I go to D.C.," he said, "it won't be a fake fight, it will be a real fight."

With candidates and outside groups crowding the TV airwaves, much of the firepower is being directed at Jenkins, a second-term congressman who in 2014 defeated longtime Democratic Rep. Nick Rahall. All told, around $1.2 million is expected to be spent against Jenkins, according to a media buyer.

Among those spending heavily against Jenkins is Duty and Country, an outside Democratic group with offices in Washington. To date the group has spent around $380,000 on TV, the vast majority of it against Jenkins.

At Monday's debate, Jenkins argued that Democrats were trying to "meddle" in the primary. He said their attacks on him was proof that the opposing party viewed him as the biggest threat to Manchin.

The Democratic effort, he added, was unprecedented in West Virginia politics.

"They're scared to death of Evan Jenkins on the ballot in November because they know Evan Jenkins can beat Joe Manchin," the congressman said.

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Back

Court chooses salmon over hydropower in Columbia River fight Back

By Annie Snider | 04/02/2018 02:34 PM EDT

The 9th Circuit Court of Appeals has sided with the state of Oregon, the Nez Perce tribe and nearly a dozen conservation groups, ruling that hotly contested dam operations on the Columbia and Snake Rivers must forgo hydropower production during key times of the year in order to protect endangered salmon.

The three-judge panel upheld a lower court's decision requiring that water be spilled over the top of dams along the Columbia River System, including the powerhouse Grand Coulee dam, the largest power station in the U.S., during periods when young salmon and steelhead migrate to the ocean. The hydropower turbines pose a threat to the fish.

The Justice Department, representing the National Marine Fisheries Service, Army Corps of Engineers and Bureau of Reclamation, had argued that requiring such operations would cause electricity rates to spike and could threaten the reliability of the electrical grid.

The ruling stems from a years-long battle over the nearly 100-year-old hydropower system along the Columbia and Snake rivers. Conservation groups and tribes with treaty fishing rights want the system altered and operated to benefit wildlife, including calling for the removal of four dams along the Snake River. As part of that litigation, the federal agencies are also working on an environmental impact statement for the system that has been the subject of congressional fights, with Rep. Cathy McMorris Rodgers (R-Wash.) filing a measure (H.R. 3144) to void that process, and Democratic lawmakers coming out in opposition.

WHAT'S NEXT: Unless they successfully appeal the decision, the federal agencies will need to release water over the top of dams beginning this spring. The ongoing environmental impact statement process will continue.

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Back

Senate spending leaders vow to open up floor debate for amendments Back

By Sarah Ferris and Kaitlyn Burton | 04/23/2018 06:20 PM EDT

Senate Appropriations Chairman Richard Shelby is vowing to restore chamber-wide debate on amendments to individual appropriations bills to help end Congress' stop-and-go funding cycle.

Shelby (R-Ala.), along with his Democratic counterpart Sen. Patrick Leahy, of Vermont, told committee members in a closed-door meeting today that leadership has agreed to allow amendments on the Senate floor for every individual spending bill.

"There is perhaps unanimity, but certainly strong consensus that if the appropriations process is going to work we're going to be casting votes on amendments and we stay here and we vote," Sen. Jerry Moran (R-Kan.) told reporters exiting the meeting, which was the committee's first bipartisan sit-down of fiscal 2019

"I think it's the single best way to restore the Senate the way the Senate's supposed to work. The full Senate gets a chance to offer a variety of amendments, and if you don't like it, you can vote against it," Sen. Lamar Alexander (R-Tenn.) added.

Shelby and Leahy have met with Majority Leader Mitch McConnell and Minority Leader Chuck Schumer in recent days about opening up the floor for debate on spending bills.

When asked if both leaders were on board, Shelby added: "They tell us they are, and I like to believe them." Leahy added: "We both talked with both of them. I think they both understand. The Senate can't go on like this."

It's a risky gambit, particularly in an election year. Contentious amendments have held up bills in both chambers in recent years.

Back in 2016, Senate Democrats blocked a largely noncontroversial Energy and Water bill because of a proposed amendment on Iran. In 2015, the House GOP's Interior-Environment bill was tripped up by an unrelated rider on the Confederate flag.

The number of amendments on Senate spending bills has dropped dramatically in the last two decades, as the chambers considers fewer and fewer individual bills.

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Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
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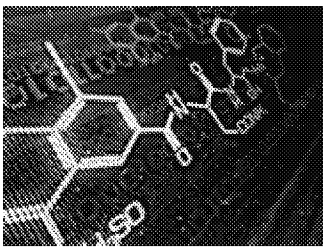
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Chemical Makers Worry Steep New EPA Fees Could Stifle Innovation



Chemical manufacturers are concerned that hefty new EPA fees to support premarket reviews could stifle innovation and pose a barrier to bringing new chemicals to market.

INSIDEEPA.COM ARTICLES

EDF Signals New Chemical-Specific Path To Target EPA SNURs Under TSCA

The Environmental Defense Fund (EDF) is warning that a draft EPA rule allowing a new use of an existing chemical is "legally vulnerable," suggesting a new chemical-specific path for environmentalists to challenge EPA's approval of new chemical uses under the revised Toxic Substances Control Act (TSCA).

GREENWIRE ARTICLES

Pruitt foes buy ad time during Trump's favorite TV shows

Kevin Bogardus, E&E News reporter

Published: Wednesday, March 28, 2018

Environmentalists launched an ad campaign in an attempt to oust U.S. EPA Adminsitrator Scott Pruitt from office. NationalSierraClub/YouTube

Environmental groups are taking their campaign to force U.S. EPA Administrator Scott Pruitt from office to a new domain: President Trump's television screen.

Ten green organizations have banded together to a launch a new effort aimed at removing Pruitt. The "Boot Pruitt" campaign begins today with the Sierra Club running television ads on what are considered Trump's favorite morning shows, Fox News' "Fox & Friends" and MSNBC's "Morning Joe."

The ad highlights Pruitt's critical comments of Trump during the 2016 campaign — calling Trump an "empty vessel" when it comes to the Constitution and rule of law — as well as the EPA chief's penchant for first-class travel. The ads will air today, tomorrow and Friday.

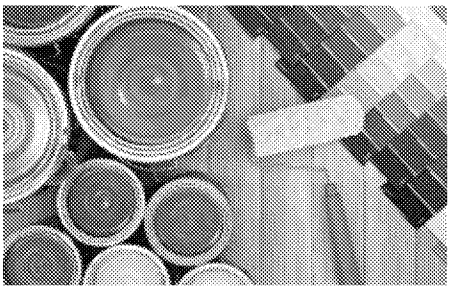
https://www.eenews.net/greenwire/2018/03/28/stories/1060077647

CHEMICAL WATCH ARTICLES

Canada draft assessment: DGEBA and novalac epoxy resins are safe

Substances associated with adverse effects on spleen and skin

28 March 2018 / Canada, Environmental Protection Act, Risk assessment, Sensitisers



A Canadian government assessment has provisionally concluded that four epoxy resins used in paints, coatings and plastics are not harmful to humans or the environment.

The substances are three diglycidyl ethers of bisphenol A (DGEBA; BADGE) epoxy resins (Cas nos 25036-25-3, 25068-38-6 and 25085-99-8) and a novolac epoxy resin (Cas no 28064-14-4).

They are all polymers, used as intermediates in the manufacture of other substances. This is in petroleum production processes to prevent corrosion and build-up, and:

- plating agents;
- adhesives and sealants in grout;
- flooring; concrete; and
- lubricants and lubricants additives.

DGEBA epoxy resins are made by polymerisation of the monomers bisphenol A and epichlorohydrin, via DGEBA.

Novolac epoxy resins are made by the same process to form novalac, followed by epoxidation using epichlorohydrin.

Both types of resin contain highly reactive epoxy groups, associated with potential adverse effects on the spleen, as well as skin sensitisation. The draft risk assessment identities these effects as the "critical" ones for characterising the risk to human health.

The authors say that consumers could be exposed to residual DGEBA as a result of migration into food from food packaging materials containing DGEBA epoxy resins. But even using a "worst-case scenario" the daily intake would be low, corresponding to a low overall risk of harm to human health.

The assessment concludes that none of the substances meet any of the criteria set out in section 64 of the Canadian Environmental Protection Act (Cepa).

Next steps

The government prioritised the substances in a previous round of screening under its Chemicals Management Plan. Assessments conducted under the plan do not normally include consideration of occupational exposure.

The government has initiated a 60-day public consultation on the draft screening assessment, meaning interested parties have until 23 May to submit comments.

Further Information:

- Draft screening assessment

Survey on REACH restriction for PFASs extended

29 March 2018 / Europe, PFCs, REACH

A survey launched to help develop a restriction proposal under REACH on PFASs (C4-C7) and other fluorinated substances, has been extended by a month.

The survey, carried out by the Ökopol Institute for Ecology and Politics for Germany's environment agency (UBA), was due to end this month, but following a number of requests the deadline has been pushed back to 15 April.

The UBA is collecting information on the manufacture and use of short-chain PFASs with the aim of identifying risks to the environment and/or human health that should be restricted under REACH.

In a paper published in late February in *Environmental Sciences Europe*, Stephan Brendel from the UBA and others looked at short-chain perfluoroalkyl acids with a particular eye on environmental concerns and the need for a regulatory strategy under REACH.

They concluded that "due to an increasing use of short-chain PFASs, an effective regulation is urgently needed. The concerns do not match the 'classical' concerns as defined under REACH, but are not of minor concern."

Data collection

Included in the agency's data collection is the availability of alternatives to the use of fluorinated compounds and the socio-economic impacts of any restriction.

The short-chain PFASs under scrutiny are those with chain lengths <7 perfluorinated carbon atoms. They include:

- per- and polyfluorinated carboxylic acids (PFCAs);
- fluorotelomer alcohols (FTOHs);
- fluorotelomer iodides (FTIs);

- fluorotelomer acrylates (FTAs) and fluorotelomer methyl acrylates (FMAs); and
- per- and polyfluorinated sulfonic acids (PFSAs).

Polymeric substances that are generated out of these building blocks are also within the UBA's scope.

Survey

The objective of the Ökopol survey is to increase information on:

- manufactured and imported amounts of the respective substance groups;
- manufactured and imported amounts of their potential alternatives;
- the type of uses the substances are applied to; and
- the economic effects that are linked to their use.

Ökopol says it is vital that survey respondents provide information on all the use cases they know of. This will, it says, help "avoid unintended consequences for market actors when a regulatory measure is implemented".

Related Articles

- Germany and Sweden propose restrictions on six PFASs

Further Information:

- Ökopol survey extension
- PFASs regulatory strategy paper

UK starts work on post-Brexit chemicals registration system

29 March 2018 / Substance registration, United Kingdom

The UK government has started work on the delivery of new IT capability, to enable the registration and regulation of chemical substances placed on the national market.

In a written answer to a question posed by an MP in mid-March, Junior environment minister Therese Coffey said that so far, the Department of the Environment, Food and Rural Affairs (Defra) has spent £330,000 on the "Alpha development phase" of the IT system for the registration of chemical substances.

She added that "no expenditure has been incurred to date on developing IT capability for the regulation of chemical substances as the initial phases of the project are focused on registration."

At the end of January the UK's Secretary of State for the Environment authorised spending of £5.8m (€6.64m) for the system.

The chemicals IT platform is one of six "planned EU Exit readiness activities" being carried out by Defra, for which it has asked £16m in advance of the EU Withdrawal Bill receiving royal assent – when the Queen formally agrees to make the bill into an Act of Parliament (law).

In related news, a Chemical Watch survey has found that just 12 months to go before Britain is expected to leave the EU, a third of UK-based companies are actively organising or planning to move some of their operations out of the country because of the regulatory uncertainty.

Chemical Watch is holding its second workshop on post-Brexit options for UK chemicals law in London on 17 April.

Related Articles

- UK authorises £5.8m for post-Brexit chemical registration IT
- Brexit uncertainty forcing UK-based firms to act

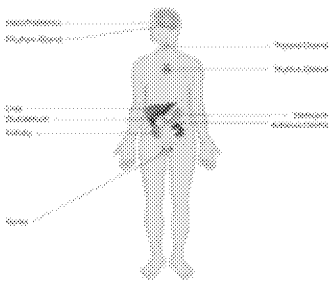
Further Information:

- Parliament Q&A
- Chemical Watch Brexit Survey 2018: Infographic

Commission comes under fire for 'patronising' approach to EDCs in EU

NGOs, scientists participate in public hearing on health impact

29 March 2018 / EDCs, Europe



The European Commission, the EU's executive arm, faced fresh criticism from the European Parliament's environment committee (Envi) and NGOs at a public hearing about its handling of endocrine disrupting chemicals (EDCs).

At one point in the 22 March proceedings, Envi vice-chair Pavel Poc told Commission representatives "I would really appreciate if your approach to this was not so self-righteous and patronising".

The hearing was organised jointly by Envi and the Petitions Committee (Peti). Speakers included experts from EU and national regulatory agencies and representatives of academia and NGOs.

It was organised in response to what the Parliament called "a high number" of petitions from citizens expressing concern over EDCs.

Threat of censure

During the hearing Mr Poc referred to an attempted motion of censure MEPs aimed at the Commission as far back as 2016 for its delay in publishing scientific criteria on EDCs. That motion had lapsed after several key MEPs withdrew their support for it but, Mr Poc warned, the outcome of a similar motion now might be different.

He said the next time the issue is debated the Commission should consider whether it has done everything it could and "should have in mind this one simple fact": MEPs could support the motion of censure.

In October last year Parliament vetoed the Commission's criteria proposal and asked it to come up with a new proposal "without delay", after MEPs argued the Commission had exceeded its mandate.

Two months later, in December, the EU's Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) adopted revised EDC criteria in December. The proposal is currently undergoing scrutiny by the Council of Ministers and the European Parliament.

NGO push

During the debate Natacha Cingotti from the Health and Environment Alliance (HEAL) called for a "coherent EU strategy" on EDCs addressing a diverse range of product groups, such as cosmetics, toys and food contact materials.

Action is "long overdue" and member states such as Denmark, France and Belgium would take individual measures if the Commission fails to act decisively, she added.

ClientEarth's Alice Bernard said the EU is obliged to control EDCs under the 7th Environment Action Plan. She called for more resources to facilitate effective controls.

However, Peter Korytar, policy officer at the Commission's environment directorate, said EDCs are not "unattended" in EU legislation. They are included in all chemicals regulations, he said, with specific provisions in some.

He said the Commission will publish a report "in a few weeks" in which it will set priorities for future work on the substances.

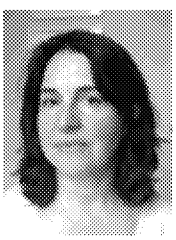
Scientists urge no delay

Scientists at the hearing said decisions should not be deferred on the basis that further research is needed, as enough tools are available to regulators.

Alberto Mantovani, a professor from the Italian Health Institute, suggested as the way forward a "mode-of-action driven approach" to support risk assessment and risk reduction. MoA refers to cellular changes, rather than molecular.

Daniel Dietrich, from the University of Konstanz in Germany, said natural and synthetic EDCs should be considered together – as the former also cause adverse effects. He gave the examples of sugar and yellow mustard. "It is a matter of dose and risk," he added.

Olwenn Martin from Brunel University in London disagreed, saying that while individuals can control their sugar intake, they must depend on policy makers to control chemical substances. She also urged wider free dissemination of more data on EDCs.



Clelia Oziel

Reporter

Related Articles

- Commission EDCs censure motion fails as MEPs withdraw signatures
- European Parliament rejects EDC criteria
- EU pesticides committee adopts revised EDC criteria

Further Information:

- Envi press release

Sweden advocates developing microplastic restrictions at EU level

29 March 2018 / Microplastics, Sweden

A Swedish investigation into whether further national restrictions on microplastics in cosmetics and other chemical products are needed concluded that such action would be better carried out at EU level in the first instance.

Sweden's chemical agency Kemi, which carried out the research, says "the work being done at EU level on restriction proposals could result in reliable decision material and clear and harmonised rules and regulations which would also be cost-effective".

The investigation follows the Swedish government's decision in February to ban microplastics with a cleansing, exfoliating or polishing effect in rinse-off cosmetics products.

With the ban already planned, the government asked Kemi in 2017 to look at the occurrence of microplastics in certain cosmetics products that are not covered by the prohibition.

The agency says its assessment is based on "striking a balance between environmental concerns and the consequences of a national restriction.

"Our assessment has also taken account of the uncertain level of knowledge we have about microplastics."

Defining microplastics as solid plastic particles smaller than 5mm in any dimension and insoluble in water, Kemi identified polymers and waxes that might be microplastics in both cosmetics and chemical products. However, it says it does not have "sufficient material at present to assess with certainty which polymers ought to be designated as microplastics ..." It is therefore difficult, it says, to identify existing alternatives or replacements that can be developed.

Kemi estimates that between 0.2 and 4.4 tonnes of microplastics per year are emitted to the water environment from cosmetics products that are sold in Sweden.

Agency intentions

In the report Kemi says it plans to:

- participate in the development of restriction proposals on intentionally added microplastics in products at EU-level;

- act to encourage the EU Commission to consider the possibilities of introducing requirements on registration and evaluation in REACH for polymers;
- act to encourage voluntary measures to be taken in the sectors responsible for detergents and cosmetics;
- participate in work on microplastics standardisation;
- work to improve knowledge of microplastics in products through its ongoing mapping of hazardous substances; and
- act to improve coordination and dissemination of knowledge about plastic nanoparticles through the Swedish National Platform for Nanosafety.

The agency says it is committed to promoting greater knowledge on the part of researchers, public authorities and companies, especially regarding occurrence and properties of the smallest types that are used in products.

It also plans to speak with relevant industries to this end and to encourage the replacement of microplastics on a voluntary basis, such as in the cosmetics sector.

Sweden proposed the broadening of its ban on microbeads in rinse-off cosmetics to all products that release them last year.

Related Articles

- Sweden adopts microbeads ban in rinse-off cosmetics
- Sweden considering wider restrictions on microplastics

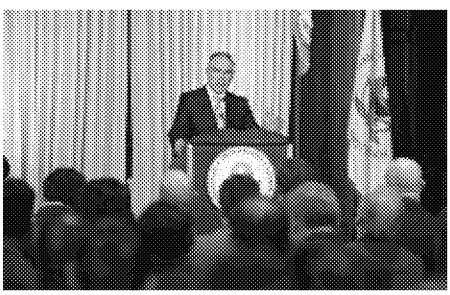
Further Information:

- Report (in Swedish with English summary)

US EPA to unveil 'secret science' details in coming weeks

Public consultation to be sought for transparency dialogue

29 March 2018 / TSCA, United States



The US EPA is preparing to make a formal announcement and solicit public feedback on its forthcoming 'secret science' policy changes within the next month.

Last week, news surfaced that the EPA was planning to unveil a new policy that would block it from using studies that are not publicly available as the basis for its regulatory decisions.

NGOs immediately raised the alarm that this change could "radically limit" the types of science used to develop public health and environmental protective policies.

The EPA press office has not responded to multiple requests for further details on what this change will include. But a source close to the issue told Chemical Watch this week that a more formal rollout will come in the next few weeks.

The initiative will entail a process for gathering ideas and information from interested stakeholders to begin a dialogue around the way the agency assesses science, according to the source. The goal will be to ensure that there is increased transparency in how the EPA evaluates the science underlying its regulatory decisions.

It was not immediately clear if this would take the form of a formal rulemaking or not.

Initial reports had indicated that the EPA's science policy would "mirror" the HONEST Act – a bill passed by the House a year ago, but which has not gained traction in the Senate. That bill calls for the science used by the agency to be "transparent and reproducible".

But Chemical Watch has been told that while the stalled legislation and the EPA's evaluation of how it looks at scientific studies are rooted in similar concerns, the latter may not be exactly in line with the former.

Nevertheless, concern at the new approach continues to swirl. Earlier this week former EPA administrator Gina McCarthy and former acting assistant administrator Janet McCabe wrote in the *New York Times* that the public should "[not] be fooled by this talk of transparency".

"[Administrator Pruitt, pictured] and some conservative members of Congress are setting up a nonexistent problem in order to prevent the EPA from using the best available science," they said.

Kelly Franklin

Editor, North America

Related Articles

- TSCA could be undercut by 'secret science' requirements
- House passes US EPA science transparency bill

Further Information:

- NYT opinion
- HONEST Act
- EPA news release

Automotive groups defend lead-acid batteries in California

Stakeholders call for SCP programme to focus on "greatest impact" products

29 March 2018 / Metals, United States

The automotive industry is pushing back on California's interest in evaluating lead-acid batteries under the Safer Consumer Products (SCP) programme.

Lead-acid batteries are one of seven product categories named in the Department of Toxic Substance Control's 2018-2020 draft priority products work plan. These represent the candidates from which the DTSC may select 'priority products'. Once a product-chemical combination is designated, manufacturers must either undertake an alternatives analysis or phase out the substance's use.

The most frequent form of lead-acid batteries are 12-volt car batteries. The work plan additionally names, among others, 'small, sealed forms', including those used in consumer electronics, and batteries used for mobility, such as in scooters, golf carts and forklifts.

And while the products may contain three SCP candidate chemicals – lead, arsenic and sulfuric acid – industry groups are protesting their inclusion in the draft plan.

The Alliance of Automobile Manufacturers – a coalition including major manufacturers like Mitsubishi, Volkswagen, General Motors and Volvo – said the product has "minimal potential for exposure" when in use.

And while there have been issues with the recycling of these batteries in the past (see box), it said, the "targeting of the entire automotive battery supply chain for the past mistakes of an individual 'bad actor' does not represent a science-based, data-driven approach to remedy any outstanding concerns associated with the product".

If the primary concerns exists with recycling and manufacture, it added, "these can be better addressed via other regulatory mechanisms".

Mema, the Motor & Equipment Manufacturers Association, which represents more than 1,000 companies who manufacture motor vehicle systems and component parts, said that lead-acid batteries do not meet the two primary criteria for a priority product listing. Namely, that there is:

- potential exposure to the chemical in the product; and
- potential that exposures contribute to or cause significant or widespread adverse impacts.

A priority product listing, it said "should be reserved for products that have the greatest impact on benefiting human health or the environment, provides the SCP programme the best chance of success, and is a legitimate use of DTC's resources and the resources of the industry that manufactures the product."

The Green Chemistry Alliance – a broad coalition incorporating more than a dozen major trade groups – cited lead acid batteries as an example where the work plan would conflict with state or federal regulatory programmes. "Every aspect of the product life-cycle is already highly regulated at both the state and federal levels," said the group.

"The department should [not] attempt to conflict with, duplicate the activities of other regulatory agencies or supersede the regulatory authority of other agencies – whether or not they've taken action to date on particular aspects of the full life cycle of products and chemicals."

Safer alternatives?

But ZincFive – a manufacturer of nickel-zinc based energy storage products – said that lead has been successfully removed from such applications as paint and gasoline, and that "viable, lead-free alternatives are now available in the form of lithium-ion and nickel-zinc batteries".

"California DTSC has the opportunity to make the monumental lead poisoning clean-up in Vernon the last of its kind and to make the lives of all Californians safer through designation of lead-acid batteries as a priority product," said the company.

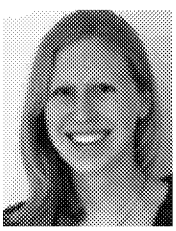
However, the Battery Council International – a lead battery trade group – countered that these are "new and unproven battery technologies with known significant environmental and public safety risks, and unknown long-term impacts".

Exide Technologies

The inclusion of lead-acid batteries in the work plan follows a highly publicised toxic cleanup at Exide Technologies. The facility's activities – which included recycling scrap from spent lead-acid batteries – resulted in widespread lead contamination impacting as many as 10,000 properties.

In 2016, California Governor Jerry Brown cited Exide when he directed the DTSC to evaluate lead-acid batteries.

The work plan says the department has begun research on exposures and hazards associated with lead-acid batteries, and will continue that work. It held a public workshop on 6 November last year to begin this process.



Kelly Franklin

Editor, North America

Related Articles

- California unveils 2018-2020 priority product work plan
- Industry seeks clarity in California SCP programme

Further Information:

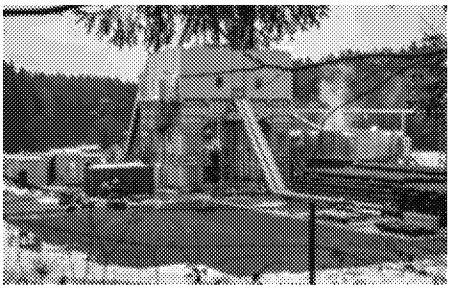
- Draft plan

- Comment portal

EU committee: knowledge of oil, gas health risks 'very poor'

Call for open access database

29 March 2018 / Accidents, emergency response & poison centres, Data, Europe, Halocarbons, Mining & minerals, Risk assessment



The quality of scientific assessment of possible public health risks posed by the EU's onshore oil and gas exploration and extraction activities is "very poor", according to the European Commission's Scientific Committee on Health, Environmental and Emerging Risks (Scheer).

The committee estimates that over 1,300 different chemicals may be emitted to the environment from onshore oil and gas activities. These include biocides, scale and corrosion inhibitors, oxygen scavengers, surfactants and various hydrocarbons.

The Commission asked Scheer to assess the public health risks and to identify the main knowledge gaps. The committee found that most studies are from the US, with evidence pointing towards possible health effects. It expressed its "surprise at the very poor scientific assessment of the possible effects of these activities in the EU".

Although the probability of chemicals being released to the environment is relatively low under normal operation, there is a high risk of accidental spillages. The physico-chemical properties and environmental behaviour of the chemicals involved in oil and gas exploration differ widely. Some are transported in the air while others pollute water systems.

Included in the 1,300 chemicals are reproductive and developmental toxicants and carcinogens. The committee suggests that "the risk of some cancers and of adverse birth outcomes may be increased in populations living around onshore oil and gas exploration and exploitation sites". Yet the evidence is "weak to moderate".

Scheer found "insufficient" quantitative information on exposure pathways and levels. It also identified a need for more data from environmental monitoring and human biomonitoring. "With the existing information on exposure and hazard, it is currently not possible to perform a thorough risk characterisation of human health risk associated with oil and gas exploration and exploitation," it concluded.

The committee says it would like to see an open access, EU database of all chemicals involved in oil and gas activities. To characterise the hazardous properties of individual chemicals, it recommends using a weight-of-evidence approach with *in vivo* and *in vitro* data, as well as Qsar and read-across.

Human health risk will result from exposure to a mixture of chemicals, says the committee. The exact mixture composition and exposure concentration will vary over time and from site to site.

Further Information:

- Scheer report

Walmart aligns disclosure policy with Californian law

Retailer finds state's Cleaning Product Right to Know Act enough for suppliers to comply

29 March 2018 / Cleaning products, Confidentiality & right-to-know, Labelling, North America, Personal care, Retail, United States, Voluntary action

An update to US retailer Walmart's ingredient disclosure policy means that product suppliers can now comply with it, by adhering to California's list of chemicals of concern.

In 2013, the company informed its suppliers that it wanted online disclosure of products containing substances on its list of priority chemicals by 2015 and on labels by 2018. Walmart's priority chemicals are compiled from 22 regulatory lists.

However, they can now use California's list of chemicals, which will be required under the state's Cleaning Product Right to Know Act, to check which substances need to be included on their product labels. Walmart has made the change to lessen the burden for suppliers, which would otherwise have to comply with two lists when California's requirements are implemented.

California's labelling requirements enter into force in 2021, while Walmart's have been in force since January.

Walmart's director of sustainability communications, Micah Ragland, told Chemical Watch: "In seeking closer alignment with California's [Act], our aim is to help enhance efficiencies for our suppliers and increase transparency and ingredient disclosures for our customers."

Work with HCPA

According to a three page statement, recently released by Jim Jones, at trade body the Household and Commercial Products Association (HCPA), his organisation worked with Walmart to "better align the company's ingredient transparency requirements with California's new law".

Commenting on suppliers having to adhere to both lists from 2021, Mr Jones, who was the former assistant administrator for chemical safety at the EPA, said that the "differences would make it challenging to comply".

In essence, he added, Walmart will expect suppliers to meet a more ambitious schedule than California, but "the substances of compliance will be the same".

The main difference between California's and Walmart's lists is that the retailer includes Minnesota's chemicals of concern that fall under the state's Toxic Free Kids Act. California's list contains around 3,200 substances, while Walmart's exceeds 4,000.

"This may appear to be a small win, but if you are a company that sells in California (almost all our members) and Walmart (almost all our members), even small differences in requirements can lead to extraordinary costs and time-consuming compliance," he said.

Mr Jones told Chemical Watch that the HCPA is reaching out to a large number of retailers, which are putting in place or have chemicals safety policies, including Target.

"The aim is to create greater dialogue so that they understand what suppliers can and can't do and how long it takes for them to do certain things, like the length of time it is possible to make a label change for example."

Products covered

Walmart's disclosure requirement covers "chemical-based" consumables products, sold through Walmart US and Sam's Club US stores. Departments and product categories covered are:

Walmart departments:	Sam's Club categories:
Health and beauty aids	Health and beauty aids
Household paper	Tabletop and bags
Pets and supplies	Pet supplies
Household chemicals	Laundry and home care
Cosmetics and skincare	Baby care
Infant consumable hardlines	Paper goods
	Janitor supplies

Leigh Stringer

Global Business Editor

Related Articles

- Walmart targets ten substances of concern in consumer products
- California cleaning disclosure bill unites NGOs and industry
- Minnesota updates chemicals of high concern list

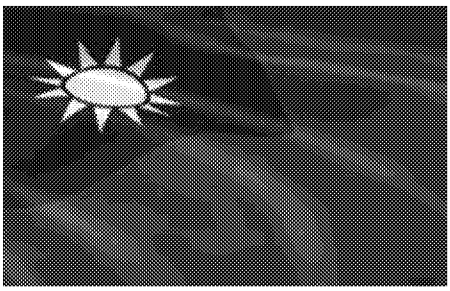
Further Information:

- Walmart's supplier guidance
- California's Act
- Jim Jones statement

Taiwan's draft Pecs list and registration changes expected April

TCSCA revisions also moving forward

29 March 2018 / New substances, Priority substances, Substance registration, Taiwan, TCSCA



Taiwan's Toxic and Chemical Substances Bureau says the publication of the long-awaited draft revisions to its registration process for new and existing chemical substances, together with a draft list of more than 100 priority existing chemicals (Pecs) is likely in April.

In an interview with Chemical Watch, Hsieh Yen-ju, director-general of the EPA's Toxic and Chemical Substances Bureau, said his agency recently submitted both documents to the office of EPA Minister Lee Ying-yuan.

Speaking on 26 March Mr Hsieh acknowledged that "industry concerns" had delayed the draft documents past their expected date of end of February. But the advance notice of 60 days of public comment on the changes should happen sometime in April, he said.

Draft revision of TCSCA under review

Mr Hsieh also said that a draft bill to revise the Toxic Chemical and Substances Control Act (TCSCA), which would be renamed the Toxic and Chemical Substances of Concern Control Act, is now being reviewed by the Social Welfare, Health and Environmental Protection Affairs Committee of the Legislative Yuan, Taiwan's parliament.

The Executive Yuan, Taiwan's Cabinet, had listed the draft package of changes as a "priority bill" for passage in the current legislative session, which will end in late June, Mr Hsieh said.

Dennis Engbarth in Taipei City

More available on CW+AsiaHub.

Related Articles

- Taiwan delays release of initial Pecs list
- Toxic chemical substances control act (2017 draft revision)

- Taiwan's draft Pecs list and registration changes expected April

Swedish nano-platform launches new website

29 March 2018 / Nanomaterials, Sweden

The Swedish National Platform for Nanosafety – SweNanoSafe – has published a website aimed at improving communication and the exchange of knowledge on the safety of nanomaterials.

It is targeted at regulators, scientists, industry, NGOs, and others interested in the safety of nanomaterials.

In Swedish with some information in English, the SweNanoSafe website offers basic information and research on how nanomaterials are regulated in various areas, such as chemicals, cosmetics and the work environment.

Safety aspects of the substances concern their whole life cycle – synthesis, development, production, use and management of waste.

The site includes:

- a knowledge bank;
- Q&As;
- a calendar; and
- links to other sources of information mainly in Sweden and Europe.

It is part of the Swedish Toxicology Sciences Research Centre (Swetox) commission from the Swedish government to create a national platform for nanosafety.

Sweden has been proactive in setting controls on nanomaterials. A rule requiring companies in the country to notify data on nanomaterials in chemical products to the national chemicals agency's product register entered into force on 1 January this year. Companies have until 28 February 2019 to comply.

On a European level, in June last year Echa launched its EU observatory for nanomaterials (Euon), a public website aimed at increasing transparency of information on nanomaterials on the EU market.

It came after the Commission opted not to create an EU nano register, given delays in the introduction of new REACH information requirements for nanomaterials.

The impact of the website "will be minimal", the Dutch National Institute for Public Health and the Environment (RIVM) said in December.

Related Articles

- Nano data will be added to Swedish product register next year
- Revise nano definition before amending REACH annexes, industry says
- Impact of EU nano observatory 'limited', RIVM says

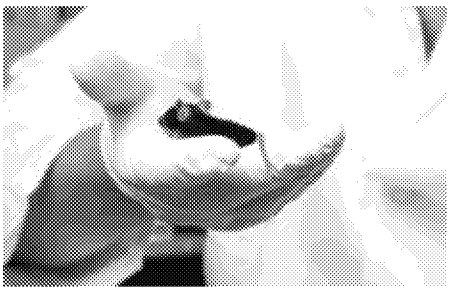
Further Information:

- SweNanoSafe website
- Press release

Global ban on animal testing hard to achieve, industry says

China could be biggest hurdle

29 March 2018 / Europe, Personal care, Test methods



The EU's call to establish a global ban on animal testing for cosmetics will prove challenging, say cosmetics industry groups.

Particular barriers, they say, include the lack of acceptance of alternative test methods internationally and getting countries that do not implement bans to reconsider their current approaches.

Last month, the European Parliament's Environment Committee (Envi) voted to advocate for a worldwide ban on animal testing for cosmetics by 2023.

It proposed drafting an international convention against the testing of animals for cosmetics within the UN framework, and called for it to be included on the agenda of the next UN General Assembly meeting.

But a Cosmetics Europe spokesperson told Chemical Watch, that despite efforts from the cosmetics industry, alternative replacement test methods have not yet been developed or accepted for all toxicological endpoints.

The EU testing and marketing ban, that entered into force in March 2013, covers all endpoints, irrespective of whether a full set of alternatives methods is available to replace corresponding animal studies.

The trade body said this has "severely limited" industry's ability to introduce new ingredients, use existing ones for new uses and respond to new questions regarding their safety.

The spokesperson added that amendments to Envi's proposal, calling for resources to be allocated for fast development, validation and introduction of alternative testing methods to replace key toxicological endpoints were "extremely important".

It was equally important that these alternative methods "received international regulatory acceptance for use in safety assessment of cosmetic ingredients and products", they added.

Developing alternatives

The US does not have a formal requirement for animal testing of cosmetic products, but the Food and Drug Administration (FDA) does require companies to test across a range of toxicological endpoints in order to prove safety.

According to the FDA's website, animal testing by manufacturers, seeking to market new products, may be used to establish product safety. "In some cases, after considering available alternatives, companies may determine that animal testing is necessary to assure the safety of a product or ingredient," it says.

Francine Lamoriello, executive vice president of global strategies for the Personal Care Products Council (PCPC), told Chemical Watch, the cosmetics industry has invested "hundreds of millions of dollars over the past several decades to develop scientifically valid alternative safety testing methods".

She added that the PCPC encouraged FDA approval of alternatives to animal testing "as part of its principles for federal cosmetics regulatory modernisation" and was committed to "the development of additional alternative testing methodologies".

China challenge

The push for a global ban is being proposed because around 80% of the world's countries still allow animal testing and the marketing of cosmetics tested on animals. China is one country with a major cosmetics market that does not implement a ban, instead requiring products to be animal tested before being allowed on the market.

Janet Winter, CEO of the US consultancy, International Cosmetics and Regulatory Specialists, told Chemical Watch that China's mandatory animal testing requirement for imported cosmetics, was likely to be the "biggest challenge" for a global ban.

She said that industry was working with the Chinese government to eliminate their animal testing requirements and hoped that as China is a member of the World Trade Organization (WTO), a resolution put before the UN would create "additional pressure" to rescind them.

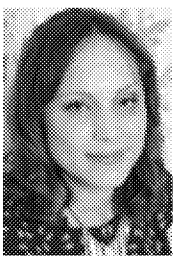
"This is another step forward, serving to increase visibility on the issue. Industry will continue to pursue the abolition of animal testing at every opportunity, and the UN message will serve as a part of that," she said.

US-based NGO, the Institute for In Vitro Sciences (IIVS), is working with China's National Institute for Food and Drug Control (NIFDC) to improve use of non-animal tests in China.

Erin Hill of IIVS told Chemical Watch, there are "many efforts" needed in order for the Chinese government to come in line with international standards - such as acceptance of data from the OECD test guideline methods.

She said: "It may be a big leap for them to pass a ban on animal testing."

A March plenary session, at which the resolution on the ban was due to be voted on, was delayed. A European Parliament spokesperson said it will now take place in either April or May.



Tammy Lovell

Business reporter

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- MEPs back push for global ban on cosmetics animal testing
- EU implements ban on sale of cosmetics tested on animals

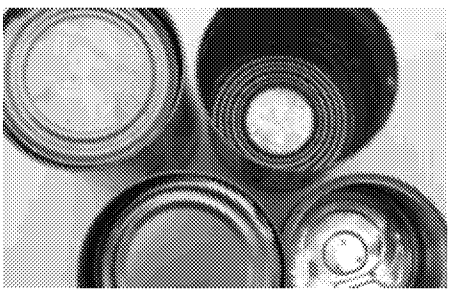
Further Information:

- Resolution

NGO urges EU phase-out of hazardous chemical groups

Report highlights BPA substitution with 'potentially harmful' BPS

29 March 2018 / Alternatives assessment & substitution, Bisphenols, Europe, Food & drink, REACH



UK-based NGO CHEM Trust has called on EU regulators to "phase out" the use of groups of similar chemicals to prevent substitution of one hazardous substance with a related one that has similar properties.

In separate letters addressed to Echa, the European Food Safety Authority (Efsa), and the European Commission's Health Commissioner, the NGO says "the only exception to this should be if industry has good data showing the chemical they wish to use does not have the same properties as those of the chemical being restricted".

The letters coincide with the publication of a report which highlights the common industry practice of substituting bisphenol A (BPA) with bisphenol S (BPS), both of which, Echa's risk assessment committee has said, may have similar toxicological profiles.

BPA is already on the REACH candidate list of SVHCs on three counts. Not only is it toxic to reproduction, but it also has endocrine-disrupting properties which cause probable serious effects to human health and the environment.

It is used in thermal paper till receipts – although that is facing a restriction from 2020 – as well as polycarbonate water bottles and food can linings.

Echa has started investigating BPS by asking industry for more safety data rather than regulating its use, CHEM Trust says.

Additionally, "as far as CHEM Trust is aware Efsa – responsible for assessing chemicals in food packaging – has not reexamined the toxicity of BPS or other bisphenols" the NGO says.

Report findings

According to the report – *From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them* – most companies selling BPS are "claiming that it has no hazards".

The report shows that people and the environment are "not being properly protected from hazardous chemicals as businesses are moving from one problem chemical in a group to another," Michael Warhurst, CHEM Trust executive director said.

"We need EU regulators to phase out groups of chemicals of concern, rather than slowly restricting one chemical at a time. We cannot continue to gamble with people's health like this."

The report is published a year after CHEM Trust's *No Brainer* study, which reviewed the evidence that a number of chemicals, including BPA and BPS, might harm brain development in children.

Recommendations

The report lists five recommendations:

- regulators should regulate groups of related chemicals, rather than take a substance by substance approach: this needs to be used in REACH and regulations such as laws on chemicals in food contact materials. Echa should also investigate the effectiveness of industry's self-classification of chemicals, and whether this is being done in accordance with the legal requirements;
- manufacturers must improve their own assessment of the safety of chemicals: it is "not acceptable", CHEM Trust says, to claim that a chemical like BPS has no hazards, when a very similar chemical is known to have substantial hazards, including endocrine disruption;
- downstream users of chemicals should not replace one "problem chemical" with another similar chemical from the same group;
- workers should ask whether they are being exposed to BPA or other bisphenols, and ask employers to move to safer non-bisphenol alternatives; and
- consumers should ask retailers whether products such as plastic bottles, till receipts and food cans are bisphenol-free, and should ensure that children do not play with till receipts.

Related Articles

- Commission calls on Echa to monitor BPS in thermal paper
- Echa's MSC agrees BPA is an endocrine disruptor in the environment
- MSC discusses bisphenol S and cosmetic fungicide climbazole
- EU testing for developmental neurotoxicity inadequate, says CHEM Trust

Further Information:

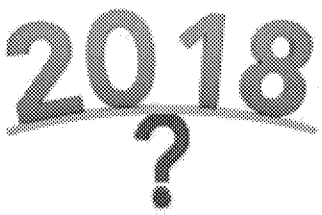
- CHEM Trust report
- CHEM Trust press release
- Letter to Echa

- Letter to Efsa
- Letter to EU Health Commissioner
- REACH candidate list

Companies likely to miss REACH 2018 'fast-track check' deadline

High number of 'exceptional case' inquiries for late test results

29 March 2018 / Data, Europe, REACH, Substance registration



An expected surge in the number of companies submitting REACH 2018 dossiers by the end of March – so as to secure a completeness check outcome on their dossiers in 21 days – does not seem likely, Echa says.

The agency had previously warned the outcome of such checks on dossiers submitted after 31 March may not arrive until August.

With two months to go until the registration deadline, Echa has received 18,037 dossiers covering 7,452 substances – 4,975 of which have not been registered before.

Overall, the agency said in comments to Chemical Watch, this is 10% behind the current 2018 deadline dossier estimations for this point in time. However, it added, the expectation has always been of a large peak in submissions during the last weeks before the deadline "so it is difficult to draw conclusions at this point".

For the 2018 deadline, 3,236 companies have filed dossiers – 544 companies are new registrants.

'Exceptional' cases

Submission inquiry and data-sharing dispute activity remains "very high", Echa said, "which is a sign that submissions are in general late".

Additionally, requests for letters of access "remain quite high" as do the number of expressions of interest received for the Directors Contact Group (DCG) solutions. This is particularly the case on the late availability of test results – "which also reflects that industry is late with the preparations and therefore submissions will arrive in the last weeks before the deadline", Echa said.

Those prospective registrants expecting late test results on their substances must secure lab testing contracts dated before 31 March in order to be considered as an "exceptional case", and to potentially be permitted to submit their dossiers after the 31 May deadline – if Echa consents.

The agency has now received around 160 expressions of interest for DCG solutions – almost all for the issue on late availability of test results. "Given the large interest we have updated the DCG webpages to make more transparent the kind of documentation that companies need to provide to apply for the DCG cases," Echa said. "It does look like this will continue to increase in the coming weeks."

Extra support

The agency has decided to open REACH-IT 24 hours a day, seven days a week, including bank holidays and weekends, so industry can continue to submit. Full Echa support is available during business hours, it said, adding it "constantly" monitors the situation.

It will run a REACH 2018 Q&A session on 19 April with a panel of experts responding to queries.

Echa says it is "ready to support" companies with all the "different difficulties" they may encounter including:

- late test results;
- issues with lead registrants and substance information exchange fora (Siefs);
- suppliers not registering; and
- data-sharing disputes.

"It is now important that companies start to submit their dossiers as soon as they are ready," the agency said. "It is also important that companies do not rush to correct their dossiers if they fail the first completeness check, but continue to focus on submitting the remainder of their dossiers.

"They get ample time to address the failure. What is important is to submit before the deadline. The dossier can validly be completed after the deadline, within the time given by Echa to address the failures."

Luke Buxton

Europe desk editor

Related Articles

- Echa offers faster REACH dossier processing before April
- New REACH registration test result deadline sparks industry concerns

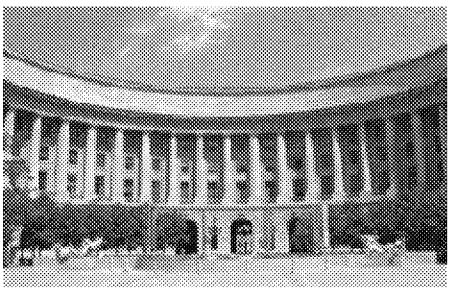
Further Information:

- Registration statistics infographic
- Echa REACH 2018 page
- Registration Q&A session

NGO scientists may reject appointment to US EPA chemical advisory panel

'Secret science' policy gives new SACC appointees pause

29 March 2018 / TSCA, United States



A recent announcement that the US EPA will be expanding the membership of its Science Advisory Committee on Chemicals (SACC) has been met with concern from members of the NGO community selected to serve on it.

The SACC – which is tasked with providing expert advice on scientific matters under TSCA – was formed in the waning days of the Obama administration. Last August, the agency signalled plans to expand it.

On 23 March, the agency announced 11 new members. These include three representing NGOs, four from industry, and four from academia or governmental organisations.

But at least one of newly chosen NGO representatives has refused to participate. And Chemical Watch has learned that all three may back out over concerns that the panel may be forced to work with limited scientific data.

Michael Wilson, national director for occupational and environmental health at the BlueGreenAlliance, "notified EPA that he was unable to accept the appointment", a spokesman for the organisation told Chemical Watch.

Ruthann Rudel, director of research at the Silent Spring Institute, is debating whether to take the position she was offered.

"I haven't decided what I'm going to do yet about my appointment," she told Chemical Watch. "I'm collecting some advice and information."

And Jennifer McPartland, senior scientist at the Environmental Defense Fund, said she had not responded to an invitation to join the panel and was surprised to see her name on the list of new appointees.

"News of [EPA Administrator Scott] Pruitt's proposal to limit the science the agency can consider has given me pause," she said in an email. She is still debating whether to accept her appointment.

Dr McPartland's concern around the EPA's so-called "secret science" policy is shared among many in the NGO community.

The new transparency initiative, signalled by Mr Pruitt in an interview with a conservative news publication last week, could bar the agency from using studies that are not publicly available to underpin regulatory decisions.

NGOs said this could result in suppressing crucial data needed to take action on hazardous chemicals under TSCA.

Science Advisory Committee on Chemicals

Formation of the SACC was required by the Lautenberg Act, to provide "independent advice and expert consultation" on the scientific and technical aspects of implementing the new TSCA. Its first 18 members were named in January last year.

The American Chemistry Council criticised the picks, of which less than a quarter were industry representatives.

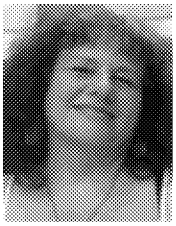
Following leadership changes to the agency under President Trump, and "after further consideration of the objectives and scope of SACC activities", the EPA said it would expand the committee.

The additional members "will increase the balance of scientific perspectives and add experts with experience in labour, public interest, animal protection, and chemical manufacturing and processing to the committee," the EPA said in its announcement.

Four of the 11 new members represent industry directly, including two of the four candidates backed by the ACC. And appointee Michael Holsapple joined the Michigan State University faculty after a long career with Dow Chemical.

The eleven new appointees are:

- Charles Barton, global manager of toxicology and risk assessment at the Valspar Corporation;
- Steven Bennett, vice president for scientific affairs at the Household and Commercial Products Association (HCPA);
- Sheri Blystone, director of regulatory affairs and product safety at SNF Holding Company;
- Susan Dempsey, risk assessor and toxicologist for the Nebraska Department of Health and Human Services;
- Thomas Hartung, a toxicology professor at Johns Hopkins University;
- Michael Holsapple, professor in the Department of Food Science and Human Nutrition at Michigan State University;
- Mark Johnson, director of toxicology at the US Army Public Health Center;
- Sidney Marlborough, senior environmental toxicologist at Noble Energy;
- Jennifer McPartland, senior scientist at the Environmental Defense Fund (EDF);
- Ruthann Rudel, director of research at the Silent Spring Institute; and
- Michael Wilson, national director for occupational and environmental health at the BlueGreenAlliance.



Julie A Miller

North American Desk Editor

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- US EPA establishes Science Advisory Committee on Chemicals
- US EPA seeks to expand Science Advisory Committee on Chemicals
- US EPA to unveil 'secret science' details in coming weeks
- TSCA could be undercut by 'secret science' requirements
- ACC backs four industry scientists for EPA chemical advisory council

OTHER ARTICLES

Gov. Inslee signs bill banning firefighting foam with toxic chemicals

NBC Right Now

Jay Inslee has signed into law a bill that makes Washington state the first to restrict the sale of firefighting foam containing certain **chemicals** of concern. The legislation bans the sale, manufacture or distribution of firefighting foam where **chemicals** known as PFAS are intentionally added, starting in July ...

Message

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Chemical Makers Worry Steep New EPA Fees Could Stifle Innovation

Posted: Mar 28, 2018, 7:29 AM EDT

By Adam Allington

Chemical manufacturers are concerned that hefty new EPA fees to support premarket reviews could stifle innovation and pose a barrier to bringing new chemicals to market.

A proposal would empower EPA to collect increased fees from chemical manufacturers and processors starting Oct. 1. The fees will allow the EPA to offset about $20 million in annual costs for implementing certain sections of the revised Toxic Substances Control Act.

EPA Administrator Scott Pruitt, in a February news release announcing the statement, said the proposed fee changes would ensure that the agency has "sufficient resources to review chemicals for safety with the highest scientific standards."

But chemical makers worry the fees could discourage innovation, particularly for developing new chemicals.

"Notifications for new chemicals in TSCA usually don't have a market yet, so many companies won't be able to afford the fees EPA is talking about," said Martha Marrapese, a partner with Wiley Rein, a Washington-based law firm specializing in chemical regulation.

"There will be a significant impact on innovation if they don't keep fees as low as possible," Marrapese told Bloomberg Environment. "If it costs thousands of dollars in fees, and EPA can't review applications in timely way...companies won't register their chemical here, they'll go somewhere else to do it."

Sticker Shock

The original TSCA capped fees for premanufacture notices (PMN) at $100 for small businesses and $2,500 for larger companies generating about $1.1 million annually. According to both industry and regulatory experts, there was general acknowledgment that the old levels—set three decades ago and never adjusted for inflation—needed to be substantially increased.

The new numbers on the table propose charging companies $16,000 for each premanufacture notice, new use notice, or microbial commercial activity notice.

"It is a sticker shock—to go from $2,500 to $16,000 for each PMN," said Rose Passarella, a senior scientific regulatory manager for Intertek, a Washington-based consultancy.

Another area of concern is the $4,700 the EPA is now proposing to evaluate requests for exemptions such as low-volume or test marketing exemptions.

"We have a number of serious concerns regarding the proposal," said Robert Helminiak, vice president of legal and government relations for the Society of Chemical Manufacturers and Affiliates, who's members include companies like Janssen Pharmaceuticals and BASF.

With exemptions, the EPA is applying substantial fees in an activity that has not historically had any assessment at all, and does not account for the market disruption it would cause, Helminiak said.

"EPA should not assess fees for processing these applications," he told Bloomberg Environment. "EPA should instead include the costs of reviewing exemption applications in the aggregate overhead costs of administering TSCA."

The Dow Chemical Co., PPG Industries Inc., and other companies contacted by Bloomberg Environment elected to defer comments about the new fees to their primary trade organization, the American Chemistry Council. That organization opted to withhold specific comments on the proposed fee structure until the end of the public comment period on April 27, according to an ACC spokesman.

PRIA Comparisons Not Accurate

The EPA already charges industry fees for pesticide registrations. But Marrapese of Wiley Rein said there are differences between the fees being discussed under TSCA and the ones collected under the Pesticide Registration Improvement Act of 2007 (PRIA).

"Pesticides are typically subject to a proprietary license, so companies are willing to invest more to pay for registrations," Marrapese said.

Marrapese notes that a substantial amount of scientific data and information are required to support the registration of a pesticide. These data can be very costly to create, which is why Congress included provisions in PRIA that provide certain rights to the data submitter. TSCA however, contains no provisions for data compensation.

"Under TSCA, once a new chemical goes onto the inventory, anyone can make it," she said.

High Enough?

EPA estimates the annual costs of carrying out testing on new and existing chemicals to be $80.2 million.

The agency also plans to collect fees to recover a portion of costs incurred it incurred from conducting chemical risk evaluations that manufacturers requested. The EPA expects the fee amount will range between $1.3 and $2.6 million per chemical.

But some said the proposed fees are not high enough—especially considering the greater scrutiny the new law requires the EPA to give new chemicals.

"Historically, the great majority of PMNs received by EPA never go on to be commercialized," said Richard Denison, lead senior scientist at the nonprofit Environmental Defense Fund.

According to EPA statistics, Denison said that of 40,000 PMNs reviewed over several decades, only about 14,000 went on to be commercialized, of which, only 5,300—or 13 percent—were subject to any kind of regulation or withdrawn by the submitter.

"This means that the great majority of PMNs were submitted with no meaningful intent by their manufacturers to commercialize them," he told Bloomberg Environment.

"This is not about innovation. In most cases, the decision not to commercialize a chemical had nothing to do with EPA's decision about it—meaning, almost two-thirds of the time, EPA had to waste public resources reviewing new chemicals that companies had no intent to commercialize," Denison said.

Focus on Exemptions

EPA officials have previously agreed with broad concern that higher fees for new chemical reviews "could create an economic barrier to innovation."

Because of that, the agency proposed a two-tier fee structure under which small businesses would pay about 80 percent less. But the definition of "small business" could change, based on criteria such as annual sales.

"More than ever, I expect you'll start to see a growing premium on TSCA exemptions," said Tom Berger, a partner with law firm Keller & Heckman LLP.

Companies could attempt to "consolidate exemptions" for things like test market R&D, or exemptions for low production volume chemicals, Berger said. "I think companies are going to start putting a lot more money into R&D, trying to get as much exemption as they possibly can," before they decide to file with EPA.

Chemical makers could soften some of the sticker shock by filing more consolidated premanufacture notices, Berger said during a March 14 webinar on fees that Keller & Heckman held.

In some cases, companies can consolidate up to six new, similar chemicals on an individual PMN, the EPA's proposed fee rule said, and he urged companies to contact the agency to make sure their chemicals meet the law's criteria for consolidation.

—With assistance from Pat Rizzuto.

Sticker Shock' on Proposed EPA Fees • German Efficiency • Raw Feelings About Raw Data

Posted: Mar 28, 2018, 6:46 AM EDT

By Chuck McCutcheon

The EPA wants to start collecting more fees from chemical manufacturers and processors to help pay for implementing parts of the recently revised toxic-chemicals law.

Those companies aren't buying the idea.

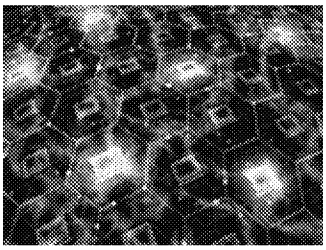
EPA Administrator Scott Pruitt said the proposal to collect "user fees" will help ensure the agency can review chemicals for safety "with the highest scientific standards," Adam Allington explains in a story being published today.

But chemical makers worry that the fees—which would be hiked from $2,500 to $16,000 in some cases—amount to "sticker shock" and could discourage innovation. Many companies won't be able to afford them, they say.

GERMANY'S BUILDINGS: Germany is trying hard to reduce greenhouse gas emissions over the next few years. But its new coalition government is looking too much at efficiency standards for new construction and not existing buildings, housing specialists tell Jabeen Bhatti in a story published today.

German cities are chock-full of older housing, ranging from prewar walk-ups to postwar reconstructed buildings. While coveted for their aesthetic appeal, many buildings still rely on antiquated heating methods and need energy-efficient renovations. Twenty percent of the country's total greenhouse gas emissions come from the nation's building sector, and 70 percent of housing stock doesn't meet current energy standards. Less than 1 percent of the needed renovations for carbon dioxide reduction have taken place.

Pruitt's Open Data Plan Could Limit Usable Research, Critics Say



EPA head Scott Pruitt's plan to ban the agency from using private or confidential data in making policy decisions would eliminate most of the scientific literature the agency reviews, scientists told Bloomberg Environment.

Washington to Be First State to Ban Firefighting Foam Chemical

Washington will be the first state to ban certain toxic chemicals in firefighting foams linked to a range of health problems when Gov. Jay Inslee (D) signs the ban into law late March 27.

INSIDEEPA.COM ARTICLES

IG Sees Uptick In Congress' Queries Into Pruitt But Budget Limits Work

EPA's Inspector General (IG) is seeing a noticeable increase in lawmakers' requests to investigate Administrator Scott Pruitt's controversial travel, security and other expenditures, but the IG says that Trump administration budget cuts, which have forced a reorganization, limit the number of such discretionary and other reviews the office can perform.

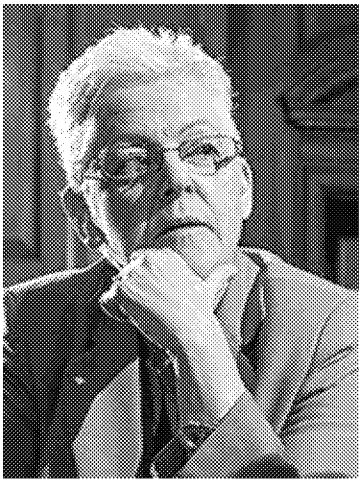
GREENWIRE ARTICLES

McCarthy, McCabe blast Pruitt's attack on 'secret science'

Maxine Joselow, E&E News

Published: Tuesday, March 27, 2018

Two former U.S. EPA officials under President Obama blasted Administrator Scott Pruitt's attack on "secret science" in a *New York Times* op-ed yesterday.



Former U.S. EPA Administrator Gina McCarthy. U.S. EPA/Flickr

Former EPA Administrator Gina McCarthy and Janet McCabe, who was acting assistant administrator of the agency's Office of Air and Radiation, sought to defend the agency's use of scientific studies when crafting regulations.

In a closed-door meeting at the Heritage Foundation earlier this month, Pruitt announced plans to restrict EPA's use of science in rulemakings (Climatewire, March 16).

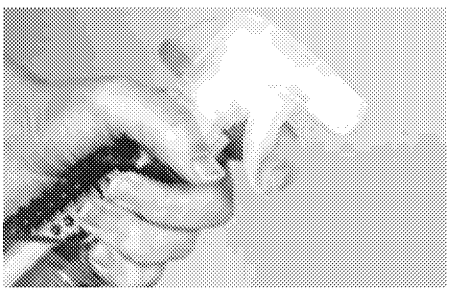
https://www.eenews.net/greenwire/2018/03/27/stories/1060077537

CHEMICAL WATCH ARTICLES

European biocides authorities agree how EDC criteria will work in practice

Papers finally adopted, criteria implemented in June

27 March 2018 / Biocides, EDCs, Europe



EU authorities have decided how the criteria for identifying endocrine disrupting chemicals will be realised in the approval processes for biocidal substances and products.

This month's meeting of the biocides competent authorities (CAs) adopted two papers after months of discussion. The endocrine disruptor criteria for biocides will begin to take effect in less than three months, on 7 June.

The criteria should have little effect on substances with an assessment report submitted before 1 September 2013. These still fall under the rules of the biocidal products Directive (BPD).

But substances with an assessment report submitted after 1 September 2013 – when the biocidal products Regulation (BPR) entered into effect – will no longer be approved, if the new criteria identify them as endocrine disrupting.

The final paper on biocidal products introduces a controversial provision: the criteria will be applied to both biocidal active and non-active substances (co-formulants) in pending product authorisation applications. This rule was met with criticism from industry, legal experts and Echa, last year.

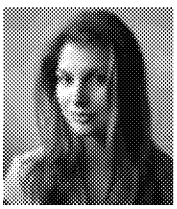
Guidance

Both the substance and product approval processes will depend greatly on the data requirements for assessing endocrine disrupting properties. Echa and the European Food Safety Authority (Efsa) are currently developing a guidance paper that will determine these. A draft of the paper was met with mixed reactions earlier this year.

Echa and Efsa's main biocides and pesticides working groups will be consulted, before publication of the final version. The biocides competent authorities and the Standing Committee on Plants, Animals, Food and Feed will also discuss it.

But Echa told the biocides CAs at this month's meeting that it is "on track" to publish the final guidance in time for June.

More detail on this story, and copies of the two CA meeting papers, are available on CW+BiocidesHub.



Vanessa Zainzinger

Biocides editor

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- EDC criteria guidance consultation ends with criticism from industry, NGOs
- EU authorities agree how EDC criteria will work in practice

EU ombudsman tells Commission to share cosmetics nano information

Official sides with NGO on catalogue notifications access

27 March 2018 / Cosmetic products Regulation, Data, Europe, Nanomaterials, Personal care

The EU Ombudsman has found the European Commission guilty of maladministration over its handling of a public access request to information pertaining to the cosmetics nano inventory.

Ombudsman Emily O'Reilly has recommended that the Commission grants NGO ClientEarth access to notifications made by cosmetics manufacturers, following a complaint made a month after the inventory was published in June last year.

Specifically, she says, the EU executive should provide them with the list of all Article 16 notifications uploaded to the cosmetic products notification portal (CPNP), redacting only those parts that are covered by an exception to access provided by law.

The Commision should also ask the NGO if it wants a sample of Article 13 notifications, she added. It has until 15 June to send its opinion on the matter.

Catalogue delay

Under the cosmetics products Regulation, the Commission had been legally required to publish a catalogue, containing the details of nanomaterials present in cosmetic products by January 2014. But this was delayed by more than three years. The EU executive put it down to poor quality notifications and the need to liaise with member states and stakeholders to jointly improve the submitted data prior to publication.

In 2016 ClientEarth asked for access to the information sent by cosmetic companies to the Commission and to the draft catalogue.

In her recommendation – published this month – the Ombudsman says she was "not convinced" by the Commission's argument, at the time of the 2016 request, that the catalogue was not completed and there were only draft internal versions. It was "neither citizen friendly, nor in line with the EU public access rules", she adds.

Some of the notifications "could in fact have been extracted from the Commission's database", Ms O'Reilly says.

Although the final version of the catalogue was not published when ClientEarth originally requested access, the Ombudsman says, the Commission "failed to consult the complainant as to whether it would want access to any of the existing draft versions. This constituted maladministration."

'Useless' catalogue

Despite the long delay to publication, ClientEarth says the catalogue still does not let people identify which cosmetics contain potentially harmful nanomaterials, or assess the threat they may pose to human health.

ClientEarth lawyer Alice Bernard says consumers need to be informed so that they can "decide for themselves" whether to use products containing them.

"Sadly, the nanomaterial catalogue finally published by the Commission is useless for consumers, since it does not identify which products contain the nanomaterials. This is not in line with the cosmetics Regulation," she says.

Notifications

ClientEarth had asked for public access to information under Article 16(10)(a) of the cosmetics Regulation or, if such a catalogue did not yet exist, to notifications under Article 13(1) for cosmetics including nanomaterials, as well as the information notified under Article 16(3).

- Article 16(10)(a) says that by 11 January 2014, the Commission had to make the inventory publicly available;
- Article 13(1) requires details, such as the category of cosmetic product and name; and
- under Article 16(3) cosmetics products containing nanomaterials shall be notified to the Commission, six months prior to being placed on the market, except where they have already been placed on the market before 11 January 2013. It also sets out a series of information requirements.

Related Articles

- Commission publishes cosmetics nano inventory
- ClientEarth files complaint over EU cosmetics nano inventory

Further Information:

- Ombudsman recommendation
- ClientEarth press release
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GREENWIRE — Tue., March 27, 2018

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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt's Open Data Plan Could Limit Usable Research, Critics Say

Posted: Mar 27, 2018, 7:21 AM EDT

By Jennifer Lu *and* Sylvia Carignan

EPA head Scott Pruitt's plan to ban the agency from using private or confidential data in making policy decisions would eliminate most of the scientific literature the agency reviews, scientists told Bloomberg Environment.

Pruitt told the Daily Caller March 19 about his intentions for allowing only "open data" in drafting regulations and said the Environmental Protection Agency could only consider studies that make their data available for public scrutiny. Further, EPA-funded studies would have to make all of their data public.

Researchers are concerned that the policy could have far-reaching effects for how the agency regulates drinking water, air quality, and chemicals including pesticides and herbicides. Supporters of the idea, however, say the public has a right to view the information used to craft rules that affect them.

The EPA estimated in 2017 that a similar requirement for open data would limit usable studies by 95 percent.

"That will essentially lead to excluding massive bodies of evidence," Jonathan Samet, a former chair of the EPA's Clean Air Scientific Advisory Committee, told Bloomberg Environment.

Pruitt's policy is similar to language in a 2017 bill (H.R.1430) introduced by Rep. Lamar Smith (R-Texas) barring the EPA from basing certain actions on anything but studies that are publicly available and substantially reproducible.

The actions include risk, exposure, or hazard assessments, air quality science documents, standards, chemical limits, waste regulations, cost-benefit reviews, and guidance.

Right to See Data

Smith believes the public has a right to see data that EPA uses to justify its regulations, Thea McDonald, a spokesperson for the House Science, Space, and Technology Committee, told Bloomberg Environment in an emailed statement March 26. Smith is the committee's chairman.

"The public, including scientists, should have the opportunity to evaluate the agency's data and independently determine whether the data supports the EPA's conclusions," Smith said in the statement. It's unclear how much of Smith's bill will be part of Pruitt's policy. The EPA didn't respond to Bloomberg Environment's emailed requests for comment.

The EPA told the Congressional Budget Office in 2017 that the provisions in Smith's bill would "strongly discourage" industry and academic researchers from working with the agency, because the EPA couldn't guarantee to protect intellectual property, trade secrets like chemical formulas, or personally identifiable information in health studies.

"It's all part of the removal of science and scientists from the decision-making process," Samet said. "We're moving away from evidence-based regulations, which is what EPA does, which is what EPA should do, which is what EPA was set up to do."

Confidential Information

There's an ongoing debate in the research world about the merits of confidentiality versus the need for reproducible results, Tony Cox, a member of the EPA's Science Advisory Board and chairman of the Clean Air Scientific Advisory Committee.

Pruitt's plans align with scientific journals' increasing desire to promote transparency with data and to make more models and analyses readily available, Cox told Bloomberg Environment in an email.

Transparency "is an important part of the process of creating sound and trustworthy science," he said.

The EPA's Office of Pesticides Programs recently relaunched an attempt to obtain data on a Columbia University public health study on the effects of the insecticide chlorpyrifos on children exposed in utero. The EPA, under the Obama

administration, justified banning the chemical in part on the study, which linked levels of the pesticide in umbilical cord blood with neurodevelopmental delays in childhood.

Chlorpyrifos manufacturer Dow AgroSciences criticized the Columbia study on grounds that the EPA didn't have access to the raw data.

Institutional Review Boards

The ability to reproduce a study's results is important, but the relevant methods and techniques are what need to be shared, not patient personal data, or trade secrets and intellectual property, Gretchen Goldman, research director at the Union of Concerned Scientists' Center for Science and Democracy, told Bloomberg Environment.

Research institutions, such as universities and military facilities, have institutional review boards, which protect sensitive information by requiring researchers to sign ethics agreements before reviewing data.

The boards review researchers' intent to view or use sensitive data, and ensure researchers have gone through training about the appropriate uses of human studies data and how to secure it.

Boards also want to ensure ethical guidelines are followed in how test animals or people are exposed to harms and that personally identifying information will not be released, Goldman said.

Foundational Fine Particulates

Rallying cries against "secret science" can be traced back two decades to when fine particulate matter was included in the list of EPA-regulated air pollutants in 1997, Samet said.

Fine particulate matter—microscopic particles 2.5 microns in diameter or smaller—is emitted by a range of sources, including motor vehicles, power plants, and factories.

The agency had based its particulate-matter standards on two landmark studies, the Harvard Six Cities study and the American Cancer Society study.

Both contained "pivotal evidence" showing that people living in cities with higher levels of air pollution were at higher risk of dying, said Samet, the dean of the Colorado School of Public Health.

"At the time, there was a lot of discussion generated by industry stakeholders where if this data was so important, the data should be public," Samet said.

Peer Review

Those who decry "secret science" don't understand or don't acknowledge that the two studies were peer-reviewed and the raw data was reanalyzed by an independent research group, C. Arden Pope III, a co-author on the Harvard Six Cities study, told Bloomberg Environment.

That independent research group, the Health Effects Institute, gets funding from government agencies, including the EPA, and the automotive industry.

Health Effects Institute researchers found similar relationships between living in more polluted areas and a higher risk of death, Daniel Greenbaum, president of HEI, told Bloomberg Environment.

Findings from the two original studies became the bedrock for how the agency justifies its air regulations, from the Clean Power Plan to rules reducing mercury and toxic air emissions from power plants.

If you look at the cost-benefit analyses the EPA has done, most of them point to fine particulate matter exposure as the single largest contributor to the number of avoidable deaths, Greenbaum said. "And that is primarily calculated using the American Cancer Society and the Harvard Six Cities results."

"For those that don't want to reduce their pollution, one of the strategies they use is to criticize the science itself," Pope said. "I think that's pretty obvious to anyone that watches what's going on."

Greenbaum also warned that limiting what kind of science can be used to set regulations would "cut both ways."

While particulate-matter studies point toward lowering the threshold to protect public health, studies on nitrogen dioxide—emitted by cars and factories, eventually forming ozone—suggest no additional health benefits at lower nitrogen dioxide standards, Greenbaum said.

If Smith's bill had been passed, the "Honest Act would say those studies aren't available," and regulated industries wouldn't receive relief, Greenbaum said.

—With assistance from Tiffany Stecker.

Furor Over EPA 'Open Data'

Posted: Mar 27, 2018, 6:41 AM EDT

By Chuck McCutcheon

Scott Pruitt wants to ban the EPA from using private or confidential data in making policy decisions. Scientists have a problem with that: They say it gets rid of much of the literature the agency reviews.

Pruitt, the EPA's administrator, has discussed allowing only "open data" in drafting regulations and said the agency should only consider studies that make information available for public scrutiny, Jennifer Lu and Sylvia Carignan write in a story being published today. The idea's backers say people have a right to view the information used to craft rules that affect them.

But the EPA estimated in 2017 that a similar requirement for open data would limit usable studies by 95 percent.

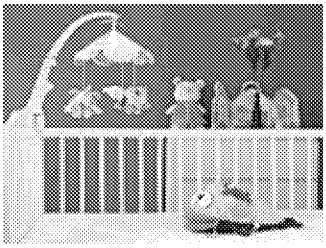
"That will essentially lead to excluding massive bodies of evidence," says Jonathan Samet, a former chair of the EPA's Clean Air Scientific Advisory Committee.

CALIFORNIA RETALIATION? As the Trump administration begins dismantling Barack Obama's ambitious auto efficiency regulations, California is said to be poised to retaliate by doing something that automakers have feared: de-coupling the state's rules with those set in Washington.

The state intends to revoke its so-called "deemed to comply" provision, two people familiar with the matter told Bloomberg News. The obscure-but-important state rule declares that carmakers that satisfy the EPA's tailpipe greenhouse gas standards automatically fulfill California's rules, too.

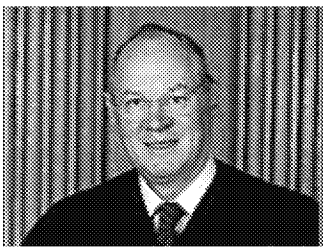
The dispute comes as an American Lung Association survey released today finds 70 percent of voters say EPA should keep its greenhouse gas standards for model years 2022-2025 at their current stringency.

Israel Limits Phthalates in Baby Changing Products After Expose



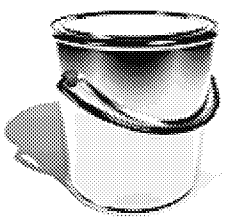
Israel is fast-tracking a strict limit on baby mattresses, changing mats, and other products found to contain high levels of endocrine-disrupting chemicals after a regulatory glitch allowed their sale.

Kennedy Recused After Late-Discovered Conflict From 1985 Case



Justice Anthony M. Kennedy will sit out of an environmental case to be argued in April because he heard an earlier iteration of the case while he was sitting on the U.S. Court of Appeals for the Ninth Circuit 33 years ago.

Brazil Begins Enforcing Old Law Limiting Lead Levels in Paint



A now-enforceable Brazilian law that limits lead in childrens' and household paints to 0.06 percent only will affect small, non-lab-tested paint producers, an association representing major producers said.

INSIDEEPA.COM ARTICLES

EDF Signals New Chemical-Specific Path To Target EPA SNURs Under TSCA

The Environmental Defense Fund (EDF) is warning that a draft EPA rule allowing a new use of an existing chemical is "legally vulnerable," suggesting a new chemical-specific path for environmentalists to challenge EPA's approval of new chemical uses under the revised Toxic Substances Control Act (TSCA).

Pruitt's Bid To End 'Secret Science' Faces Legal, Implementation Hurdles

Administrator Scott Pruitt's pending plan to apply a sweeping new data transparency requirement at EPA is expected to face legal and implementation controversies likely as soon as it is released, agency watchers say, including potential violations of medical privacy protections, trade secret information and other data that form the basis for air quality standards, pesticide and chemical approvals and other rules.

EPA Seeks An Extra 90 Days To Propose TSCA Lead Dust Rule Update

EPA is formally asking a federal appellate court to clarify when it made final its Dec, 27 order requiring the agency to propose -- within 90 days -- an update to its lead dust hazard standard for residential buildings and to grant an additional 90 days to comply with the order, though environmentalists indicate they oppose the request.

California DTSC Faces Debate Over Reach Of Review For PFAS In Carpets

Industry and environmentalists are battling over which per- and polyfluoroalkyl substances (PFAS) California's toxics department should assess in its proposal to list carpets and rugs containing the substances as a "priority product" under its green chemistry program, a decision that could drive how strictly the products are regulated.

EPA Adds 11 Members To TSCA Advisory Panel For Increased 'Balance'

EPA has boosted the size of its new panel dedicated to advising the agency on chemical science and management issues, adding 11 new members to the now 29-member panel.

EPA Gets Budget Reprieve In FY18 But Some Query Whether It Will Last

EPA appears to have largely escaped Trump administration plans to cut its budget by 31 percent in fiscal year 2018 after lawmakers unveiled a spending bill for the remainder of the year that funds the agency at essentially FY17 levels while also increasing funding for key infrastructure programs.

GREENWIRE ARTICLES

Trump picks Ford executive to lead international office

Kevin Bogardus, E&E News reporter

Published: Monday, March 26, 2018

President Trump will nominate a senior manager at Ford Motor Co. to head U.S. EPA's international and tribal affairs office.

Chad McIntosh has spent nearly 20 years at Ford, where he has helped manage the auto giant's environmental policies.

The engineer and attorney led Ford's effort to have its American, Canadian and Mexican assembly plants comply with environmental law. McIntosh has also worked on regulatory compliance, permitting and response to enforcement actions for several of the company's plants across the world.

https://www.eenews.net/greenwire/2018/03/26/stories/1060077407

Judges want more info from EPA on chemical rule delays

Amanda Reilly, E&E News reporter

Published: Monday, March 26, 2018

Federal judges sought additional details Friday from U.S. EPA in a lawsuit challenging the agency's delay in Obama-era chemical safety rules.

The three-judge panel of the U.S. District Court for the District of Columbia Circuit asked EPA to provide instances where any federal agencies have changed the effective or compliance dates for a regulation based on administrative reconsideration of that rule.

EPA is to provide a "comprehensive list of examples" by April 3.

"If a comprehensive list would be excessively burdensome to produce, EPA shall explain why that is so and shall produce as many examples as practicable," the judges ordered around 5 p.m. Friday.

https://www.eenews.net/greenwire/2018/03/26/stories/1060077437

CHEMICAL WATCH ARTICLES

EU withdrawal guidelines exclude UK role in Echa

26 March 2018 / United Kingdom

In guidelines adopted last week on the UK's withdrawal from the EU, the European Council has repeated its stance that Britain will play no role in EU agencies, such as Echa, once it leaves the trade bloc in one year's time.

The Council also "further reiterates" that the Union "will preserve its autonomy as regards its decision making, which excludes participation of the United Kingdom as a third-country in [its] institutions and in the decision making of [its] bodies, offices and agencies".

There can be no "cherry picking", it adds, through participation in the single market based on a sector-by-sector approach. This "would undermine the integrity and proper functioning of the single market".

And the role of the EU's Court of Justice will also be "fully respected", it says.

The wording will unsettle British prime minister Theresa May who, earlier this month, said the UK government is to seek "associate membership" of Echa and other European agencies as part of the EU withdrawal negotiations.

Also this month, Cefic and the UK chemicals industry broadly welcomed a conditional agreement on the transition period after the country leaves the Union.

Negotiations between the EU and the UK continue, with a deal expected to be finalised at the European Council summit this October.

Related Articles

- Prime minister: UK to seek 'associate membership' of Echa

- Chemicals industry welcomes Brexit transition period agreement

Further Information:

- Guidelines

European Commission consults on two draft cosmetics nano opinions

26 March 2018 / Europe, Nanomaterials, Personal care

The European Commission's Scientific Committee on Consumer Safety has opened consultations on two draft opinions on nanomaterials in cosmetics. They are for:

- styrene/acrylates copolymer (nano) and sodium styrene/acrylates copolymer (nano) when used in leave-on cosmetics products with a maximum concentration limit of 0.06%; and
- colloidal silver (nano) when used in cosmetics, including toothpastes and skin care products, with a maximum concentration limit of 1%.

In both of SCCS's preliminary opinions, the committee was not able to decide on the safety of the materials due to insufficient data.

The consultation periods will close on 11 and 15 May respectively.

Further Information:

- Colloidal silver (nano) draft opinion
- Styrene/Acrylates copolymer (nano) draft opinion

Danish Consumer Council says SVHC app is a success

'High hopes' that EU-wide app will put pressure on companies

27 March 2018 / Confidentiality & right-to-know, Denmark, Europe, Retail, SVHCs

The Danish Consumer Council said its Tjek Kemien app, which helps consumers identify substances of very high concern (SVHCs) in products, has been a success, despite a decrease in usage.

At Chemical Watch's Global Business Summit, held in Amsterdam earlier this month, Jakob Zeuthen, head of environment policy at the Danish Chamber of Commerce, said the number of scans made through the app had fallen.

But Claus Jørgensen, senior project manager at the council, told Chemical Watch: "It's been a success in the way that business knows the app and consumers are more aware of their right to know, but it's not a success if you want increasing numbers of scans every year."

The app allows consumers to scan a product barcode and automatically send an Article 33 request to the manufacturer or retailer, asking if the product contains SVHCs. Under Article 33 of REACH, suppliers are legally obliged to provide the information, free of charge, within 45 days.

Statistics from the two major Danish supermarkets - Coop and Dansk Supermarched - show the number of requests they received from Tjek Kemien dropped from 88 in 2016 to 16 in 2017.

But Mr Jørgensen said these figures do not reflect the total number of scans made in the supermarkets. This is because some would have been answered immediately through the app's database of product information or been sent directly to the manufacturer.

The app was used to make 14,000 scans last year and more than 120,000 times since its launch in 2014. It was used 832 times in January this year.

'High hopes'

Mr Jørgensen said the council had stopped promoting Tjek Kemien in order to focus on the AskREACH project, which will launch an EU-wide app next year. It is one of 20 partnership organisations involved in the initiative, led by the German Environment Agency (UBA).

Tjek Kemien will be discontinued when the EU-wide app launches and existing users will be redirected towards the new app through a system update.

He said there were "high hopes" that it would be popular with consumers and encourage companies to be prepared for Article 33 requests.

"On a larger scale we'll have greater success than we do here in Denmark, because [it] is such a little market. Our goal in the campaign is to get many millions of scans to put pressure on the companies," he said.

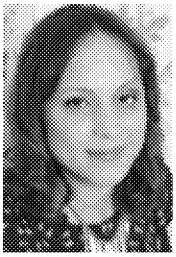
Another reason for the decline in use of the Tjek Kemien app is the 45-day period to receive information from manufacturers, which Mr Jørgensen said was off-putting for consumers.

He said: "If you see a big TV in the sale and you find out you have to wait 45 days to get an answer about SVHCs, you might not wait. The 45 days is a barrier."

AskREACH is encouraging companies to add product information to its database, so requests can be processed immediately without waiting for a response from the manufacturer.

The council is in the process of getting permission from companies in its Tjek Kemien database to be added to that of AskREACH.

Mr Jørgensen said this could be used as a "marketing tool" for companies which do not use SVHCs in their products.



Tammy Lovell

Business reporter

Related Articles

- EU-wide app to learn from Danish project problems
- SVHCs
- Commission study shows low industry response to Article 33 requests
- EU-wide consumer app aims to foster substitution of SVHCs

Further Information:

- Tjek Kemien website
- AskREACH

OTHER ARTICLES

Toxic Chemicals May Increase Chances of Regaining Weight After Dieting

Environmental Working Group

Exposure to fluorinated industrial chemicals, known as PFAS or PFC chemicals, may increase the amount of weight that people, especially women, regain after dieting, according to a new study by Harvard University researchers, published in PLOS Medicine. It found that women with higher levels of ...

Shupe: Protecting Vermonters from toxic chemicals

Bennington Banner

Among other changes, the agency will no longer require that manufacturers who want to produce new, potentially **hazardous chemicals** sign legal agreements that restrict their use under certain conditions. This begs the question: If the EPA is no longer protecting citizens from toxic pollution, do the states ...

The EPA planned to ban a deadly paint-stripping chemical. Will it follow through?

Center for Public Integrity

Even if these efforts bear fruit, they represent a patchwork approach that Congress seemed intent on avoiding when it amended the **Toxic Substances** Control Act in 2016. That legislation gave the EPA clear authority to ban chemicals presenting an "unreasonable risk" to health or the environment. Often ...

Message

From: EPA Press Office [press=epa.gov@cmail20.com]
on behalf of EPA Press Office [press@epa.gov]
Sent: 3/27/2018 11:05:01 AM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: The EPA Cleans Up Its Science

THE WALL STREET JOURNAL

The EPA Cleans Up Its Science

Now Congress Should Act To Lock In Place Data Transparency
Steve Milloy
March 26, 2018
https://on.wsj.com/2IV9LeH

The Environmental Protection Agency will no longer rely on "secret" scientific data to justify regulations, Administrator Scott Pruitt announced last week. EPA regulators and agency-funded researchers have become accustomed to producing unaccountable, dodgy science to advance a political agenda.

The saga began in the early 1990s, when the EPA sought to regulate fine particulate matter known as PM2.5—dust and soot smaller than 2.5 microns in diameter. PM2.5 was not known to cause death, but by 1994 EPA-supported scientists had developed two lines of research purporting to show that it did. When the studies were run past the EPA's Clean Air Science Advisory Committee, it balked. It believed the studies relied on dubious statistical analysis and asked for the underlying data. The EPA ignored the request.

As the EPA prepared to issue its proposal for PM2.5 regulation in 1996, Congress stepped in. Rep. Thomas Bliley, chairman of the House Commerce Committee, sent a sharply written letter to Administrator Carol Browner asking for the data underlying studies. Ms. Browner delegated the response to a subordinate, who told Mr. Bliley the EPA saw "no useful purpose" in obtaining the data. Congress responded by inserting a provision in a 1998 bill requiring that data used to support federal regulation must be made available to the public via the Freedom of Information Act. But it was hastily written, and a federal appellate court held the law unenforceable in 2003.

The controversy went dormant until 2011, when a newly Republican Congress took exception to the Obama EPA's anticoal rules, which relied on the same PM2.5 studies. Again the EPA was defiant. Administrator Gina McCarthy refused requests for the data sets and defied a congressional subpoena.

Bills to resolve the problem died in the Senate. Democrats argued that requiring data for study replication is a threat to intellectual property and an invasion of medical privacy. In fact, the legislation would protect property by requiring a confidentiality agreement, and no personal medical data or information would have been released.

This sort of data is already routinely made public for research use. In 2012 I was desperate for a way around the Obama EPA's secrecy on the PM2.5 issue, I found out in 2012 that I could get California death-certificate data in electronic form. The state's Health Department calls this sort of data "Death Public Use Files." They are scrubbed of all personal identifying and private medical information. Some of my colleagues used this data to prepare a 2017 study, which found PM2.5 was not associated with death.

The best part is that if you don't believe the result, you can get the same data for yourself from California and run your own analysis. Then we'll compare, contrast and debate. That's how science is supposed to work.

It would be better if Congress would pass a law requiring data transparency. A future administrator may backslide on the steps Mr. Pruitt is taking. In the meantime, we have science in the sunshine.

To Read The Full Article Click Here

Visit The EPA's Newsroom

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
Sent: 8/24/2018 5:44:47 PM
To: Dunton, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ffa0e71e87448cc9fd86ba1379ea93a-Dunton, Cheryl]
Subject: Re: Quote from you in NYT article today

Yes!

****

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273
Personal Phone / Ex. 6
beck.nancy@epa.gov

On Aug 24, 2018, at 1:42 PM, Dunton, Cheryl <Dunton.Cheryl@epa.gov> wrote:

> Oh ok, whew.
>
> **From:** Beck, Nancy
> **Sent:** Friday, August 24, 2018 1:42 PM
> **To:** Dunton, Cheryl <Dunton.Cheryl@epa.gov>
> **Subject:** Re: Quote from you in NYT article today
>
> **Deliberative Process / Ex. 5**
>
> **********
>
> Nancy B. Beck, Ph.D., DABT
> Deputy Assistant Administrator
> Office of Chemical Safety and Pollution Prevention
> P: 202-564-1273
> Personal Phone / Ex. 6
> beck.nancy@epa.gov
>
> On Aug 24, 2018, at 1:38 PM, Dunton, Cheryl <Dunton.Cheryl@epa.gov> wrote:
>
> **Deliberative Process / Ex. 5**
>
> https://www.nytimes.com/2018/08/24/business/epa-pesticides-studies-epidemiology.html?action=click&module=Top%20Stories&pgtype=Homepage

Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science'

Backed by agrochemical companies, the current administration and Congress are moving to curb the role of human health studies in regulation.

Aug. 24, 2018

A strawberry field in California's Salinas Valley, where a yearslong study, funded in part by the Environmental Protection Agency, has linked pesticides to ailments in children of farm workers.Carlos Chavarría for The New York Times

SALINAS, Calif. — José Camacho once worked the fields here in the Salinas Valley, known as "the Salad Bowl of the World" for its abundance of lettuce and vegetables. His wife still does.

But back in 2000, Mr. Camacho, who is 63, got an unusual phone call. He was asked if he wanted to work for a new project studying the effects of pesticides on the children of farm workers.

"This seemed really crazy," he recalled saying at the time, since he barely spoke English. "A research study?"

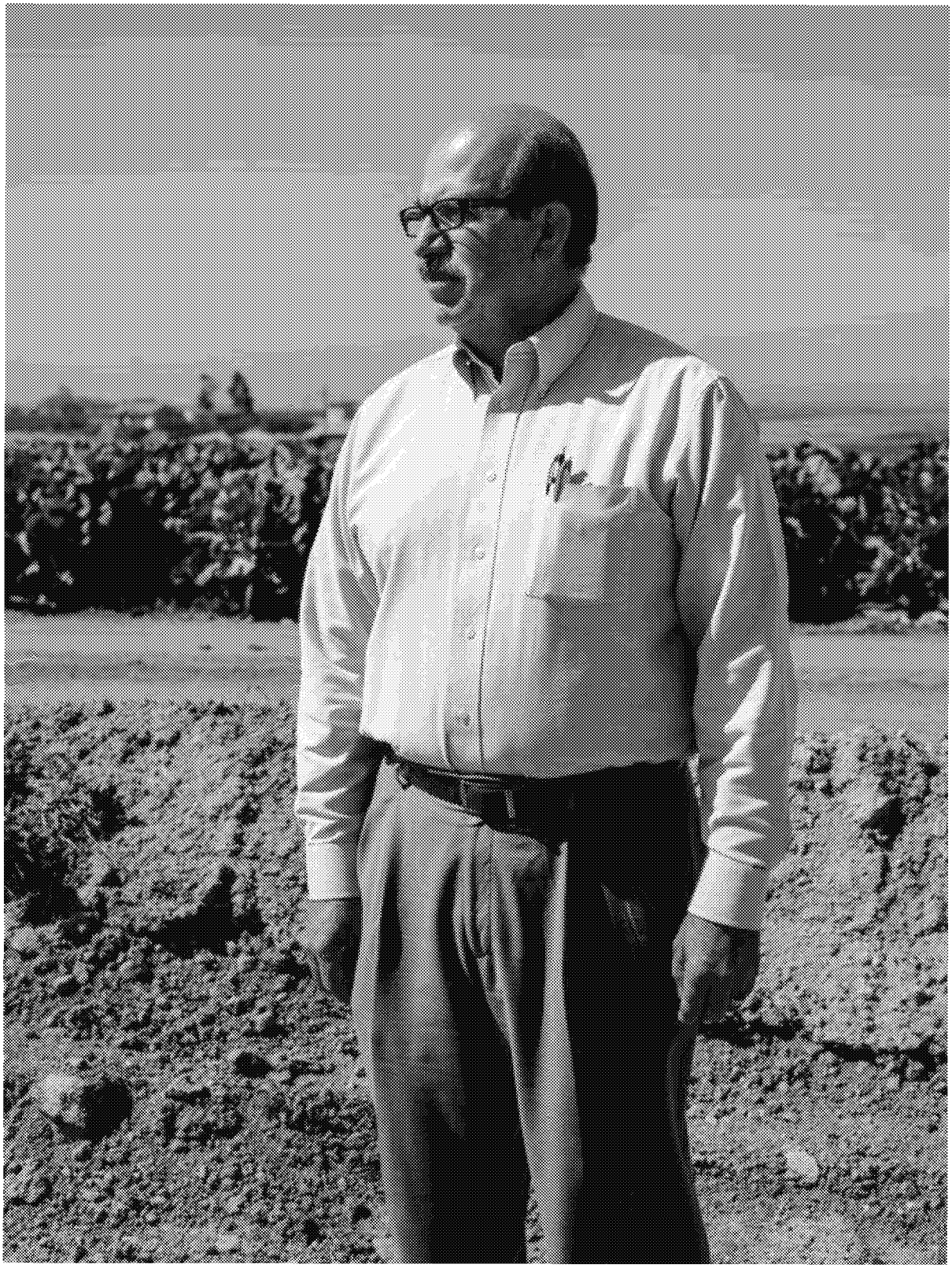
The project, run by scientists from the University of California, Berkeley, and funded in part by the Environmental Protection Agency, is still going all these years later. Known as Chamacos, Spanish for "children," it has linked pesticides sprayed on fruit and vegetable crops with respiratory complications, developmental disorders and lower I.Q.s among children of farm workers. State and federal regulators have cited its findings to help justify proposed restrictions on everything from insecticides to flame-retardant chemicals.

But the Trump administration wants to restrict how human studies like Chamacos are used in rule-making. A government proposal this year, called Strengthening Transparency in Regulatory Science, could stop them from being used to justify regulating pesticides, lead and pollutants like soot, and undermine foundational research behind national air-quality rules. The E.P.A., which has funded these kinds of studies, is now labeling many of them "secret science."

Studying disease trends in specific groups of people — a branch of medicine known as epidemiology — started to gain currency at the E.P.A. in recent years. These studies can be difficult because they require adjusting for all the various substances people are exposed to beyond pesticides. But researchers had amassed years of data from a wave of compelling chemical studies begun in the 1990s, giving regulators a new body of research to incorporate into their decision-making.

Under the Obama administration, the E.P.A., which had long favored tests on rats and other laboratory animals in its pesticide regulation, began considering epidemiological studies more seriously. The agency leaned on this type of research in proposing to ban an insecticide called chlorpyrifos in late 2016, and has been repeatedly prodded to take action on the chemical by federal courts.

But weeks after Donald J. Trump was elected president, CropLife America, the main agrochemical trade group, petitioned the E.P.A. to "halt regulatory decisions that are highly influenced and/or determined by the results of epidemiological studies" unless universities were forced to share more of their data.



José Camacho was asked in 2000 to participate in the study, which tracks families as they go about their normal lives. Such research was embraced by the E.P.A. during the Obama administration.Carlos Chavarría for The New York Times

Industry leaders aggressively challenged such studies in high-level meetings and emails with E.P.A. leaders, according to thousands of pages of documents obtained through Freedom of Information Act requests. One trade group invited a top E.P.A. official to meet with its Washington lobbyist last year, complaining that "carefully controlled" animal studies were giving way to "conclusions reflected in epidemiological papers."

Gary W. Van Sickle, executive director of the California Specialty Crops Council, wrote to the agency last September that "there have been serious flaws with E.P.A.'s conclusion to use these data."

The council, representing growers of crops as diverse as carrots, garlic, pears and peppers, cited "inappropriate use of the epidemiology."

The E.P.A., whose new leadership is seeded with industry veterans, has responded. In a mid-July assessment of atrazine, a widely used weed killer long banned in Europe, the agency reviewed and dismissed 12 recent epidemiological studies linking the herbicide to such ailments as childhood leukemia and Parkinson's disease. It echoed the conclusions of research funded by Syngenta, atrazine's manufacturer, finding the chemical unlikely to cause cancer.

Before scandals forced Scott Pruitt out last month as head of the E.P.A., he proposed the transparency regulation. It would ban many epidemiological studies, and other outside research, unless more data behind the studies was made public. In doing so, he revived a strategy advanced for years by congressional Republicans and corporate interests like tobacco companies.

"The era of secret science at E.P.A. is coming to an end," Mr. Pruitt proclaimed at the time. The agency's new acting administrator, Andrew R. Wheeler, says he's moving forward with the proposal, as the agency re-evaluates a class of widely used insecticides, called organophosphates, that have been the subject of numerous epidemiological studies like Chamacos.

Nancy B. Beck, a chemical industry veteran who is the E.P.A.'s deputy assistant administrator, said there was no attempt to thwart epidemiology, adding that the agency was committed to "the best available science in the most transparent manner."

But academics and state health officials say universities are being pressured to release data that would ultimately divulge the identities of study

participants, a strategy once used by tobacco companies seeking to undermine research on the dangers of smoking. While participant data is shared with regulators in drug trials, academics fear that the E.P.A.'s proposal would additionally require divulging confidential personal information, potentially violating privacy regulations for federally funded research.

Ana Lilia Sanchez, a farm worker and the mother of a participant in the Salinas Valley study, said her family took precautions to avoid pesticide contamination.Carlos Chavarría for The New York Times

"It is a naked attempt to use a false claim that something nefarious is going on with these studies in an effort to allow industry to challenge conclusions that are not in their favor," said James Kelly, a manager of environmental surveillance at the Minnesota Department of Health.

A Wave of Studies, an Uneasy Industry

An advertisement in a Nebraska student newspaper was looking for people who wanted to "earn extra money." Thirty-six college student volunteers and others from the community who responded were paid $460 to drink gelatin capsules filled with the pesticide chlorpyrifos, at up to 300 times levels the E.P.A. considered safe, without a full discussion of the risks.

Sponsored by Dow Chemical, this study, conducted in 1998, was one of the last of its kind. That year, the E.P.A. banned the use of studies exposing people to pesticides, and it continues to severely restrict them.

Epidemiology, which has been used to examine everything from the effects of climate change to childhood obesity, offered a way to continue studying disease trends, amid new legal requirements to examine how pesticides particularly affect infants and children. And it could do so by tracking people during their normal lives instead of treating them as if they were lab rats. Chamacos and other studies began almost immediately, although it took decades to collect sufficient data and study how participants changed over time.

One study by Columbia University researchers linked an insecticide to developmental delays in toddlers. Another, by scientists at the University of California, Los Angeles, connected pesticides to Parkinson's disease. Academics at the University of Rochester found that pesticides lower sperm counts in men, while researchers from the Harvard School of Public Health found lower fertility in women.

By 2015, there was a growing body of research, often funded in part by the E.P.A. The agency decided that year to consult epidemiology more seriously in its evaluation of glyphosate, the world's most popular weed killer and the active ingredient in Monsanto's Roundup.

"This is a watershed event in our Program, and one which I feel particularly proud to be a part (go epi!!)," Carol Christensen, then an E.P.A. epidemiologist, wrote in a 2015 email to a colleague — using "epi" as shorthand for epidemiology. "In the 35 year history of our program, this will be the FIRST time epi studies are actively considered in the decision making."

Yet even then, there was friction over what to make of studies aiming to determine whether glyphosate causes cancer.

One E.P.A. division, the Office of Research and Development, closely examined epidemiological research and came to believe either that glyphosate was likely to cause cancer or that there was at least some evidence suggesting a problem. But another division, the Office of Pesticide Programs, was dismissive of epidemiological studies and determined that glyphosate was not a carcinogen, a view that prevailed at

the E.P.A., according to interviews, emails and an internal memo obtained by The New York Times. Those involved in the agency's debates on epidemiology spoke on the condition of anonymity because the discussions weren't public.

Monsanto said in a statement that "we cannot speak to the internal E.P.A. discussions" but emphasized the agency's ultimate finding that glyphosate was not likely to cause cancer.

The cancer question received renewed attention this month when a California jury awarded $289 million to a groundskeeper who alleged that the chemical had sickened him. In his closing argument, the plaintiff's attorney, R. Brent Wisner, called epidemiology one of "the three pillars of cancer science" that the case relied on.

At the E.P.A., the debate swung in favor of epidemiology. While such studies are often complex and can be of varying quality, the agency was reluctant in the past to give them as much weight as lab experiments on animals. But by the Obama administration's final months, the agency moved for the first time to ban a pesticide largely because of epidemiological research.

The pesticide, chlorpyrifos, was the same one ingested years earlier by unwitting Nebraskans. It is applied to crops like apples, oranges and strawberries to combat insects like spider mites and sap-sucking bugs.

In California alone, chlorpyrifos was sprayed on 640,000 acres in 2016, according to state data. And research from Salinas, and the Chamacos study, became a central element in the E.P.A.'s recommendation.

"There is a breadth of information available on the potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos," the agency concluded in 2016, also citing epidemiological research from Columbia University and the Icahn School of Medicine at Mount Sinai.

The pesticide industry's reaction was loud and intense.

Monsanto, in emails with the E.P.A., was dismissive of critical epidemiological research related to Roundup, writing that "such studies are well known to be prone to a number of biases."

A Trump administration proposal would prevent the E.P.A. from using many epidemiological studies, like the one in Salinas, unless more data behind them was made public.Carlos Chavarría for The New York Times

Dow Chemical said in reports submitted to the E.P.A. that "the evidence from these studies is insufficient" and called chlorpyrifos a "proven first-line of defense" against new pest outbreaks.

A month after taking over the E.P.A., Mr. Pruitt acted. He disregarded agency scientists and rejected the proposed chlorpyrifos ban, later calling for "a new day, a new future, for a common-sense approach to environmental protection."

View From the Field

Ana Lilia Sanchez, 50, has worked in the fields in Salinas more than half her life, and one of her daughters has been a Chamacos study participant.

Ms. Sanchez has learned to watch for drifting droplets or the whir of a helicopter spraying overhead.

"Sometimes when we feel it, or we hear it, we start talking about it," she said recently, sitting with her 5-month-old granddaughter at her home on a Salinas cul-de-sac. "Why wouldn't they tell us, you know, to get out of

here, to not come today?" she asked. "Women, they cover themselves, but men are working in short sleeves, so they are more exposed."

Insecticides like chlorpyrifos are organophosphates, from the same chemical family as nerve agents like sarin and Novichok, the Russian-developed compound linked to recent attacks in Britain. While the safety of insecticides is extensively tested, long-term health impacts, or even how far pesticides drift, are the subject of continuing disagreement.

Ms. Sanchez showers after work, before touching her granddaughter.

"I also put my clothes aside," she said. "We separate the clothes we use when we're working, both my husband and I, and wash them separately so they're not contaminated."

While some human studies examine potential harm from pesticide residue found on fruits and vegetables, the Chamacos project is more personal, following hundreds of children in the heart of where American food is grown. California has the nation's largest agricultural industry and uses more than 200 million pounds of pesticides annually.

Brenda Eskenazi, the director of the Salinas Valley project, said that "well-controlled epidemiologic studies" were essential for understanding "how things affect human health."Carlos Chavarría for The New York Times

For locals, pesticides are part of life. "It's a big difference from when I was working," Mr. Camacho said, while standing in a strawberry field framed on three sides by distant hills. Men and women were bent over nearby, pulling weeds. "My supervisor would say: 'That's not dangerous. Just keep working.' There was no information."

Chamacos is built on an unsettling premise: What happens to children of pregnant mothers certain to have pesticides in their bloodstreams? The E.P.A. and other government agencies have spent millions of dollars funding Chamacos.

Half the Chamacos children have been tracked since before birth. Researchers have collected 350,000 samples of blood, urine, breast milk and even household dust and spent nearly two decades studying maturing children. They perform neurodevelopmental and physical assessments and study factors like diet and school performance. After nearly two decades, the study's data appears in more than 160 academic papers.

During a visit to the Chamacos office in Salinas, Brenda Eskenazi, the director of the project and a professor of epidemiology at Berkeley, was testing out brain monitoring equipment, wearing what looked like a black swim cap strewn with knobs and wiring. She has long been fascinated with cognitive development, going back to when she saw a Woodstock reveler — one having a bad acid trip — dive into pavement.

"Why did he do that?" Ms. Eskenazi remembers wondering at the time. "What was he thinking? What's going on in that brain?"

"Any science is imperfect," she said, but stressed that "well-controlled epidemiologic studies" were essential for understanding "how things affect human health." She added, "Otherwise you're just making huge assumptions that a rodent is the same as a human."

A Bitter Debate

The day after Mr. Pruitt made his March 2017 decision to reject a ban on chlorpyrifos, he hosted top executives from one of the nation's largest farming and pesticide trade organizations for a closed-door conversation.

Near the top of the meeting agenda was "Epidemiology Study Policy" in the aftermath of the "chlorpyrifos matter," according to internal records.

McKinnon Elementary School in Salinas. The pesticide industry contends that epidemiological studies are prone to biases and not as reliable as testing on lab animals.Carlos Chavarría for The New York Times

"There are no guideposts, if you will, for what is a legitimate, useful epidemiology study and what is not," Jay Vroom, CropLife America's president, said in an interview, explaining what he had told agency officials at this and other meetings.

In a subsequent letter to the E.P.A., a CropLife America lobbyist said the agency was relying on a "shortsighted approach," and the group submitted formal proposals to curb the embrace of epidemiology the E.P.A. undertook under the Obama administration.

Mr. Pruitt responded with his proposal, made this past spring, to ban epidemiological and other studies that did not make study details public, including at least some information on study participants.

Academics have resisted previous requests to review their data, notably at Columbia University. In a 2016 letter to the agency, a university official wrote that it could not provide "extensive individual level data to E.P.A. in a way that ensures the confidentiality" of "our research subjects."

David Michaels, an epidemiologist at George Washington University's School of Public Health and head of the Occupational Safety and Health Administration during the Obama administration, said Mr. Pruitt's plan was not about transparency but about discrediting studies that made pesticides look bad.

"The underlying justification for this 'transparency' proposal is a caricature of how science really works," Mr. Michaels said at a recent hearing. "The cynical approach proposed by E.P.A. can be best described as 'weaponized transparency.'"

It is no coincidence, he said, that the term "secret science" was also used in the 1970s when the tobacco industry was trying to forestall critical research about smoking.

Researchers have had wins. This month, a federal appeals court ordered the E.P.A. to ban chlorpyrifos, citing findings from human studies. The Trump administration is mulling whether to appeal.

But epidemiologists are unsettled. In mid-July, after nearly two decades of work on Chamacos, the E.P.A. emailed Ms. Eskenazi requesting "the original data" from her research, citing "uncertainty around neurodevelopmental effects associated" with pesticides she has studied. The agency made a similar request to Columbia.

Ms. Eskenazi, worried about her study participants' privacy, alerted university lawyers. She is now concerned that the E.P.A. may try to undermine her study's repeated findings that some pesticides may be harming children.

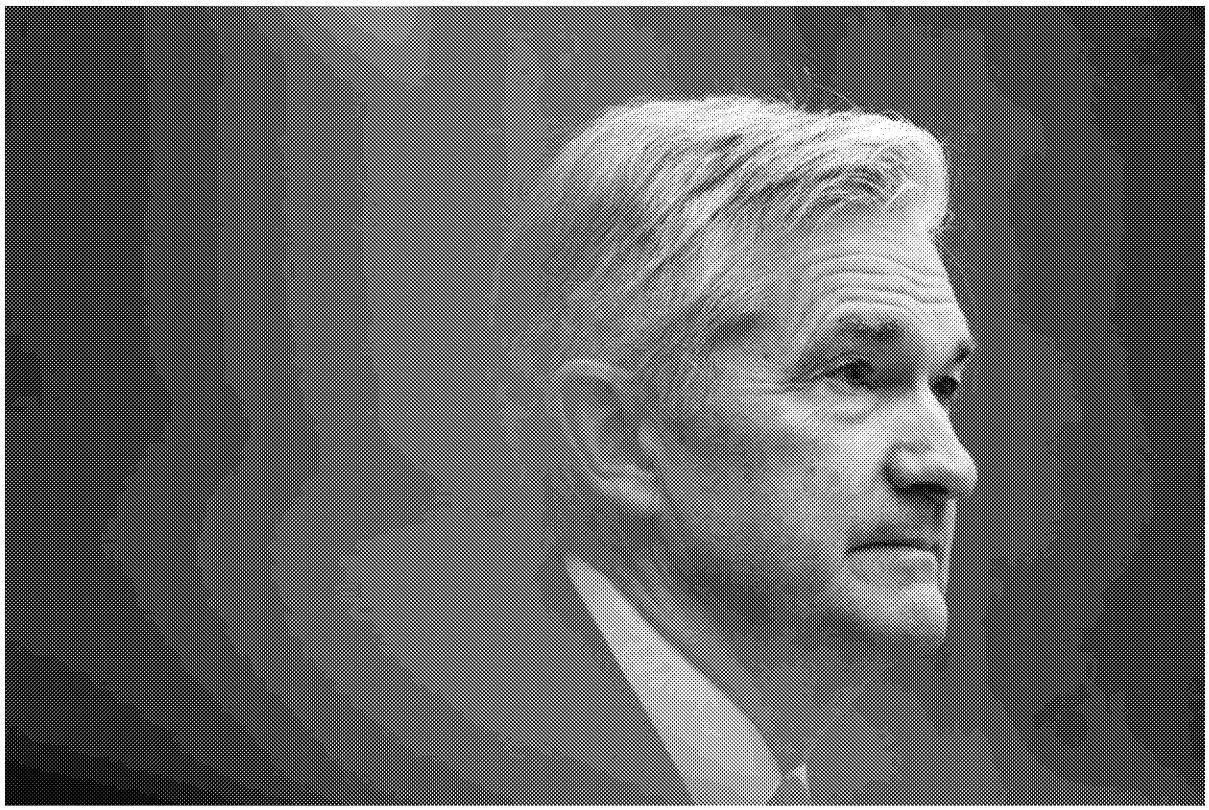
"I knew this was going to come sooner or later," she said. "And here it is."

Danny Hakim reported from Salinas, and Eric Lipton from Washington.

The All-New DealBook

Our columnist Andrew Ross Sorkin and his Times colleagues help you make sense of major business and policy headlines — and the power-brokers who shape them.

More in Business Day



Erin Schaff for The New York Times

Editors' Picks

Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]
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CC: Derrick Bolen (bolen.derrick@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]; Mary Hanley (Hanley.Mary@epa.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58e0d3d52d424d45ae88e4386ae4f8dd-Hanley, Mary]; Keller, Kaitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a6b15adfd745c6ada1c121dec27ac4-Keller, Kai]
Subject: Strengthening Transparency in Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

FYI—Please see attached.

Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."
I thought everyone would be interested in reading the document themselves, rather than just relying on other interpretations.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Please let me know if you have questions.

Nancy

Nancy B. Beck, Ph.D., DABT
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August 16, 2018

Dr. Thomas Sinks
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Submitted electronically to www.regulations.gov

Re: EPA Docket EPA-HQ-OA-2018-0259;
Comments of the American Chemistry Council on EPA's Strengthening Transparency in Regulatory Science Proposed Rule

Dear Dr. Sinks:

The American Chemistry Council is pleased to submit the attached comments on the Environmental Protection Agency's proposed rule, Strengthening Transparency in Regulatory Science.

Please contact me should you have any questions regarding these comments at 202-249-6406 or Christina_Franz@americanchemistry.com.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council

Comments of the American Chemistry Council on EPA's Strengthening Transparency in Regulatory Science Proposed Rule

EPA Docket EPA-HQ-OA-2018-0259

August 16, 2018

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Table of Contents

Executive Summary

The American Chemistry Council (ACC) is pleased to provide the following comments on the Environmental Protection Agency's (EPA) proposed rule, Strengthening Transparency in Regulatory Science (Strengthening Transparency), published in the Federal Register on April 30, 2018.[1] ACC and its members are directly impacted by the science-based regulatory actions of EPA under a myriad of federal environmental statutes. As such, ACC has a keen interest in EPA's adoption and implementation of a proposal as important as this one, which will reach across the breadth of the Agency's authority.

In the following comments, ACC offers its support for the proposed rule; responds to a number of questions posed by EPA in its preamble; and provides a number of specific recommendations regarding how the proposed rule can be improved and strengthened. Specifically, ACC suggests the following:

- Implementation of the rule would benefit from policy and/or guidance regarding the weight to be accorded the science informing significant regulatory decisions
- EPA should provide better historical context and applicability to the proposed rule
- EPA has not in all circumstances properly identified from where its authority is derived under the various federal environmental statutes cited in the proposed rule
- The regulation should apply to Executive Order 12866 significant regulatory actions at the proposal stage
- Key regulatory definitions and regulatory text require greater clarity
- Clarifications to the preamble are needed
- Implementation of the rule should be statute specific
- The proposed rule should apply to enforcement and permit proceedings
- EPA should incorporate stronger data and model access requirements into its Cooperative Agreements and Grants while complying with privacy and confidentiality requirements and laws
- The rule should apply to all EPA programs, including its IRIS program
- Methodologies and technologies providing protected access to confidential and sensitive data should be employed

[1] 83 FR 18768 (April 30, 2018).

- The rule should generally apply prospectively to EPA decision making
- Bias should not be presumed
- EPA should work with entities where scientific data are not publicly available in a manner sufficient for independent evaluation

I. Introduction and Background

ACC strongly supports EPA's demonstrated commitment in this proposal to build upon the principles underlying the Administrative Procedure Act (APA), Executive Orders 12866, 13777, and 13783, and guidance of Office of Management and Budget (OMB). In addition, ACC supports the proposal's expansion of the 2013 "Increasing Access to the Results of Federally Funded Scientific Research" memorandum directing federal agencies and offices to develop and submit plans to the White House Office of Science and Technology (OSTP) that ensure peer-reviewed publications and digital scientific data resulting from federally-funded scientific research are accessible to the public, the scientific community, and industry—to the extent practicable.

The OSTP directive required each agency to develop a public access plan that maximizes access to federally-funded "digitally formatted scientific data"[2] while also protecting confidentiality, personal privacy, confidential business information (CBI), intellectual property rights, and U.S. competitiveness.[3] In 2016, EPA issued its Plan to Increase Access to Results of EPA-funded Scientific Research in response to the OSTP directive.[4] Importantly, EPA's Strengthening Transparency proposal appears to extend such commitments beyond the government-funded requirement of the OSTP directive to "dose response data and models underlying pivotal regulatory science regardless of the source of funding or identity of the party conducting the regulatory science."[5]

ACC believes that EPA's proposal correctly codifies an important good governance principle—that government agencies should be as transparent as possible, within the bounds of the law, about scientific information relied upon and the justifications for the significant regulatory decisions they make.

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[2] As defined in OMB circular 110 as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications. . ." It is a definition consistent with that of "research data" in the regulatory text of EPA's proposal.

[3] More than 20 federal agencies have developed and implemented Data Access Plans, including EPA, the National Institutes of Health (NIH), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA).

[4] Plan to Increase Access to Results of EPA-Funded Scientific Research (USEPA, November 29, 2016) https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[5] ACC suggests improvements to EPA's terminology in the preamble that are described later in these comments in sections VI and VII.

The Agency's focus on dose-response data and models appropriately reflects the evolution of toxicology from a largely observational science to a discipline that applies advanced scientific techniques and knowledge. Research programs within academia, government, and private sector labs have greatly improved our ability to investigate and understand the underlying biological mechanisms, modes of action, and dose responses of toxicants. We can now evaluate biological events leading to toxicity and consider how (in a dose-response manner) these biological events relate to potential risks to human health. This was not possible 10-to-20 years ago. This improvement should directly translate to the application of transparent weight-of-the-evidence approaches to the assessment of human relevance; the development of points of departure; and the derivation of protective human health equivalent dosages that minimize the use of uncertainty factors and variability. A goal has been to apply this knowledge to improve the scientific basis of government regulatory policies and industry product stewardship.

For environmental concerns, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. Toxicity information and—when available—knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making.

Despite significant scientific progress in the understanding of mechanisms of action (MOA) and adverse outcome pathways (AOP), the movement away from default precautionary assumptions has been slow to occur, particularly in certain EPA programs. Significant investments by government, academia, and the private sector into toxicological research are counteracted by the failure to move away from default assumptions toward science-based decisions.

ACC encourages EPA to implement best available scientific procedures under this rulemaking. The Agency should move away from the outdated linear concept of how biology operates toward biologically-based mechanisms, i.e., mode of action (MOA) and adverse outcome pathways (AOP) for both cancer and non-cancer effects, that clearly establish the threshold nature of toxicological endpoints for derivation of points of departure for establishing regulatory values and making regulatory decisions.[6] [7]

In the following discussion, ACC offers its comments to help clarify and strengthen the proposed rule.

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[6] Critics of this proposed policy appear to overlook the fact that the call to evaluate different dose response models is entirely consistent with the Agency's Cancer Guidelines, which have been in place since 2005. See Guidelines for Carcinogen Risk Assessment https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/

II. Implementation of the Rule Would Benefit from Policy and/or Guidance Regarding Weight Accorded the Science Informing Significant Regulatory Decisions

As EPA has noted, the proposed rule is consistent with and builds upon the EPA policies implemented by previous administrations. Implementation would be aided by a policy statement or guidance that indicates greater weight will be given to studies using validated test methods and procedures, models, and approaches when and where those data are based on publicly accessible data, and transparent computer algorithms.

Other scientifically relevant and reliable studies and data should not be eliminated from consideration, but rather, accorded less weight when integrating evidence from multiple studies within and across different lines of evidence. Any guidance and other relevant documents developed to assist EPA staff to comply with this rule should include specific examples and/or case studies, perhaps drawing from recent EPA rulemakings, to demonstrate what constitutes regulatory science that is material to EPA's significant regulatory decisions.

III. EPA Should Provide Better Historical Context and Applicability to the Proposed Rule

EPA is proposing to add this rule to 40 C.F.R. 30, contained in Chapter 1, Subchapter B, dedicated to "Grants and Other Federal Assistance," without explaining how or why this rule fits within this subchapter, thereby creating potential confusion regarding its applicability. The potential for confusion was enhanced by the fact that EPA's public website currently contains information regarding the content that was formerly within 40 C.F.R. 30 but was repealed on December 19, 2014, i.e., general terms and conditions applicable to grant recipient and sub-recipients.[8] In addition, a number of questions on which EPA seeks comment relate solely to EPA cooperative agreements and grants or access to EPA-funded data.

In contrast, Section 30.3 of the proposed regulatory text state that "the provisions of this section apply to dose-response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science." Stakeholders would benefit greatly from EPA providing clarification regarding the applicability of Subchapter B and whether and to what extent this rule applies to government-funded and/or beyond government-funded scientific research. We believe the broader approach is warranted.

[8] https://www.epa.gov/grants/epa-general-terms-and-conditions-applicable-40-cfr-part-30-and-31-recipients-effective and see, 79 Fed. Reg. 244 at 76054 (Dec. 19, 2014).

IV. EPA Authority under Federal Environmental Statutes

The provisions cited by EPA under the Clean Air Act (CAA), the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Emergency Planning and Community Right-To-Know Act (EPCRA) in support of its authority to develop and implement its proposed rule all provide broad regulatory authority to promulgate regulations "as are necessary to carry out [the Administrator's] functions" under the statute. The citation to the Resource Conservation and Recovery Act (RCRA) speaks to Labor Standards in the issuance of grants, and does not appear applicable to this rulemaking authority. EPA cites Section 25(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which does provide the Agency with broad authority to "prescribe regulations to carry out the provisions of this subchapter [FIFRA]." It should be noted, however, that the statutory language is a bit different from the other cited statutes and does not read as "as are necessary to carry out....". In addition, FIFRA Section 136r(a) does not relate to rulemaking and instead provides the Agency broad authority to undertake research necessary to carry out the purposes of FIFRA. As such, EPA may mistakenly have included Section 136r(a) to support the proposal as cited on 83 Fed. Reg. 18769. EPA's reference to section 10 under the Toxic Substances Control Act (TSCA) also does not appear on-point. ACC believes EPA's authority to implement this rule is derived from TSCA Section 26(h), which speaks directly to scientific information and standards to which the Agency must adhere in the administration of its work under TSCA Sections 4, 5, and 6.

V. The Regulation Should Apply to E.O. 12866 Significant Regulatory Actions at the Proposal Stage

A. Definitions in E.O. 12866 Are Well-Established, Understood, and Applied.

The proposed rule would apply to significant regulatory actions as defined by E.O. 12866 at Section 3(f) as:

> (f) ''Significant regulatory action'' means any regulatory action that is likely to result in a rule that may:
>
> > (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
> > (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> > (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> > (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

This definition has been applied by the Executive Branch since the Clinton Administration promulgated E.O. 12866 in 1993. Its meaning is well-established with more than twenty-

five years of use. The underlying principles, however, precede its adoption. For example, the E.O. carried over the threshold of an annual $100 million effect on the economy that had been in place since 1978. This (3)(f)(1) threshold for economically significant regulatory actions is the same threshold that requires cost-benefit review for proposed and final regulations considered by OIRA.

A significant benefit of using the E.O. 12866 definition in the final rule is that EPA can easily apply it, against substantial practice and precedent, in a reliable, consistent, and predictable manner. This reduces the burden on the agency, and importantly, provides greater predictability to stakeholders and the public so they can understand to which agency actions the regulation will apply.

B. Conformity with E.O. 12866 Definitions Promotes Efficient OIRA Review.

Similarly, the process by which significant regulatory actions are identified under E.O. 12866 is also well-established. Here, with respect to application of the proposed rule, EPA would retain primary responsibility to identify the significant regulatory actions to which the rule should apply. OIRA would assess EPA's identification against the criteria set out in E.O. 12866. Neither EPA nor OIRA would be charged with applying a new or unfamiliar definition, nor a new process for review.

C. The Range of Agency Actions to Which the Rule Will Apply Should Not be Narrowed.

The significant regulatory elements of E.O. 12866 already require OIRA review and have for the past 25 years of established practice. The proposed rule respects that principle, and indeed, leverages it for maximum efficiency.

EPA specifically invites comment on whether a narrower definition might be appropriate, such as final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under E.O. 12866. Either of these approaches would lose the efficiency and predictability benefits of using the E.O. 12866 definition—and would increase work for both EPA and OIRA. Further, many significant and precedential agency actions do not meet the "economically significant" threshold. For example, many federal agencies administer environmental, health and safety requirements for workers, consumer products, and environmental media—air, water, soil. It should never be the case that EPA, or EPA and other agencies, establish and/or enforce conflicting and irreconcilable health values for the same compound; require the use of different personal protective equipment; or simultaneously prohibit and permit use or discharge of a particular compound. The same rigorous scientific standards, best available science and weight-of-the-evidence approaches should be applied across programs and media to protect human health and the environment. Adoption of the E.O. 12866 definition of significant regulatory action helps avoid inconsistent regulatory decisions by federal agencies that might interfere with policies designed to protect human health and the environment, unfairly burden businesses, and impede the protection of human health and the environment.

D. The Final Rule Should Apply to Significant Guidance Documents.

OMB's Final Bulletin for Agency Good Guidance Practices defines a "significant guidance document" as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

> (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
> (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866, as further amended.

EPA already maintains and publishes a list of significant guidance documents that meet the OMB definition.[9] [10] Applying the rule to EPA's significant guidance allows for greater parity and consistency with respect to the application of scientific principles in regulatory and guidance contexts. It ensures that the same quality and rigor will underpin decision making. It also helps ensure that EPA will apply the same principles to both regulatory requirements and implementing guidance, which provides greater certainty to the regulated community and the public.

VI. Key Regulatory Definitions and Regulatory Text Require Greater Clarity

EPA's terminology and regulatory definitions should be more concise and applied consistently to achieve greater clarity regarding the meaning and proposed application of the rule. For example, proposed section 30.2 refers to "**pivotal** regulatory science as the studies or analyses that **drive** the requirements and/or quantitative analysis of EPA final significant regulatory decisions." [Emphasis added]. This definition is distinguished from "regulatory science," defined as "scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions." These two definitions can be interpreted as simultaneously referencing something identical as well as one being a subset of the other. Therefore, the definitions are vague and need clarification.

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[9] See https://www.epa.gov/laws-regulations/significant-guidance-documents

[10] Notably, EPA's list of significant guidance documents include guidance that applies directly to the regulated community, such as the agency's *2017 Guidance To Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act* (EPA-HQ-OPPT-2017-0341-0002) and *Interpretive Guidance for the Real Estate Community on the Requirements for Disclosure of Information Concerning Lead-Based Paint in Housing, Part I* (EPA-HQ-OPPT-2007-0765-0001).

Assuming the intent is to define and distinguish the subset of scientific studies and analyses that form the scientific foundation for EPA's regulatory decisions from the larger universe of *all* the scientific information reviewed and considered by the agency, a more precise word than "pivotal" would be "material." In other words, those scientific studies and analyses that are material to its regulatory decision must be or be made publicly available in a manner sufficient for independent validation.

The regulatory text in 30.4 and 30.5 should be clarified. Section 30.4 appears to apply to EPA's use of studies (or other regulatory science) relied upon when EPA takes *any* final agency action (emphasis added). In those instances, EPA should make all such studies available to the public to the "extent practicable." Section 30.5 refers specifically to the requirements that apply when "EPA uses dose response data and models underlying "pivotal" (which ACC believes is more aptly expressed as "material") regulatory science." ACC interprets this to mean that in these specific circumstances, the dose response data and models must be "publicly available in a manner sufficient for independent validation," which EPA defines as in a manner "consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." Information considered "publicly available in a manner sufficient for independent validation" when it includes the information "necessary for the public to understand, assess, and replicate findings." As noted above, for environmental safety, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. EPA should provide greater clarity regarding what it intends to do in circumstances where raw data cannot be made publicly available.

EPA should include a discussion in the final rule regarding how it proposes to address exposure assessments and risk characterization data and models in the future extensions of related rules on Transparency in Regulatory Science.

Section 30.7 appears to be missing one or more words in the header to the section. It states: "What role does independent peer review in this section?" ACC believes the missing word is likely "have," but EPA should clarify and correct this section in the final rule.

EPA uses the word "justify" frequently throughout the various sections of proposed regulatory text when referencing the use of regulatory science to make its decisions. For example, section 30.7 states: "EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions.*" ACC suggests that there are more precise words that EPA should use to link "pivotal regulatory science" with "regulatory decisions," such as "underpin" or constitute the "foundation" of the "scientific basis" of its regulatory decisions.

ACC has offered some additional, specific language suggestions in a redline version of the proposed regulatory text that is included in these comments in Appendix A.

VII. Clarifications to the Preamble are Needed

A. Definition of "Pivotal Regulatory Science" is needed.

The definition in the proposed regulatory text and may lead to confusion among stakeholders. We recommend consistency between the preamble and the regulatory text and that EPA clarify its terminology.

Importantly, in footnote three on page 18769 of the preamble, EPA states:

> EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [of] non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'n v. EPA,* 283 F.3d 355, 372 (D.C. Cir.2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

ACC believes that this footnote should be clarified to be consistent with the regulatory text that provides that there are exemptions to this policy outlined in sections 30.5 and 30.9. EPA's preamble should not be at odds with the regulatory text.

Invariably there will be circumstances where underlying data no longer exist for studies and/or models that are high quality and reliable. For example, most organizations have data retention policies that have resulted in the disposal of underlying data. Furthermore, Good Laboratory Practices (GLP) regulations include defined periods of time to retain data and study records.[11] EPA should address how it will continue to use those studies and models in light of these policies.

B. Assertions about proposal not "directly regulating entities outside of federal government" and not having "substantial direct effects" on the states.

On page 18769 under section A, EPA states that the proposed regulation does not "directly regulate any entity outside the federal government" and on page 18772, EPA states under section E that "this action imposes no enforceable duty on any state, local or tribal governments or the private sector." Under Section F, EPA asserts that this action does not have federalism implications and will not have "substantial direct effects on the states." ACC is not certain that these statements are accurate. Consider, for example, the establishment of water quality standards (WQS).

[11] 40 C.F.R. 160.

Under Section 303(c) of the CWA, states and authorized tribes must develop WQS and submit them to EPA for its approval or disapproval. To help them develop the standards, EPA provides scientific guidance through its "Section 304(a) National Criteria Recommendations," which specify quantitative concentrations/level and qualitative measures of pollutants that, if not exceeded, generally will ensure acceptable water quality. In developing these recommendations, EPA evaluates acceptable water quality. When developing these recommendations, EPA evaluates available scientific data on a pollutant's effects on public health and welfare, aquatic life, and recreation. EPA recommends that states and tribes consider the Agency's water quality criteria when developing their WQS, though states and tribes may also consider other scientific criteria that differ from EPA's recommendations.

While EPA's national water quality criteria recommendations are not regulations and do not impose binding requirements, they do serve as the scientific basis for the development of water quality standards and WQS are the foundation of a number of CWA programs. As EPA states in its Water Quality Standards Handbook, these standards "establish the baseline used for measuring the success of the CWA programs, so adequate protection of aquatic life and wildlife, recreational uses, and sources of drinking water, for example, depends on developing and adopting well-crafted WQS."[12]

C. Publications should be cited.

ACC suggests that EPA revise its statement that the proposed rule "takes into consideration the policies or recommendations of third-party organizations who [sic] advocated for open science." The recommendations referenced by EPA actually emanate from a survey of the members of three professional organizations whose memberships represent repositories of knowledge and experience in regulatory assessment.[13] As such, reference 10 in EPA's proposal should also be revised to cite the publication, Expert Opinion on Regulatory Risk Assessment, A Survey by the Center for Media and Public Affairs (CMPA) and Center for Health and Risk Communication (CHRC) at George Mason University" (December 6, 2013).[14]

D. Definition of "reproducibility" is needed.

EPA uses the term "reproducibility" in the preamble, but never defines the term and does not include the term in the definitions in the proposed regulatory text. It is unclear what constitutes a reproducible versus non-reproducible finding. It is important to consider that there are different types of reproducibility, such as methods reproducibility, results reproducibility, and reproducibility of conclusions.

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[12]Water Quality Standards Handbook, Office of Water, EPA 820-B-14-008, September 2014, at p. 2.
[13] The Risk Assessment Specialty Section of the Society of Toxicology (SOT-RASS), the Dose Response Section of the Society for Risk Analysis (SRADRS), and the International Society for Regulatory Toxicology and Pharmacology (ISTRP).
[14] https://cmpa.gmu.edu/wp-content/uploads/2013/12/GMU-Study-Report.pdf.

For example, OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies defines "capable of being substantially reproduced" as "independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision." [15] However, the inability to reproduce research studies can be related to issues of study design, variability or differences in biological test systems, data integrity, data analyses, and in some cases, scientific misconduct. As Carl Sagan stated, "extraordinary claims require extraordinary evidence." Accordingly, new or novel findings that purport to indicate effects that have little or no biological basis, based on the weight of the evidence coupled to first principles of relevant scientific disciplines, should be subjected to suitable reproducibility requirements, which could include causal analytics.

E. Definition of "publicly available" is needed.

EPA does not define what it means by its use of the term, "publicly available." There is more than one definition of the term currently in use by federal agencies.[16] EPA should clarify the level of access and disclosure to the public that is intended. If it intends to determine this on a case-by-case basis, that also should be made clear.

F. Greater clarity on data refinement issues is needed.

Another important aspect relevant to "public availability" is the level of data refinement EPA will require. The National Academies of Science, Engineering, and Medicine (NAS) held a workshop in 2016 to discuss obstacles for sharing data.[17] The NAS defined several key terms to ensure clarity at the workshop. EPA should consider adopting a similar lexicon to increase the clarity of its regulation. (See Table 1 in Appendix B). In addition, the NAS Report suggests a "cleaned dataset" would be acceptable to use for all routine analyses and verification. (See Table 2 in Appendix B). EPA should establish clear standards on the acceptability of "*cleaned datasets*." This will help to standardize data reporting and formatting. It will also prevent over- and under-reporting.

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[15] https://obamawhitehouse.archives.gov/omb/fedreg_final_information_quality_guidelines/

[16] Publicly available information means "any information that you reasonably believe is lawfully made available to the general public from: (i) Federal, state or local government records;(ii) Widely distributed media; or (iii) Disclosures to the general public that are required to be made by federal, state or local law." 17 CFR 160.3 [Title 17 -- Commodity and Securities Exchanges; Chapter I -- Commodity Futures Trading Commission; Part 160 -- Privacy of Consumer Financial Information]. Publicly available information is information that has been published or broadcast for public consumption, is available on request to the public, is accessible on-line or otherwise to the public, is available to the public by subscription or purchase, could lawfully be seen or heard by any casual observer, is made available at a meeting open to the public, or is obtained by visiting any place or attending any event that is open to the public. Office of the Director of National Intelligence & Office of the Director of National Intelligence, National Counterintelligence and Security Center, CI Glossary 2011.

[17] National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703.

VIII. Implementation of the Rule Should be Statute-Specific

EPA requested comment on the effect this proposed rule may have on individual EPA programs. Each of the federal environmental statutes referenced by EPA as a source for its authority to propose this rule, was enacted and designed to achieve a specific environmental goal and purpose (e.g., TSCA regulates new and existing chemicals, CAA controls air pollution on a national level, and SDWA regulates public drinking water supplies across the nation). Each statute confers its unique authority upon the agency, requiring agency review according to different scientific standards; each has its own regulations designed to effectuate the specific corresponding program's mission; and, in many cases, each statute relies on different and variable scientific disciplines. As such, ACC believes that this rule, while applicable to all the statutes identified, should be implemented by regulations specific to the objectives and scientific disciplines of each statute. ACC believes that just as the Freedom of Information Act (FOIA), which is overseen by the US Department of Justice (DOJ), is implemented by each agency with specific and separate regulations relevant to the requirements of each statute, this policy rule should be implemented by each EPA program office charged with implementing a given statute in a manner consistent with the authorities granted and requirements unique to that statute.[18]

IX. The Proposed Rule Should Apply to Enforcement and Permit Proceedings

EPA should apply the final rule to both ". . . enforcement activities or permit proceedings (including site-specific permitting actions) . . ." 83 Fed. Reg. 18768, 18771. In both these areas, EPA staff routinely use scientific evidence to make case-specific policy decisions that raise the same type of problems that occur when EPA promulgates regulations; therefore, this proposed regulation should apply to those to ensure that decisions in those areas are made appropriately.

For example, in both administrative and civil judicial enforcement programs, EPA routinely makes discretionary decisions targeting cases to pursue on the basis of scientific data on exposure of humans and ecological resources to pollutants. To do so, EPA relies on data regarding the inherent hazards of the chemical pollutants, and then estimates exposure potential and risks in a manner essentially the same as the approach EPA used to craft the regulations under the applicable environmental statute. Then, on an enforcement case-specific basis, EPA enforcement staff routinely use exposure/risk information to determine whether violations of the law (for regulatory enforcement under the CAA, CWA, RCRA, FIFRA, etc.) or releases to the environment (CERCLA, RCRA corrective action, OPA) have occurred warranting enforcement and determining the extent of sanctions and relief EPA will seek in an enforcement proceeding.

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[18] See, for example, the discussion of CWA criteria earlier in these comments under section VII. B., which is a good example of why it is important that EPA consider each statute it regulates when applying this proposed rule.

In CAA New Source Review enforcement cases, EPA must decide whether a violation of the program occurred by constructing a "major modification" to a source by assessing whether the pollutant-specific regulatory thresholds were exceeded; analyze emissions calculations using emission factors and/or test data collected from engineering studies; and then extrapolate to the specific plant. To identify the remedial action to impose, EPA must decide which Best Available Control Technology (BACT) limits are for the modifications and that decision, in turn, requires a complex analysis of data regarding costs and efficacies of various control technologies.

In a CWA enforcement case, EPA must decide whether a facility is subject to CWA jurisdiction by determining if a discharge into a jurisdictional "waters of the United States" is subject to the National Pollutant Discharge Elimination System (NPDES) permitting and then whether the discharge violates effluent discharge requirements. If so, EPA must analyze what remedial measures are necessary, including to the receiving waters. In both the CAA and CWA cases, EPA must also prepare proposed civil penalty and pollution "mitigation" assessments, each of which require the analysis of complex economic and environmental data. This policy will require EPA to be more transparent regarding its assessment and analysis of this complex data, which is much needed.

In a CERCLA enforcement case, EPA has to decide what the removal or remedial action should be, which necessitates among other things, a site-specific risk assessment and remedial technologies selection, using a wide variety of environmental and engineering data, which should be publicly available to be verified and replicated.

Similarly, for permitting purposes under environmental statutes, EPA must routinely analyze scientific studies to decide whether to grant a permit and, if so, what conditions to impose in the permit to mitigate environmental impacts to acceptable levels. For example, in a CWA NPDES permit review, EPA determines the level of each pollutant that would be discharged to waters of the United States, whether the proposed discharge will comply with effluent limits required by technology-based effluent guidelines and water-quality standards (including Total Maximum Daily Load programs), and whether control technologies will ensure that the effluent limits will be achieved consistently. Each of those decisions requires analyzing complex environmental/engineering data on a case-specific basis.

X. Incorporate Stronger Data and Model Access Requirements into Cooperative Agreements and Grants while Complying with Privacy and Confidentiality Requirements and Laws

EPA requested comment on how EPA can incorporate stronger data and model access requirements into the terms and conditions of Cooperative Agreements and Grants. ACC believes EPA can accomplish this by implementing requirements that all models and results developed under EPA Cooperative Agreements and Grants be open access and not proprietary. EPA should also require all grant proposal applicants to include as part of any

grant proposal a data management plan, similar to those required by the National Institutes of Health (NIH).[19] EPA may elect to exclude from these requirements grants/agreements of some specified annual amount, but that annual amount should be reasonable and ensure that the vast majority of models and results developed under grants/agreements is shared.

EPA should adopt model evaluation criteria to apply the greatest weight and credibility to models that are open access, describe the endpoint predicted clearly, are based on unambiguous open access computer algorithms, have a defined domain of applicability, have been transparently verified with publicly available datasets, and are shown to be robust and scientifically sound for the intended use.

In addition, EPA should develop common data templates and digital platforms for the most common types of research studies to be used by entities subject to Cooperative Agreements and Grants to facilitate public use and validation.

XI. The Rule Should Apply to all EPA Programs, including its IRIS Program

EPA established the Integrated Risk Information System (IRIS) in 1985 to develop and maintain a database of human health hazard assessments for chemicals. EPA's website states: "The goal of the IRIS Program was to foster consistency in the evaluation of chemical toxicity across the Agency."[20] However, the IRIS Program has been plagued for years by its slow pace generating IRIS assessments and lack of scientific transparency and reproducibility, among other deficiencies. The U.S. Government Accountability Office included IRIS in its High Risk Report, which noted that EPA has not "developed sufficient chemicals assessment information under these programs to limit exposure to many chemicals that may pose substantial health risks"[21] Although the IRIS Program has initiated changes to address some of these deficiencies, no final IRIS assessment to date reflects the full panoply of recommendations issued by the NAS in its review of the IRIS program in 2011.

Appendix C offers several specific examples of IRIS assessment that failed to reflect the best available science. We strongly recommend that the Agency apply this rule to any IRIS assessment that could be used as the basis for significant regulation.

XII. Methodologies and Technologies Providing Protected Access to Sensitive or Confidential Data

In circumstances where company CBI and other intellectual property may be implicated, EPA should confer with the CBI data owner to determine how to make that data available to the greatest extent possible without disclosing the CBI within that data, study, or model. How this is handled will likely be impacted by the type of

[19] https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
[20] See https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system
[21] https://www.gao.gov/highrisk/transforming_epa_and_toxic_chemicals/why_did_study#t=0

regulatory decision and statute involved.

For example, under TSCA, while the summarized study results, analysis, and final report may be publicly available, the underlying data in a health and safety study may qualify as CBI when the underlying data are not in the public domain and that data provides a commercial value to its owner.[22] In such circumstance, it is the availability of the underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data owner of the value of its investment in the underlying data. Current EPA regulations require chemical manufacturers to submit health and safety studies under some circumstances. However, it is noteworthy that none of these regulations routinely require study submitters to submit underlying data along with a final report. This indicates that the final report likely communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting.[23]

ACC believes that making a final study report publicly available where the underlying data are CBI would, in most circumstances, be an effective way to make relevant information publicly available about studies and data EPA may rely on, but which must be protected as CBI in circumstances triggering this policy. In these situations, EPA can access the underlying data to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If necessary, when specialized expertise is needed, EPA could contract with an independent third-party science reviewer to confirm those findings, although we believe this would likely only be necessary in unusual circumstances. In addition, EPA might also consider an approach followed under FIFRA where Data Evaluation Records of studies are made publicly available, but not full studies.[24] Another approach is that of the European Union's REACH program, which makes Robust Study Summaries (RSS) publicly available, while protecting from disclosure the competitively sensitive underlying data of health and safety studies.

When protecting data while also promoting data access, NIH guidelines should be consulted.[25] ACC believes many of these guidelines could be applied in EPA's implementation of this proposed policy under each of the statutory programs EPA administers to ensure the guidelines adopted suit the specific needs of each statute.

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[22] See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996).

[23] 40 C.F.R. §720.50(a)(3)(i) requires that if data do not appear in the open scientific literature, the submitter must provide a full study report, including the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

[24] See, e.g., https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf

[25] See https://osp.od.nih.gov/2016/05/02/protecting-data-promoting-access-improving-our-toolbox/; https://www.niaid.nih.gov/research/data-security; and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302472/

EPA should ensure that it implements its final rule in a manner that enables it to use confidential health records that may exist with certain kinds of studies, such as long-term air pollution and workplace exposure studies that involve confidential health records. Several agencies and organizations, in addition to NIH, have successfully addressed the issue of data access while maintaining confidentiality that should be considered by EPA. For example:

- The existing rule requiring federally funded research to be made available to other researchers. This standard could be adopted and applied to third-party funded researchers.
- Health care claims and related data are now being made available to researchers in de-identified form by some health insurance companies, such as Optum, which offers a "proprietary research database of health care and administrative data that links patient, physician, and treatment attributes from millions of geographically diverse individuals in the U.S." Optum appears to have developed methods and procedures to appropriately address confidentiality concerns.
- Medicare claims data are already available to researchers in de-identified form. Algorithms and methods developed by the Center for Medical Services should be examined by the EPA.
- Several professional societies have guidance on the protection of health data and de-identification, such as the Institute of Electrical and Electronic Engineers and the International Association of Privacy Professionals. [26]

EPA should develop clear guidance on protecting privacy, de-identifying data, and settling disputes should a breach occur. It may also want to consider establishing an office similar to that of NIH's Office of Research Integrity to adjudicate any issues that may arise in the administration of its practices under this rule.[27]

XIII. The Rule Should Generally Apply Prospectively to EPA Decision Making

ACC does not support retrospective application of the final rule in cases where the Agency follows a periodic review schedule for updating regulations, which includes review of underlying scientific assessments. Retrospective application of any regulation (and its underlying scientific evaluations) is rife with complication, confusion, and significant ambiguity for EPA and stakeholders alike. For example, each NAAQs review under the CAA is based on a substantial amount of scientific and policy information used to inform EPA's determinations of appropriate levels for each standard. The retroactive application of this proposal to those administrative records would only serve to confuse, distress, and impede a NAAQS review process that is already severely overburdened. For example, it is unclear which administrative NAAQS records would be covered by the proposal and how far back it would apply.

[26] http://www.ehealthinformation.ca/wp-content/uploads/2014/08/2010-Risk-based-de-identification-of-health-data.pdf and https://iapp.org/media/pdf/knowledge_center/Perspectives_on_Health_Data_De-Identification_final.pdf

[27] https://ori.hhs.gov/

Without a clear statement, the proposal could potentially cover more than a decades' worth of NAAQS administrative records and scientific analyses. The value of such an application is similarly uncertain. While ACC remains supportive of increased transparency in significant regulatory actions in the future, we encourage EPA to avoid the creation of unnecessary ambiguity and burdens and refrain from the application of this proposal to previous administrative NAAQS records. ACC recommends the final rule be applied prospectively in a manner that integrates its application within the periodic review schedule established for each criteria air pollutant.

However, in cases where EPA has developed analytical tools and models, e.g., ECOSAR, in the past that incorporate dose response data, it may be valuable to apply this rule retrospectively. In other cases, such as IRIS assessments, where the Agency has yet to articulate a periodic review schedule for updating scientific assessments dating back 10-20 years or longer, EPA should develop appropriate mechanisms for application of the rule.[28]

XIV. Bias Should not be Presumed

EPA requested comment on how application of the proposal might inadvertently introduce bias regarding the timeliness and quality of the scientific information available. If EPA uses a weight-of-the-evidence approach (as required under TSCA)[29] and EPA has concerns about bias having been introduced, it can evaluate this using a sensitivity analysis by evaluating the impact of each study and/or model on the overall outcome of the analysis.[30] That said, bias should not be inferred if newer, more scientifically robust studies based on modern, up to date knowledge of biology and dose response are determined to be of better quality, relevance, and evidentiary value.

XV. EPA Should Work with Entities Where Scientific Data are not Publicly Available in a Manner Sufficient for Independent Evaluation

Where data are not available in a manner sufficient for independent evaluation, EPA should attempt to work with data owners to reach an agreement to make the information available to the public to the greatest extent practicable without

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[28] In addition, stakeholders who seek to urge EPA to undertake a retrospective review do have options at their disposal, e.g., they can develop a voluntary new evaluation under TSCA, petition EPA, or file an Information Quality Request (IQA) requesting a correction.

[29] The TSCA Risk Evaluation rule provides an excellent definition of "weight-of-the-scientific-evidence" that should be adopted across the federal government, but certainly across EPA, at a minimum. That definition is: " a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." See 82 Fed. Reg. 33726, 33733 (July 20, 2017).

[30] EPA's implementation and adherence to systematic review in the implementation of this proposal as it has committed under TSCA, will serve to guard against the introduction of bias. See EP's *Application of Systematic Review in TSCA Risk Evaluations* at https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

jeopardizing the privacy, confidentiality, or the proprietary interests that deserve protection. In circumstances where there is significant difficulty making data available in a meaningful way, EPA should consider contracting with external experts in the scientific discipline at issue, have them sign confidentiality agreements, analyze the data, and prepare a confidential report with a non-confidential summary for EPA to share publicly.

APPENDIX A: Proposed Regulatory Text

Section 30.1 What is the purpose of this subpart?
This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

Section 30.2 What definitions apply to this subpart?
As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meaning given them.

- **Dose Response data and models** – the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a measured or predicted response or health or environmental impact.

  A dose response and concentration response can be empirical, e.g., it can describe the measured relationship from experimental measurements. A response can be just a response and not an actual "impact."

- **Material Regulatory Science** – specific scientific studies and analyses that represent the best available science that, based on weight-of-the-evidence, are material to and represent the scientific basis of the requirements and/or quantitative analyses of EPA final significant regulatory decisions.

- **Regulatory decisions** – final regulations determined to be "significant regulatory actions" by OMB per EO 12866, which is defined as any regulatory action that is likely to result in a rule that may:

  - Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health, or safety, or state, local, or tribal governments or communities;
  - Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
  - Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
  - Raise novel legal or policy issues arising out of legal mandates, the president's priorities, or the principles set forth in the Executive Order 12866.

- **Regulatory science** – scientific information, including assessments, models, criteria documents, and regulatory impact analyses that provide the basis for EPA's policies, procedures, guidance, proposed and final significant regulatory decisions.

- **Research data** – as defined by UAR is: the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This ''recorded'' material excludes physical objects (e.g., laboratory samples).

  "Research data" do not include:

  (i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
  (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

Section 30.3 How do the provisions of this subpart apply?
"To dose response data and models underlying pivotal regulatory science that are used to justify significant regulatory decisions regardless of who funded it or the identity of the party conducting the regulatory science." These provisions do not apply to "physical objects (like laboratory samples), drafts, and preliminary analyses." Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of regulatory action, including enforcement actions and permit proceedings, etc.

Section 30.4 What requirements apply to EPA's use of studies when taking final action?
EPA shall clearly identify all studies or other regulatory science relied upon when it takes any agency action and make all studies available to the public to the "extent practicable."

Section 30.5 What requirements apply to use of dose response data and models?
When promulgating significant regulatory actions, the Agency shall ensure that the dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation, **verification,** and analysis.
This may include:

- Data (where necessary, could be subject to access and use restrictions)
- Associated protocols
- Computer algorithms and models[31]
- Recorded factual materials
- Detailed descriptions of how to access and use such information

But in a manner consistent with law, protects privacy, confidentiality, CBI, and is sensitive to national and homeland security.

[31] We suggest substituting "algorithms" in place of "codes" because specific computer codes can be proprietary.

Information is "publicly available in a manner sufficient for independent evaluation" when it includes the information necessary for the public to "understand, assess, and replicate findings."

Section 30.6 What additional requirements pertain to the use of dose response and models underlying pivotal science?
EPA shall describe and document any assumptions and methods used and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold response, on a case-by-case basis. EPA shall clearly explain scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high-quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models the incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

Section 30.7 What role does independent peer review [have] in this section?
EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions, consistent with OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions therein apply. EPA will ask peer reviewers to articulate the strengths/weaknesses of EPA's justification for assumptions applies and the implications of those assumptions for the results.

Section 30.8 How is EPA to account for cost under this subpart?
EPA shall implement the provisions of this subpart in a manner that minimizes costs.

Section 30.9 May the EPA Administrator grant exemptions to this subpart?
Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:
(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or
(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

Section 30.10 What other requirements apply under this subpart?
EPA shall implement the provisions of this section consistent with the definition of ''research data'' in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in Public Law 89–487, and other applicable federal laws. Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

ACC notes here its support for the text of Public Law 89-487, which is incorporated by reference in Section 30.10 provides the following exemptions are applicable to this proposed regulation:

1) Specifically required by Executive Order to be kept secret in the interest of national defense or foreign policy;
2) Related solely to the internal personnel rules and practices of any agency;
3) Specifically exempted from disclosure by statute;
4) Trade secrets and commercial or financial information obtained from any person and privileged or confidential;
5) Inter- or intra-agency memorandums or letters which would not be available by law to a private party in litigation with the agency;
6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
7) Investigatory files compiled for law enforcement purposes except to the extent available by law to a private party;
8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of any agency responsible for the regulation or supervision of financial institutions; and
9) Geological and geophysical information and data (including maps) concerning wells.

Where appropriate, data-sharing agreements and data-masking techniques may be used.

APPENDIX B: Definitions of NAS Principles

Definitions in NAS Principles and obstacles for sharing data from environmental health research: Workshop summary.
Definition: meta-analysis *Meta-analysis* is a way of quantitatively combining data from many different studies using a statistical process.
Definition: reanalysis The term "*reanalysis*" is defined as conducting further analyses of the exact same data to determine if the same results are obtained and may include use of the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies.
Definition: replication The term "*replication*" is the repetition of a scientific experiment or a trial using exactly the same protocols and statistical programs but with data from a different population to determine if consistent results are obtained with data from a different population.
Definitions: reproduction The term research "*reproduction*" refers to an experiment conducted to addresses the same research question as the original work, but examines the question from a different angle.
Definition: raw data The term "raw data" is defined as the unmodified or unprocessed data that is obtained directly from a survey or experiment (modified from NAS, 2016 P6)
Definition: cleaned-up data *Cleaned-up data* consist of the raw data modified to remove obvious errors.
Definition: processed data The term "processed data" refers to information that has been computed and analyzed to extract relevant information (NAS, 2016), and may include: • Aggregation – combining multiple pieces of data. • Analysis – collection, organization, analysis, interpretation and presentation of data • Classification – separation of data into various categories. • Reporting – list detail or summary data or computed information. • Sorting – the arrangement of items in some sequence and/or in different sets. • Summarization – reducing detail data to its main points. • Validation – Ensuring that supplied data is correct and relevant. (wiki https://en.wikipedia.org/wiki/Data_processing)
Definition: final clean data set

The term "*final clean data set*" is the information provided with a scientific publication (modified IOM, 2016 P6)
Definition: metadata *Metadata* is a set of data that describes other data

TABLE 2 – Data flow from NAS Report

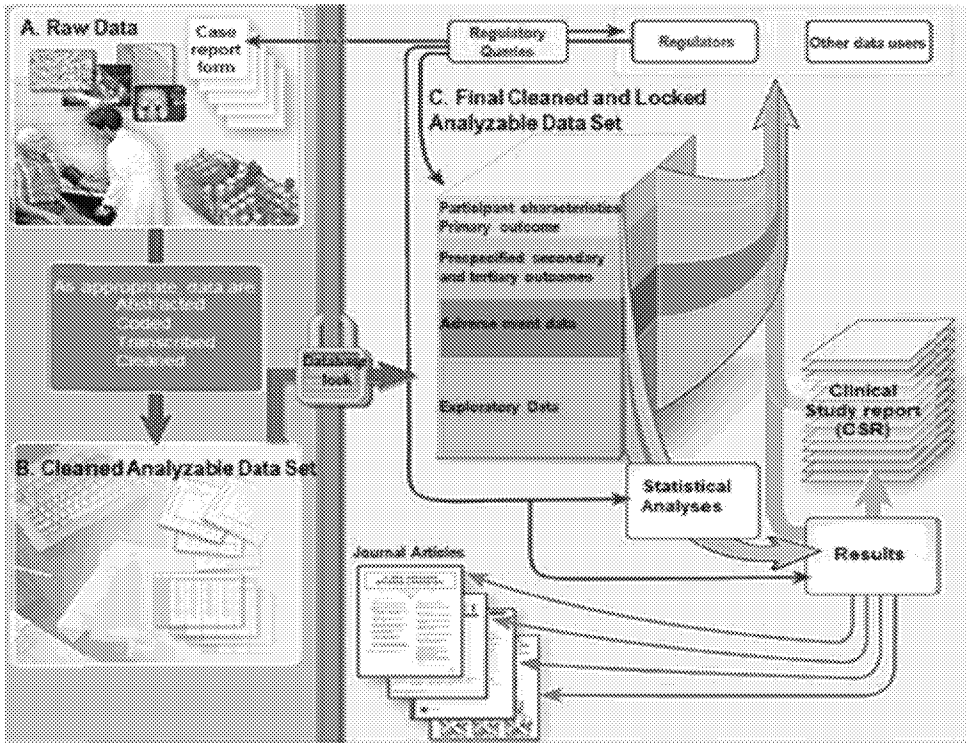


FIGURE 2-1 Data flow from participant to analyzed data and reporting.
SOURCE: IOM, 2014.

APPENDIX C: Chemical-Specific Case Studies

Case Study 1: Trimethylbenzenes (TMBs)

On September 9, 2016, EPA issued its final report on the IRIS assessment of Trimethylbenzenes (TMBs), which addresses the potential non-cancer and cancer human health effects from long-term exposure to TMBs. Humans are not exposed to individual TMB compounds, but to complex mixtures. According to EPA, the primary uses for TMBs are: as a blending agent in gasoline formulations (C9 aromatic fraction); solvents; and paint thinner.

In its review of TMBs, the EPA fell far short in meeting its obligations to improve its IRIS processes and assessment reports. Without explanation, EPA failed to respond to public comments on the draft TMBs assessment, even though the IRIS process for developing assessments explicitly includes a response to comments element.

The IRIS assessment of TMBs does not accurately represent the health effects associated with exposure to TMBs because it failed to utilize a consistent and transparent data evaluation procedure for evaluating and weighing the full body of evidence.
In particular, EPA failed to rely on available guideline studies on commercial complex C9 aromatic mixtures that industry conducted under EPA's TSCA program. The entire commercial C9 aromatic blend, which contains a high percentage of TMBs, has similar toxicological properties and health effects as the individual isomers of TMB. Thus, guideline studies on the commercial complex of aromatic mixtures are highly relevant to assessing the toxicology of TMBs.
EPA's Office of Pesticide Programs (OPP) has also reviewed the toxicology of TMBs and determined that the health effects of TMBs can be efficiently assessed by relying on C9 aromatic mixture studies. OPP reached different scientific conclusions, including different quantitative health effect numbers, than that of EPA's IRIS Program. EPA, however, did not resolve these differences during the IRIS assessment of TMBs.

Case Study 2: Formaldehyde

Formaldehyde occurs naturally in every living system – from plants to animals to humans – all of which produce formaldehyde as a normal part of metabolism. In addition, its unique and versatile chemical properties make it a common and beneficial part of modern life. Formaldehyde has been the subject of extensive and robust scientific inquiry. EPA has been involved in assessing the human health risk of formaldehyde since the late 1970s. Large numbers of epidemiology, toxicology and biomechanical studies have informed the science surrounding formaldehyde, so that there a rich body of data exists.

The most recent draft Integrated Risk Information System (IRIS) formaldehyde assessment (2010) proposed exposure limits so low that the trace levels of formaldehyde found in human breath would present a cancer risk. The 2010 draft assessment also noted that: *"Human epidemiological evidence is sufficient to conclude a causal association between formaldehyde exposure and nasopharyngeal cancer, nasal and paranasal cancer, all*

leukemias, myeloid leukemia and lymphohematopoietic (LPH) cancers as a group." The National Academy of Sciences (NAS) then conducted a peer review of this draft and issued its final report in April 2011. The NAS report was critical of the draft IRIS assessment---an assessment that the IRIS program took 12 years to develop.

The NAS stated that EPA's claims regarding all leukemias, myeloid leukemia or related hematopoietic cancers were not supported. It noted that EPA's preliminary conclusions appeared subjective and that no clear scientific framework had been used by EPA to reach its conclusion. The NAS recommended that EPA revisit its determination of causality for specific LHP cancers, using methodology that integrates lines of evidence and addresses the specific criticisms in the NAS report. The NAS also made numerous recommendations for the improving the overall process and application of science used in all assessments generated by the IRIS program. Now, seven years since that NAS report was published, EPA continues to revise its assessment while not disclosing how emerging scientific evidence or modern risk assessment methods are being employed.

Meanwhile, newly published research based on the recommendations in the NAS report has advanced the state of the science. Raw data (made available after multiple years of FOIA requests) from studies conducted by the Federal government ---and upon which EPA relied on for its previous assessment conclusions--- were re-analyzed and the findings contradicted the original study conclusions. Today our knowledge regarding formaldehyde is much greater; yet it does not appear that this new knowledge has been applied in the EPA's assessment of formaldehyde risk. Published research demonstrates that inhaled formaldehyde cannot reach the bone marrow where leukemia occurs and that safe thresholds for formaldehyde exposure exist. This formaldehyde case study is an example of the long-term problems with the lack of consistent, transparent application of modern scientific knowledge regarding chemical exposures and human health risk.

Case Study 3: Ethylene Oxide

The Integrated Risk Information System (IRIS) assessment of ethylene oxide (EO) originated with a carcinogenicity assessment in 1985. The first comprehensive draft was published in 1998. An external review draft was issued in 2006, followed by a Science Advisory Board (SAB) review in 2007. Revisions of the EO assessment were made in 2011 and 2013, and an additional SAB review was conducted in 2014-2015. The final IRIS assessment for EO was posted in December 2016.

Using unsupportable and un-reviewed conservative risk assessment modeling, the IRIS assessment concludes that the one-in-a-million lifetime cancer risk value associated with exposure to EO is less than 1 part per trillion (ppt). This value is far below both EO background levels in the environment and EO levels naturally converted from ethylene in humans through breathing. This conclusion is not plausible and not scientifically supportable. It is based on an inadequate evaluation of a body of evidence from human studies that include historical exposure levels to EO that are far higher than current occupational exposure limits. Other, more accurate data sources are available, and alternative scientific risk assessment modeling approaches could have been used, but the

IRIS Program did not systematically integrate all of the evidence. Public comments on the EO IRIS assessment can be found in Docket No. EPA-HQ-ORD-2006-0756.

EO has dozens of important applications, including the manufacture of ethylene glycol based antifreeze, aircraft deicers, and PET plastics. EO is also used to produce higher-value derivatives such as ethoxylates, ethanolamines, glycol ethers, and polyether polyols. A small but critical use of EO is for the sterilization of medical equipment.

EPA's SAB 2007 review concluded that substantial revisions were needed to the draft IRIS assessment including:

- Acquiring and using individual data for modeling rather than grouping populations, which results in overly conservative estimated cancer risks;
- Considering using both linear and non-linear approaches to estimate cancer risk due to the distribution of and questionable association with certain cancer types; and
- Providing more transparency and correcting flaws associated with inappropriately grouping lymphohematopoietic cancers and combining genders for the dose-response analysis.

Meeting materials, including public comments, can be found at https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/7E3E313F627541D78525711400470D01.

The 2015 SAB Committee that reviewed the revised 2013 EO draft IRIS assessment did not conduct an independent, unbiased review. Problems included:

- Several SAB members made inaccurate public statements indicating industry produced scientific studies should be not be considered due to potential industry influence, although no evidence of biased data sponsored by industry was ever presented.
- SAB members did not understand new evidence-based medicine concepts regarding mutagenicity of cancer cells and the contribution of naturally occurring EO in DNA repair mechanisms.
- The SAB recommended using epidemiology data sets with questionable or scientifically unsound characteristics to estimate cancer risk and rejected alternative data sets that are as or more robust than those selected.

EPA still did not use individual data for modeling as recommended by the SAB in 2007, and did not adequately explore alternatives to the linear low dose modeling approach.

Meeting materials, including public comments, can be found at https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/17F305EC43EB1A6585257E2D0050255F.

The IRIS Program used a spline approach (piecewise linear model that was not presented during either SAB review) for exposure-response analyses for each of the lymphoid and breast cancer endpoints and ultimately combined the results. This approach results in higher risk at lower exposure levels and leads to proposed regulatory levels that are orders of magnitude lower than what the epidemiologic and genotoxicity scientific evidence would support.

Further, the IRIS Program did not fully consider all available evidence in finalizing the EO assessment. Scientific evidence clearly indicates that EO is a weak mutagen and a unit risk factor of less than 1 ppt is not realistic or reliably measurable, and is orders of magnitude lower than levels of EO in ambient air and the normal, endogenous levels of EO present in human bodies. Moreover, the assessment fails to consider the difference between exposures to EO produced outside the human body and exposure to EO produced within the human body as a normal metabolic product.

ORD Mission Measures Workshop Report-out 10/5/17						
Key Function	Product or Service	Customer	What Customers Value	Investor	Investor ROI Demand (Mission Outcome)	Measure: Increasing Customer Value and/or Investor ROI
Conduct Research	Data, methods, models, and technologies Assistance Agreements, research and leading edge science Peer reviewed publications, and science translation products, including dashboards, tools, synthesis documents, webinars, meetings, and conferences.	Program offices, regions, states, scientific community, citizen scientists, regulated and non-regulated community, and the public	Quality, reliability, timeliness, utility, ease of use, reduced uncertainty, cost effectiveness	Taxpayer	Standard test methods accepted internationally providing business stakeholders cross-market consistency and harmonization; Public access to data and models to inform and enable broader stakeholder community; Provide comprehensive, quality, credible, and reliable information to public health and environmental decision-makers	Increase public access to reports, data and tools by x% % of projects with an approved Scientific Data Management Plan (SDMP), a QA project plan, and a Project Plan. % of APR products that go through external to EPA peer review (peer review required unless justified) % of key products (APRs), including external peer review, that are delivered by the end of the 2d quarter of the fiscal year in which they are due

ORD Mission Measures Workshop Report-out 10/5/17						
Key Function	Product or Service	Customer	What Customers Value	Investor	Investor ROI Demand (Mission Outcome)	Measure: Increasing Customer Value and/or Investor ROI
						Time between the completion of a key product (APR) and the date when it is made publically available with a communications plan. (Steve's draft version) % of APR Products made publically available with communications plans and/or factsheets within 4 months of delivery (Mike's original.)
Perform Assessments	A portfolio of fit-for-purpose human and ecological assessment products that optimize the application of best available science and technology. Examples include ISAs, IRIS,	Diversity of customers, including EPA Administrator, program and regional offices, states, tribes, other federal agencies, and industry. Industry might also use	Scientific Excellence; Fit for Purpose and Relevant; Transparent; Timely and Responsive.	Taxpayer	Informs decisions to protect human health and the environment. Robust and high quality synthesis of science that can withstand scrutiny and review.	Percent of planned assessment products completed on time for agency review. Percent of agency decisions using NCEA assessment products.

ORD Mission Measures Workshop Report-out 10/5/17						
Key Function	Product or Service	Customer	What Customers Value	Investor	Investor ROI Demand (Mission Outcome)	Measure: Increasing Customer Value and/or Investor ROI
	PPRTVs, and ecological risk assessments.	upstream to evaluate decision options. For example, chemical manufacturers might use for selection of safe chemical alternatives.				
Provide Tech Support	Technical support – Scientific advice, technical reviews, analysis of data and demonstration of tools and technologies to evaluate and solve environmental issues/concerns.	EPA program offices and regions, states, tribes, communities.	State-of-the science advice, data, tools, etc. Support readily accessible when needed. Timely delivery of support. Available for follow-up as needed. No/limited cost to requestor.	Taxpayers	Informs immediate, mid- and long-term decisions to protect human health and the environment.	# of Superfund sites supported ORD technical support measured using TechTracker Percent of time meeting customer needs following a request Increase in number of times ORD science was used in or to support site-specific decisions

ORD Mission Measures Workshop Report-out 10/5/17						
Key Function	Product or Service	Customer	What Customers Value	Investor	Investor ROI Demand (Mission Outcome)	Measure: Increasing Customer Value and/or Investor ROI
						% of technical support requests (from 5 TSCs) that result in a publically available synthesis report % of ORD technical staff contributing to TechTracker

Message

From: Noel, Glenda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B4B623A1613B46AF874225422C979326-NOEL, GLENDA]
Sent: 7/17/2018 5:13:27 PM
To: Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]
Subject: RE: strengthening transparency in science rulemaking

We discussed it and agreed on me and David. Thank you!

Glenda Noel
(919) 541-2656

From: Blancato, Jerry
Sent: Tuesday, July 17, 2018 8:51 AM
To: Noel, Glenda <Noel.Glenda@epa.gov>
Subject: FW: strengthening transparency in science rulemaking

Have a look.

Jerry
919-541-2854

From: Doa, Maria
Sent: Monday, July 16, 2018 10:53 AM
To: Blancato, Jerry <Blancato.Jerry@epa.gov>
Subject: strengthening transparency in science rulemaking

Hi Jerry,

As I mentioned on Friday on the call on the impacts to ORD of the science transparency rule, we are pulling together an internal team to address public comments submitted in response to the science issues raised in the proposed rule. One of the areas we need support on is the infrastructure for housing and accessing the raw data for studies considered to be "pivotal regulatory science". Could we get someone from OSIM to participate on this group? It would be helpful to have someone with a broad view.

This internal team will help us identify issues and draft responses to comments. This would be a collaborative effort with us in OSP and to some extent OGC. We would ask that if needed they participate in one or more Agency workgroup meetings. We are conscious of their time and would only ask them to participate in these meetings when necessary. The participation would start in mid-August and would continue for about 7 months.

Please let me know if you have any questions or need additional information.

Maria J. Doa, Ph.D.
Office of Science Policy
Office of Research and Development
Environmental Protection Agency
Tel. 202.566.0718

Message

From: Dunn, Nathan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=42088A6911EB4BDBA3561651C75D41FD-DUNN, NATHA]
Sent: 5/8/2018 6:23:15 PM
To: Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]; Noel, Glenda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4b623a1613b46af874225422c979326-Noel, Glenda]
CC: Montilla, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b148b5335ff44aea8970035668052f01-Montilla, Alex]
Subject: Updated Tom Sinks Data Request Graph
Attachments: Tom Sinks Graph.docx; Tom_Sinks_Quarterly_Public_Access_Report.xlsx

Hi Jerry,

Here is the updated version of the graph we had that meeting about this morning. Let me know if you have any questions or want any changes made.

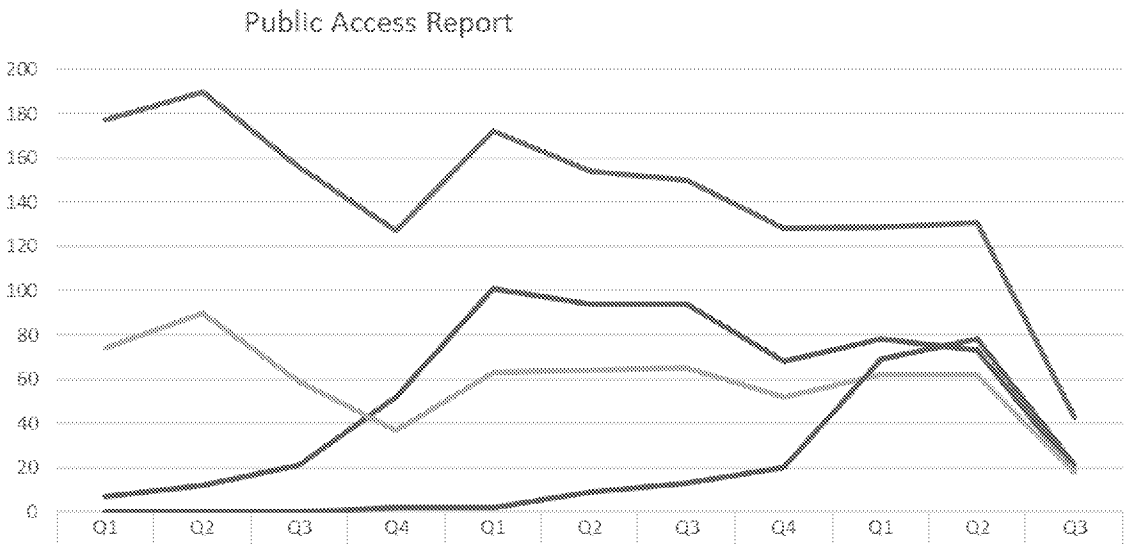
Thanks,

Nathan Dunn
Student Services Contractor
PH: 919-541-1839

*All AED articles and GED articles published before 7/1/2017 are exempt from publishing data due to a union agreement

*PMC submission process began on 10/27/2017

*STICS wasn't modified to track articles with associated EPA data until FY17 Q1 (Dec)



	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	FY16				FY17				FY18		
Number of Published Articles	177	190	156	127	172	154	150	128	129	131	43
Number of Articles with Associated Data	7	12	21	52	101	94	94	68	78	73	18
Number of Articles with Published Data	74	90	59	37	63	64	65	52	62	62	18
Number of Articles sent to PMC	0	0	0	2	2	9	13	20	69	78	21

Initiator's L/C/O	Clearance Tracking Number	Title	PI/PO	Cleared Date
ord,nerl,mceard,barb	ORD-008481	EPA Method 1615. Measurement of Enterovirus and Norovirus Occurrence in Water by Culture and RT-qPCR. Part III. Virus Detection by RT-qPCR	Shay Fout	1/7/2015
ord,nrmrl,std,sab	ORD-008519	System learning approach to assess sustainability and forecast trends in regional dynamics: The San Luis Basin study, Colorado, U.S.A.	Heriberto Cabezas	5/12/2014
ord,nrmrl,wswrd,uwmb	ORD-008612	Evaluating the Accuracy of Common Runoff Estimation Methods for New Impervious Hot-Mix Asphalt	Mike Borst	6/20/2014
ord,ncct,N/A	ORD-008734	(REPRODUCTIVE TOXICOLOGY) Computational Modeling and Simulation of Genital Tubercle Development	Thomas Knudsen	7/12/2016

ord,nhsrc,wipd	ORD-008819	Appropriatenes s of simulants for Bacillus anthracis in studying Multi-Generation Cross-contamiantion of Mail	Alan Lindquist	7/24/2014
ord,nheerl,istd,pb	ORD-008834	Development of a Human Physiologically Based Pharmacokineti cs (PBPK) Model For Dermal Permeability for Lindane	Marina Evans	6/10/2014
ord,nheerl,aed,pe b	ORD-008873	Internet-Based Approaches to Building Stakeholder Networks for Conservation and Natural Resource Management.	Betty Kreakie	7/7/2014
ord,ncct,N/A	ORD-008897	(Envir. Health Perspect.) Using ToxCast data to reconstruct dynamic cell state trajectories and estimate toxicological points of departure	Imran Shah	7/22/2014

ord,nheerl,aed,heb	ORD-008919	Population Status of the Seaside Sparrow in Rhode Island: A 25-Year Assessment.	Walter Berry	11/6/2014
ord,nerl,eerd,erb	ORD-008922	Effectiveness of a stream-restoration effort using natural material instream structures	Joseph Flotemersch	4/28/2016
ord,nerl,esd,leb	ORD-008924	Global Forest Area Trends Underestimate Threats from Forest Fragmentation	James Wickham	8/17/2015
ord,nrmrl,std,sab	ORD-001121	Using ecological stoichiometry as an indicator of ecological function of headwater streams	Matthew Hopton	8/20/2012
ord,nrmrl,std,seb	ORD-001775	Stoichiometry of excreta in larval stream salamanders: implications regarding the ecological roles of salamanders	Matthew Hopton	8/22/2012
ord,nerl,eerd,erb	ORD-002037	Eight river principles for navigating the science– policy interface	Joseph Flotemersch	4/6/2016

ord,nheerl,ephd,eb	ORD-002135	Genetic Variants in the Bone Morphogenic Protein Gene Family Modify the Association between Residential Exposure to Traffic and Peripheral Arterial Disease cardiovascular disease cohort.	Lucas Neas	9/19/2012
ord,nhsrc,wipd	ORD-002355	Redesign of Water Distribution Systems for Passive Containment of Contamination	Regan Murray	1/25/2016
ord,nerl,sed,eib	ORD-002917	Authorship Guidance in a Federal Research Laboratory: A Case Study	Joseph Flotemersch	12/21/2012
ord,nrmrl,std,seb	ORD-003000	Factors that influence natural abundances of stable isotopes in headwater stream taxa located across urban and natural green spaces	Matthew Hopton	12/7/2012

ord,nerl,eerd,mirb	ORD-003085	Part 2: Sensitivity comparisons of the insect Centroptilum triangulifer to Ceriodaphnia dubia and Daphnia magna using standard reference toxicants; NaCl, KCl and CuSO4	Jim Lazorchak	4/26/2013
ord,nheerl,wed,eeb	ORD-003542	Weighing the relative potential impacts of climate change and land-use change on an endangered bird	Nathan Schumaker	2/13/2013
ord,nheerl,med	ORD-003606	Variation in bird-window collision mortality and scavenging rates within an urban landscape	Matthew Etterson	2/19/2013
ord,nerl,eerd,mirb	ORD-003702	Complex watersheds, collaborative teams: Assessing pollutant presence and effects in the San Francisco Delta	Adam Biales	5/24/2016

ord,nerl,sed,efab	ORD-003798	Estimation of pyrethroid pesticide intake using regression modeling of food groups based on composite dietary samples..	Lisa Melnyk	6/15/2016
ord,nheerl,ephd,eb	ORD-004191	Effect of Microcystin-LR on human placental villous trophoblast differentiation in vitro	E Hilborn	4/23/2013
ord,nrmrl,std	ORD-004213	Controllability of complex networks for sustainable system dynamics	Heriberto Cabezas	5/2/2013
ord,nerl,eerd,merb	ORD-004292	Genetic linkage map and comparative genome analysis for the estuarine Atlantic killifish (Fundulus heteroclitus)	Eric Waits	5/15/2015
ord,ncea,nceawa,eigc	ORD-004332	Mercury exposure and omega-3 fatty acid intake in relation to renal disease risk in the US population: NHANES 2003-2004	Yu-Sheng Lin	5/6/2013

ord,nrmrl,std,seb	ORD-004403	Estimating Green Net National Product for Puerto Rico: An Economic Measure of Sustainability (Journal article)	Matt Heberling	5/14/2013
ord,nerl,eerd,erb	ORD-004526	Hydrogeomorphic zones characterize riverbed sediment patterns within a river network	Sean Collins	10/28/2014
ord,nrmrl,appcd,ecpb	ORD-004816	Episodic Impacts from California Wildfires Identified in Las Vegas Near-Road Air Quality Monitoring	Sue Kimbrough	4/22/2015
ord,nrmrl,appcd,iemb	ORD-005040	Source emission and model evaluation of formaldehyde from composite and solid wood furniture in a full-scale chamber	Xiaoyu Liu	2/12/2015

ord,ncea,nceacin, brab	ORD-005150	Multivariate Condition Assessment of Watersheds with Linked Micromaps	Michael McManus	9/24/2013
ord,nheerl,ephd,eb	ORD-005432	Exposure to the elemental carbon, organic carbon, nitrate and sulfate fractions of fine particulate matter and risk of preterm birth in New Jersey, Ohio, and Pennsylvania (2000-2005).	Danelle Lobdell	9/6/2013
ord,nerl,erd	ORD-005555	Evaluating relative sensitivity of SWAT-simulated nitrogen discharge to projected climate and land cover changes for two watersheds in North Carolina, USA	Mark Gabriel	11/18/2015

ord,nerl,mceard,merb	ORD-005687	Statistical approaches to developing a multiplex immunoassay for determining human exposure to environmental pathogens (journal article)	Swinburne Augustine	1/19/2016
ord,nheerl,aed,wdb	ORD-005730	Preliminary Evidence for the Amplification of Global Warming in Shallow, Intertidal Estuarine Waters	Autumn Oczkowski	10/25/2013
ord,nheerl,istd	ORD-005822	Systems Biology and Biomarkers of Early Effects for Occupational Exposure Limit Setting	Stephen Edwards	9/23/2013
ord,nerl,ced	ORD-005847	A modified eco-efficiency framework and methodology for advancing the state of practice of sustainability analysis as applied to green infrastructure	JohnM Johnston	6/6/2017

ord,nheerl,ephd,cib	ORD-005872	Rat Models of Cardiometabolic Diseases: Baseline Clinical Chemistries, and Rationale for their Use in Examining Air Pollution Health Effects	Urmila Kodavanti	1/21/2014
ord,nheerl,ephd,cib	ORD-005879	Whole Body Plethysmography Reveals Differential Ventilatory Responses to Ozone in Rat Models of Cardiovascular Disease	Urmila Kodavanti	1/6/2014
ord,nheerl,ephd,cib	ORD-005884	Clinical and pathological manifestations of cardiovascular disease in rat models: the influence of acute ozone exposure	Urmila Kodavanti	1/7/2014
ord,nheerl,ephd,cib	ORD-005900	Variability in Ozone-Induced Pulmonary Injury and Inflammation in Healthy and Cardiovascular Compromised Rat Models	Urmila Kodavanti	1/7/2014

ord,nheerl,ephd,cib	ORD-005902	Strain Differences in Antioxidants in Rat Models of Cardiovascular Disease Exposed to Ozone	Urmila Kodavanti	1/21/2014
ord,nrmrl,wswrd,uwmb	ORD-005992	Water Consumption Estimates of Biodiesel Process in the US	Jeff Yang	3/18/2014
ord,nhsrc,wipd	ORD-006175	The effect of a loss of model structural detail due to network skeletonization on contamination warning system design: case studies	Robert Janke	10/23/2017
ord,nheerl,aed,peb	ORD-006191	Approaches for predicting effects of unintended environmental exposure to an endocrine active pharmaceutical, tamoxifen	Lesley Mills	9/30/2013
ord,nrmrl,std,seb	ORD-006363	Energy sustainability: consumption, efficiency, and environmental impact	Leisha Vance	10/29/2013

ord,nrmrl,std	ORD-006371	Process synthesis involving multi-period operations by the P-graph framework	Heriberto Cabezas	11/5/2013
ord,nheerl,ephd,cib	ORD-006386	Left Ventricular Gene Expression Profile of Healthy and Cardiovascular Compromised Rat Models Used in Air Pollution Studies	Urmila Kodavanti	1/6/2014
ord,nheerl,ephd,cib	ORD-006387	Lung transcriptional profiling: insights into the mechanisms of ozone-induced pulmonary injury in Wistar Kyoto rats	Urmila Kodavanti	1/6/2014
ord,nheerl,ephd,cib	ORD-006390	Pulmonary Transcriptional Response to Ozone in Healthy and Cardiovascular Compromised Rat Models	Urmila Kodavanti	1/6/2014

ord,nheerl,med	ORD-006651	Distribution of sediment measurements in Lake Michigan as a case study: Implications for estimating sediment and water interactions in eutrophication and bioaccumulation models	Davidh Miller	12/10/2013
ord,nheerl,ged	ORD-006762	A Spatially-Explicit Technique for Evaluation of Alternative Scenarios in the Context of Ecosystem Goods and Services	Marc Russell	11/26/2013
ord,nerl,sed,efab	ORD-006797	Retrospective Surveillance of Wastewater To Examine Seasonal Dynamics of Enterovirus Infections	Nichole Brinkman	11/9/2016
ord,ncea,nceawa, eigc	ORD-006858	Association of body burden of mercury with liver function test status in the U.S. population	Yu-Sheng Lin	12/24/2013

ord,nrmrl,appcd,apb	ORD-007089	Canopy Level Emissions of 2-methyl-3-buten-2-ol, monoterpenes, and sesquiterpenes from a Pinus taeda Experimental Plantation	Chris Geron	6/19/2014
ord,nheerl,ged	ORD-007138	Evaluating the Transferability of a U.S. Human Well-being Index (HWBI) Framework to Native Americans Populations	Lisam Smith	1/13/2014
ord,nerl,esd,cmb	ORD-007145	Riparian Proper Functioning Condition (PFC) Assessment to Improve Water Quality	Daniel Heggem	9/15/2014
ord,nrmrl,wswrd,uwmb	ORD-007176	Simulating the hydrologic impacts of land cover and climate changes in a semi-arid watershed	Jeff Yang	3/6/2015
ord,nrmrl,wswrd,uwmb	ORD-007178	Hydrologic impacts of climate change and urbanization in Las Vegas Wash Watershed, Nevada	Jeff Yang	6/6/2014

ord,nerl,esd,leb	ORD-007188	Hydrologic and Water Quality Models: Sensitivity Analysis	Yongping Yuan	10/6/2014
ord,nerl,erd	ORD-007206	Rainfall-induced release of microbes from manure: model development, parameter estimation, and uncertainty evaluation on small plots	Gene Whelan	5/25/2016
ord,nheerl,med	ORD-007257	Review of existing terrestrial bioaccumulation models and terrestrial bioaccumulation modeling needs for organic chemicals	Lawrence Burkhard	6/4/2014
ord,nheerl,ged	ORD-007311	Habitat and Recreational Fishing Opportunity in Tampa Bay: Linking Ecological and Ecosystem Services to Human Beneficiaries	Richard Fulford	2/5/2014

ord,nheerl,ephd,eb	ORD-007318	Associations Between Residential Proximity to Traffic and Vascular Disease in a Cardiac Catheterization Cohort	Lucas Neas	2/4/2014
ord,nrmrl,std,seb	ORD-007330	Adaptive governance to promote ecosystem services in urban green spaces	Ahjond Garmestani	2/6/2014
ord,nheerl,aed,heb	ORD-007374	Nutrient Effects on Belowground Organic Matter in a Minerogenic Salt Marsh, North Inlet, SC	Cathleen Wigand	4/14/2014
ord,nheerl,istd,gctb	ORD-007470	Differential genomic effects on signaling pathways by two different CeO2 nanoparticles in HepG2 cells	Kirk Kitchin	2/11/2014
ord,nrmrl,aemd,ensb	ORD-007478	Analysis of Emissions Reduction Strategies for Power Boilers in the U.S. Pulp and Paper Industry.	Gurbakhash Bhander	9/22/2016

ord,nrmrl,std,sab	ORD-007529	Comparing the Life Cycle Energy Consumption, GlobalWarming and Eutrophication Potentials of Several Water andWaste Service Options	Troy Hawkins	2/19/2014
ord,nheerl,ephd,crb	ORD-007540	Dietary Supplementation with Olive Oil or Fish Oil and Vascular Effects of Concentrated Ambient Particulate Matter Exposure in Human Volunteers	Haiyan Tong	2/26/2014
ord,nheerl,wed,eeb	ORD-007624	Modeling Agassiz's Desert Tortoise Population Response to Anthropogenic Stressors	Nathan Schumaker	3/21/2014
ord,nerl,emmd,mieb	ORD-007759	Harvested rainwater quality before and after treatment in six full-scale residential systems	Dennis Lye	8/27/2014

ord,nerl,heasd,ecab	ORD-007778	The Impact of Commercially Treated Oil and Gas Produced Water Discharges on Bromide Concentrations and Modeled Brominated Trihalomethane Disinfection Byproducts at two Downstream Municipal Drinking Water Plants in the Upper Allegheny River, Pennsylvania,	Matthew Landis	7/13/2015
ord,nheerl,istd,sbb	ORD-007859	In vitro screening of metal oxide nanoparticles for effects on neural function using cortical networks on microelectrode arrays	Tim Shafer	3/12/2014
ord,nheerl,istd,sbb	ORD-007866	Expanding the test set: Chemicals with potential to disrupt mammalian brain development	William Mundy	4/18/2014

ord,ncea,nceawa, eigc	ORD-007912	Low serum zinc is associated with elevated risk of cadmium nephrotoxicity	Yu-Sheng Lin	3/20/2014
ord,nheerl,aed,w db	ORD-008008	Nitrogen retention in salt marsh systems across nutrient-enrichment, elevation, and precipitation regimes: a multiple stressor experiment	Autumn Oczkowski	6/10/2014
ord,nerl,amd,amb	ORD-008045	The Effects of Global Change upon United States Air Quality	Chris Nolte	10/8/2015
ord,nrmrl,wswrd, mccb	ORD-008110	Metabolic and genomic analysis elucidates strain-level variation in Microbacterium spp. isolated from chromate contaminated sediment	Jorge Santodomingo	6/13/2014

ord,nerl,mceard,barb	ORD-008140	The development and implementation of a method using blue mussels (Mytilus spp.) as biosentinels of Cryptosporidium spp. and Toxoplasma gondii contamination in marine aquatic environments	Eric Villegas	9/2/2015
ord,nheerl,tad,nb	ORD-008185	Testing for Cognitive Function in Animals in a Regulatory Context	Philip Bushnell	5/12/2014
ord,nerl,eerd,erb	ORD-008264	Relative effects of geographically isolated wetlands on streamflow: a watershed-scale analysis	Heather Golden	6/15/2015
ord,nerl,emmd,mieb	ORD-008307	EPA Method 1615. Measurement of Enterovirus and Norovirus Occurrence in Water by Culture and RT-qPCR. II. Total Culturable Virus Assay	Shay Fout	6/12/2017

ord,nerl,esd	ORD-008336	A data fusion approach for spatial analysis of speciated PM2:5 across time	David Holland	8/20/2014
ord,ncea,odd,pos	ORD-008393	Susceptibility based upon Chemical Interaction with Disease Processes: Potential Implications for Risk Assessment	Bob Sonawane	5/23/2014
ord,nheerl,wed,feb	ORD-008438	Regional patterns of total nitrogen concentrations in the National Rivers and Streams Assessment	Steve Paulsen	8/21/2015
ord,nrmrl,std,cpb	ORD-008469	Core–shell nanoparticles: synthesis and applications in catalysis and electrocatalysis	Rajender Varma	5/12/2014
ord,nheerl,ephd,eb	ORD-008947	Environmental Exposure to Manganese in Air: Associations with Tremor and Motor Function	Danelle Lobdell	7/16/2014

ord,nheerl,med	ORD-008976	Modeling TiO2 nanoparticle phototoxicity: The importance of chemical concentration, ultraviolet radiation intensity, and time	Shibin Li	7/10/2014
ord,nrmrl,lrpcd,wmb	ORD-009025	Analytical Characterisation of Nanoscale Zero-Valent Iron: A Methodological Review	Kirk Scheckel	7/11/2014
ord,nerl,esd,leb	ORD-009053	Combining NLCD and MODIS to Create a Land Cover-Albedo Dataset for the Continental United States	James Wickham	4/14/2015
ord,nrmrl,wswrd,uwmb	ORD-009099	Large-Diameter Sewer Rehabilitation Using a Spray Applied Fiber Reinforced Geopolymer Mortar	Ariamalar Selvakumar	9/5/2014
ord,nheerl,ephd,eb	ORD-009112	Measuring the Storm: Methods of Quantifying Hurricane Exposure in Public Health	Danelle Lobdell	7/15/2014

ord,nerl,sed,efab	ORD-009125	Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States	Susan Glassmeyer	9/25/2014
ord,nheerl,ephd,cib	ORD-009205	Suppression of antigen-specific antibody responses in mice exposed to perfluorooctanoic acid: Role of PPARalpha and T- and B-cell targeting	Robert Luebke	9/5/2014
ord,nerl,emmd,ieib	ORD-009206	Aquatic concentrations of chemical analytes compared to ecotoxicity estimates	Mitchell Kostich	5/5/2016
ord,nrmrl,lrpcd	ORD-009210	Aggregate Measures of Watershed Health from Reconstructed Water Quality Data with Uncertainty	Mohamed Hantush	8/27/2014

ord,nrmrl,std,seb	ORD-009220	Asian longhorned beetle complicates the relationship between taxonomic diversity and pest vulnerability in street tree assemblages	Matthew Hopton	7/15/2014
ord,ncct,N/A	ORD-009273	(ENVIRONMENTAL HEALTH PERSPECTIVES) Systems Toxicology of Male Reproductive Development: Profiling 774 Chemicals for Molecular Targets and Adverse Outcomes	Thomas Knudsen	6/30/2015
ord,ncea,odd,pos	ORD-009284	A Conceptual Framework for Evaluating the Interaction of a Chemical and Nonchemical Stressor in Human Health Risk Assessments: A Case Study for Lead and Psychosocial Stress	Deborah Segal	8/4/2014

ord,nerl,emmd	ORD-009383	Effects of chronic alcohol consumption on neuronal function in the non-human primate BNST	Jon Sobus	2/23/2017
ord,nrmrl,appcd,iemb	ORD-009388	Remediation of Methamphetamine in Clandestine Laboratories.A Literature Review	Clyde Owens	9/28/2016
ord,nrmrl,std,cpb	ORD-009399	Magnetically Separable Fe3O4@DOPA-Pd: A Heterogeneous Catalyst for Aqueous Heck Reaction	Rajender Varma	8/11/2014
ord,nheerl,med	ORD-009420	Global and regional contributions to total mercury concentrations in Lake Michigan water	Kenneth Rygwelski	9/29/2014
ord,nheerl,ged	ORD-009435	Adaptation of a weighted regression approach to evaluate water quality trends in anestuary	Jim Hagy	8/12/2014

ord,nerl,sed,eib	ORD-009438	Microbial pathogens in source and treated waters from drinking water treatment plants in the United States and implications for human health	Stacy Pfaller	9/25/2014
ord,nrmrl,std,sab	ORD-009508	Analyzing the environmental impacts of laptop enclosures using screening-level life cycle assessment to support sustainable consumer electronics (j/a)	David Meyer	9/4/2014
ord,nheerl,med	ORD-009552	Sequence Alignment to Predict Across Species Susceptibility (SeqAPASS): A web-based tool for addressing the challenges of cross-species extrapolation of chemical toxicity	Dan Villeneuve	9/22/2014

ord,nerl,eerd,erb	ORD-009585	Phosphorus retention of forested and emergent marsh depressional wetlands in differing land uses in Florida, USA	Charles Lane	8/17/2015
ord,ncea,odd,pos	ORD-009610	The use of glia in human health assessments of environmental contaminants	Andrew Kraft	9/5/2014
ord,nerl,heasd,ecab	ORD-009634	Application of ICP-OES for Evaluating Energy Extraction and Production Wastewater Discharge Impacts on Surface Waters in Western Pennsylvania	Gary Norris	7/9/2015
ord,nheerl,ged	ORD-009695	Improved method for calibration of exchange flows for a physical transport box model of Tampa Bay, FL USA	Johne Rogers	8/29/2014

ord,nrmrl,std,cpb	ORD-009700	Cleaning Water Contaminated With Heavy Metal Ions Using Pyrolyzed Banana Peel Adsorbents	Endalkachew Sahle-Demessie	9/4/2014
ord,nerl,heasd,emab	ORD-009707	Uses of NHANES biomarker data for chemical risk assessment: Trends, challenges and opportunities	Jon Sobus	11/18/2015
ord,nrmrl,wswrd	ORD-009709	Comparison of Sewage and Animal Fecal Microbiomes using Oligotyping Reveals Potential Human Fecal Indicators in Multiple Taxonomic Groups	Orin Shanks	9/19/2014
ord,nerl,heasd,emrb	ORD-009731	Modeling tribal exposures to methyl mercury from fish consumption	Jianping Xue	6/22/2015

ord,nheerl,wed,pceb	ORD-009732	Effect of Climate Change on Water Temperature and Attainment of Water Temperature Criteria in the Yaquina Estuary, Oregon (USA)	Cheryl Brown	9/18/2014
ord,nheerl,aed,heb	ORD-009821	Carbon and nitrogen isotope ratios of juvenile winter flounder as indicators of inputs to estuarine systems	Richard Pruell	10/28/2014
ord,nrmrl,lrpcd,esmb	ORD-009875	Effects of Dispersants on the Biodegradation of South Louisiana Crude Oil at 5 and 25oC	Robyn Conmy	9/19/2014
ord,nhsrc,wipd	ORD-009882	Testing Contamination Source Identification Methods for Water Distribution Networks	Terra Haxton	10/2/2014
ord,nerl,esd	ORD-009888	Role of Sustainability and Pollution Prevention in Reducing EnvironmentalContamination by Drugs	Christian Daughton	6/3/2015

ord,nrmrl,std,sab	ORD-009896	Evaluating Consumer Product Life Cycle Sustainability with Integrated Metrics: A Paper Towel Case Study	Wesley Ingwersen	9/29/2014
ord,nheerl,ged	ORD-009903	A Practical Probabilistic Graphical Modeling Tool for Weighing Ecological Risk-Based Evidence	Mace Barron	9/12/2014
ord,nrmrl,gwerd, artsb	ORD-009905	Quantifying groundwater dependency of riparian surface hydrologic features using the exit gradient	Bart Faulkner	9/15/2014
ord,nerl,sed	ORD-009915	Who is Next? Identifying Communities with the Potential for Increased Implementation of Sustainability Policies and Programs	Michael Nye	8/4/2016
ord,nerl,eerd,erb	ORD-009925	A Watershed Integrity Definition and Assessment Approach to Support Strategic Management of Watersheds	Joseph Flotemersch	4/28/2016

ord,nrmrl,lrpcd,esmb	ORD-009933	Field studies measuring the aerosolization of endotoxin during the land application of Class B biosolids	Ronald Herrmann	9/19/2014
ord,nheerl,med,wdb	ORD-009954	Analyzing peatland discharge to streams in an Alaskan Watershed: An integration of end-member mixing analysis and a water balance approach	Mary Moffett	9/22/2014
ord,nrmrl,std,seb	ORD-009966	Comparing drinking water treatment costs to source water protection costs using time series analysis.	Matt Heberling	9/15/2014
ord,nheerl,med	9971	Modeling the relative importance of nutrient and carbon loads, boundary fluxes, and sediment fluxes on Gulf of Mexico hypoxia	James Pauer	6/29/2016

ord,nrmrl,appcd,apb	ORD-009986	Application of an online ion chromatography-based instrument for gradient flux measurements of speciated nitrogen and sulfur	Johnt Walker	9/24/2014
ord,nheerl,istd	ORD-009999	Identification and prioritization of relationships between environmental stressor and adverse human health impacts	Stephen Edwards	10/6/2014
ord,ncea,nceacin,brab	ORD-010003	Physiology of ionoregulation and osmoregulation of major ions by freshwater animals: Teleost fish, Crustacea, aquatic insects, and Mollusca- New TITLE: Toxicological Perspective on the Osmoregulation and Ionoregulation Physiology of Major Ions by Freshwat	Michael Griffith	9/30/2014

ord,nheerl,istd	ORD-010025	Developing Toxicogenomics as a Research Tool by Applying Benchmark Dose-Response Modeling to inform Chemical Mode of Action and Tumorigenic Potency	Susan Hester	10/6/2014
ord,nheerl,aed,wdb	ORD-010047	Quantifying Urban Watershed Stressor Gradients and Evaluating How Different Land Cover Datasets Affect Stream Management	Nathan Smucker	6/19/2015
ord,nrmrl,std,sab	ORD-010061	The Emergy Perspective of Sustainable Trends in Puerto Rico From 1960 to 2013 -	Cissy Ma	9/19/2014
ord,nrmrl,appcd,aptb	ORD-010066	Emissions Removal Efficiency from Diesel Gensets Using Aftermarket PM Controls	Tiffany Yelverton	10/10/2014

ord,nrmrl,std,sab	ORD-010071	Comparing Green and Grey Infrastructure Using Life Cycle Cost and Environmental Impact: A Rain Garden Case Study in Cincinnati, OH.	Wesley Ingwersen	9/30/2014
ord,nheerl,ephd,eb	ORD-010099	Neighborhood and Family Environment of Expectans Mothers May Influence Prenatal Programming of Adult Cancer Risk: Discussion and an Illustrative DNA Methylation Example	Katherine King	10/6/2014
ord,nerl,ced	ORD-010125	Holistic impact assessment and cost savings of rainwater harvesting at the watershed scale	JohnM Johnston	6/13/2017

ord,nerl,emmd,phcb	ORD-010139	Development and Multi-laboratory Verification of US EPA Method 543 for the Analysis of Drinking Water Contaminants by Online Solid Phase Extraction-LC–MS-MS	Jody Shoemaker	3/20/2016
ord,nerl,amd,aspmb	ORD-010149	A modeling framework for characterizing near-road air pollutant concentration at community scales	Vlad Isakov	1/11/2016
ord,nrmrl,wswrd	ORD-010168	Impact of Water Quality on Chlorine Demand of Corroding Copper	Darren Lytle	9/26/2014
ord,nerl,erd	ORD-010180	Net Zero Fort Carson: Integrating Energy, Water, and Waste Strategies to Lower the Environmental Impact of a Military Base	Rochelle Araujo	12/11/2014

ord,nerl,ced,web	ORD-010181	An integrated ecological modeling system for assessing impacts of multiple stressors on stream and riverine ecosystem services within river basins	JohnM Johnston	4/27/2017
ord,nrmrl,appcd	ORD-010201	Characterization of the Particulate Emissions from the BP Deepwater Horizon Surface Oil Burns	Brian Gullett	3/10/2015
ord,nheerl,ephd,cib	ORD-010212	Executive Summary: Variation in Susceptibility to Ozone-Induced Health Effects in Rodent Models of Cardiometaboli c Disease	Urmila Kodavanti	10/6/2014
ord,nhsrc,tcad	ORD-010227	Computational Fluid Dynamics Modeling of Bacillus anthracis Spore Deposition in Rabbit and Human Respiratory Airways [HS4.44.02]	Sarah Taft	10/16/2014

ord,nheerl,wed,feb	ORD-010262	Geographically Isolated Wetlands: Why We Should Keep the Term	Scott Leibowitz	10/2/2014
ord,nerl,heasd,pmrb	ORD-010284	Seasonal Contribution of Mineral Dust and Otlher Major Components to Particulate Matter at Two Remote Sites in Central Asia	Paul Solomon	6/29/2015
ord,nheerl,aed,heb	ORD-010361	Responses of Spartina alterniflora to Multiple Stressors: Changing Precipitation Patterns, Accelerated Sea Level Rise, and Nutrient Enrichment	Cathleen Wigand	6/18/2015
ord,nheerl,tad,nb	ORD-010395	Caloric Restriction in Lean and Obese Strains of Laboratory Rat: Effects on Body Composition, Metabolism, Growth, and Overall Health	Christopher Gordon	10/14/2014

ord,nrmrl,std,sab	ORD-010411	An industrial ecology approach to municipal solid wastemanagement: I. Methodology	Raymond Smith	10/28/2014
ord,nrmrl,std,sab	ORD-010412	An Industrial Ecology Approach to Municipal Solid Waste Management: II. Case Studies for Recovering Energy from the Organic Fraction of MSW	Raymond Smith	10/20/2014
ord,nhsrc,wipd	ORD-010434	Pulsed and Continuous UV LED Reactor for Water Treatment	Matthew Magnuson	10/29/2014
ord,nheerl,med	ORD-010442	Sampling design for early detection of aquatic invasive species in Great Lakes ports	Joel Hoffman	1/28/2015
ord,nheerl,ephd,eb	ORD-010451	A prospective study of marine phytoplankton and reported illness among recreational beachgoers in Puerto Rico, 2009	E Hilborn	11/3/2014

ord,nerl,eerd,erb	ORD-010466	Ecological research and management of intermittent rivers: an historical review and future directions	Ken Fritz	4/28/2015
ord,nrmrl,lrpcd,wmb	ORD-010557	Influence of Reservoir Water-Level Fluctuations on Mercury Methylation Downstream of the Historic Black Butte Mercury Mine, OR	Todd Luxton	2/9/2015
ord,ncea,odd,pos	ORD-010600	Improving Concordance in Environmental Epidemiology: A Three-Part Proposal	Susan Makris	2/13/2015
ord,nheerl,aed,heb	ORD-010685	A Climate Change Adaptation Strategy for Management of Coastal Marsh Systems	Cathleen Wigand	2/13/2015

ord,nerl,heasd,edrb	ORD-010687	A Workflow to Investigate Exposure and Pharmacokinetic Influences on High-Throughput in Vitro Chemical Screening Based on Adverse Outcome Pathways	Cecilia Tan	5/19/2015
ord,nrmrl,lrpcd,wmb	ORD-010708	Impact of Leaching Conditions on Constituents Release from Flue Gas Desulfurization Gypsum (FGDG) and FGDG-Soil Mixture	Souhail Al-Abed	4/9/2015
ord,nrmrl,lrpcd,wmb	ORD-010712	Bench-Scale and Pilot-Scale Treatment Technologies for the Removal of Total Dissolved Solids from Coal Mine Water: A Review	Souhail Al-Abed	5/7/2015

ord,nheerl,aed,peb	ORD-010744	Translating crustacean biological responses from CO2 bubbling experiments into population-level predictions	Jason Grear	11/18/2014
ord,nheerl,ephd	ORD-010748	Diesel exposure suppresses natural killer cell function and resolution of eosinophil inflammation: a randmonized controlled trial of exposure in allergic rhinitics	Steve Jackson	11/17/2014
ord,ncea,odd,gcas	ORD-010755	Impact of the Renewable Fuels Standard on U.S. Conservation Reserve Program Enrollment and Conversion	Christopher Clark	2/16/2016

ord,nheerl,ephd,eb	ORD-010762	Environmental influences on the seasonal distribution of Vibrio parahaemolyticus in the Pacific Northwest of the USA	E Hilborn	12/2/2014
ord,nheerl,ephd,crb	ORD-010765	Iron and iron-related proteins in asbestosis.	Andy Ghio	2/2/2015
ord,ncea,odd,gcas	ORD-010773	Conditional vulnerability of plant diversity to atmospheric nitrogen deposition across the United States	Christopher Clark	12/10/2014
ord,nrmrl,aemd,ensb	ORD-010777	Universal industrial sectors integrated solutions module for the pulp and paper industry	Gurbakhash Bhander	11/30/2016

ord,nerl,mceard,barb	ORD-010786	Molecular detection of Legionella spp. and their associations with Mycobacterium spp., Pseudomonas aeruginosa and amoeba hosts in a drinking water distribution system (Journal Article)	Jingrang Lu	2/8/2016
ord,nrmrl,lrpcd	ORD-010800	Anaerobic Biodegradation of Soybean Biodiesel and Diesel Blends under Methanogenic Conditions	Robyn Conmy	2/12/2015
ord,nerl,sed,efab	ORD-010846	The importance of quality control in validating concentrations of contaminants of emerging concern in source and treated drinking water samples.	Angela Batt	4/28/2016

ord,ncea,odd,pos	ORD-010850	Assessment of Learning, Memory and Attention in Developmental Neurotoxicity Regulatory Studies: Introduction	Susan Makris	12/8/2014
ord,nerl,mceard, merb	ORD-010866	Statistical approaches to developing a multiplex immunoassay for determining human exposure to environmental pathogens	Swinburne Augustine	4/28/2015
ord,nheerl,aed,mab	ORD-010897	Benefit transfer with limited data: An application to recreational fishing losses from surface mining	Marisa Mazzotta	2/24/2015
ord,nerl,heasd,emab	ORD-010901	Computational Exposure Science: An Emerging Discipline to Support 21st-Century Risk Assessment	Peter Egeghy	12/17/2015
ord,nrmrl,appcd,ecpb	ORD-010911	Influence of Solid Noise Barriers on Near-Road and On-Road Air Quality	Richard Baldauf	1/23/2015

ord,nheerl,med	ORD-010978	Sequencing and De novo Draft Assemblies of the Fathead Minnow (Pimphales promelas)Reference Genome	Dan Villeneuve	12/4/2014
ord,nheerl,aed	ORD-010991	Ecosystem services as assessment endpoints for ecological risk assessment	Wayne Munns	3/6/2015
ord,nheerl,aed	ORD-010994	Ecosystem services in risk assessment and management.	Wayne Munns	12/17/2015
ord,nhsrc,wipd	ORD-011009	Wide-Area Decontamination in an Urban Environment after Radiological Dispersion: A Review and Perspectives	Matthew Magnuson	1/20/2015
ord,nheerl,ephd,eb	ORD-011014	Self-reported acute health symptoms and exposure to companion animals	Tim Wade	12/9/2014
ord,nheerl,wed,feb	ORD-011017	Relationship between the natural abundance of soil nitrogen isotopes and condition in North Dakota wetlands	Amanda Nahlik	12/10/2014

ord,nrmrl,appcd,apb	ORD-011021	A Meta-Analysis of Urban Climate Change Adaptation Planning in the U.S.	Sara Hughes	9/30/2015
ord,nheerl,tad,nb	ORD-011073	Neurodevelopmental malformations of the cerebellar vermis in genetically engineered rats	Mary Gilbert	12/10/2014
ord,nheerl,aed,mab	ORD-011075	Modeling lake trophic state: a random forest approach	Jeff Hollister	4/6/2015
ord,nheerl,istd	ORD-011115	Disruption of STAT5b-Regulated Sexual Dimorphism of the Liver Transcriptome by Diverse Factors Is a Common Event	Chris Corton	1/26/2015
ord,nerl,emmd,mieb	ORD-011119	A Spike Cocktail Approach to Improve Microbial Performance Monitoring for Water Reuse	Jay Garland	6/1/2016

ord,nheerl,ephd,eb	ORD-011125	Use of Quantitative Microbial Risk Assessment to Improve Interpretation of a Recreational Water Epidemiological Study	Tim Wade	1/23/2015
ord,nrmrl,lrpcd,esmb	ORD-011145	Characterization of Solidifiers used for Oil Spill Remediation	Robyn Conmy	5/15/2015
ord,nheerl,tad,nb	ORD-011148	Translational Biomarkers of Neurotoxicity: A Health and Environmental Sciences Institute Perspective on The Way Forward	David Herr	12/23/2014
ord,nheerl,med	ORD-011157	The first US National Coastal Condition Assessment survey in the Great Lakes: Development of the GIS frame and exploration of spatial variation in nearshore water quality results	Johnr Kelly	2/2/2015

ord,ncct,N/A	ORD-011159	(Journal of Statistical Software) HTTK: R Package for High-Throughput Toxicokinetics	John Wambaugh	2/19/2015
ord,ncea,nceacin,brab	ORD-011182	Multivariate Condition Assessment of Watersheds with Linked Micromaps	Michael McManus	2/27/2015
ord,nrmrl,std,sab	ORD-011183	Using GREENSCOPE Indicators for Sustainable Computer-Aided Process Evaluation and Design	Raymond Smith	1/5/2015
ord,nerl,amd,aspmb	ORD-011194	Global evaluation of ammonia bidirectional exchange and livestock diurnal variation schemes	Jesse Bash	12/28/2015
ord,nerl,heasd,mdab	ORD-011196	Kidney injury biomarkers and urinary creatinine variability in nominally healthy adults	Joachim Pleil	11/30/2015

ord,nheerl,med	ORD-011208	Development of the larval amphibian growth and development assay: Effects of chronic 4-tert-octylphenol or 17ß-trenbolone exposure in Xenopus laevis from embryo to juvenile	Sigmund Degitz	1/28/2015
ord,nheerl,med,stb	ORD-011209	Effects of the anti-microbial contaminant triclocarban and co-exposure with the androgen 17â-trenbolone, on reproductive function and ovarian transcriptome of the fathead minnow (Pimephales promelas)	Dan Villeneuve	3/7/2016
ord,nheerl,aed,heb	ORD-011213	Growth and photosynthesis responses of two co-occurring marsh grasses to inundation and varied nutrients	Elizabeth Watson	1/8/2015

ord,nheerl,ephd,eb	ORD-011218	Are fecal indicator bacteria appropriate measures of recreational water risks in the tropics: A cohort study of beach goers in Brazil?	Tim Wade	1/23/2015
ord,nrmrl,wswrd,tteb	ORD-011240	Monochloramine Cometabolism by Mixed-Culture Nitrifiers under Drinking Water Conditions	David Wahman	2/11/2015
ord,nheerl,tad,nb	ORD-011248	Comparison of in vitro estrogenic activity and estrogen concentrations in source and treated waters from 25 U.S. drinking water treatment plants	Vickie Wilson	1/12/2015
ord,nerl,heasd,pmrb	ORD-011249	Chemical mass balance source apportionment of fine and PM10 in the Desert Southwest, USA	Paul Solomon	2/11/2016

ord,nheerl,med	ORD-011250	Great Lakes nearshore-offshore: Distinct water quality regions	Peder Yurista	3/17/2015
ord,nrmrl,appcd,iemb	ORD-011253	Chamber study of polychlorinated biphenyl (PCB)emissions from caulking materials and light ballasts	Xiaoyu Liu	2/12/2015
ord,nheerl,ephd,eb	ORD-011272	Medication Use Associated with Exposure to Manganese in Two Ohio Towns	Danelle Lobdell	2/11/2015
ord,nerl,emmd,aqb	ORD-011274	Source identification of coarse particles in the Desert Southwest, USA using Positive Matrix Factorization	Paul Solomon	1/20/2017
ord,nheerl,istd	ORD-011296	Effects of biological and behavioral factors on urinary arsenic metabolic profiles in a U.S. population	David Thomas	2/3/2015

ord,nrmrl,lrpcd,wmb	ORD-011304	Phosphorus Amendment Efficacy for In Situ Remediation of Soil Lead Depends on the Bioaccessible Method	Kirk Scheckel	5/21/2015
ord,nheerl,aed,peb	ORD-011310	Genetic basis for rapidly evolved tolerance in the wild: adaptation to toxic pollutants by an estuarine fish species	Diane Nacci	4/13/2015
ord,nheerl,aed	ORD-011311	Effects of climate on the expression of the urban stream syndrome	Nathan Smucker	7/29/2015
ord,nerl,esd,leb	ORD-011314	Completion of the 2011 National Land Cover Database for the Conterminous United States – Representing a Decade of Land Cover Change Information	James Wickham	10/26/2015

ord,nrmrl,wswrd,uwmb	ORD-011325	Source or sink: Insight on controls of nitrous oxide biogeochemistry from a 20 reservoir survey	Jake Beaulieu	2/20/2015
ord,nerl,heasd,pmrb	ORD-011341	Perceptions of environmental health risks among residents in the “Toxic Doughnut”: Opportunities for risk screening and community mobilization	EricS Hall	12/15/2015
ord,ncea,nceacin,crab	ORD-011343	Journal Article-"Estimating Inorganic Arsenic Exposure from U.S.Rice and Total Water Intakes"	Jack Creed	2/6/2015
ord,nrmrl,appcd,ecpb	ORD-011357	Volatile and semivolatile organic compounds in laboratory peat fire emissions	Brian Gullett	2/23/2015

ord,nheerl,istd,sbb	ORD-011396	Screening a mouse liver gene expression Compendium Identifies Effectors of the Aryl Hydrocarbon reeptors (AhR)	Chris Corton	3/2/2015
ord,nheerl,aed	ORD-011397	Potential roles of past, present, and future urbanization characteristics in producing varied stream responses	Nathan Smucker	4/14/2015
ord,nheerl,ephd,crb	ORD-011431	Wood smoke particle sequesters cell iron to impact a biological effect.	Andy Ghio	2/19/2015
ord,ncea,nceartp,emag	ORD-011434	Key ecological responses to nitrogen are altered by climate change	Tara Greaver	2/10/2016
ord,nheerl,wed,eeb	ORD-011435	Managing Climate Change Refugia for Climate Adaptation	Joe Ebersole	1/29/2015

ord,nheerl,ged	ORD-011436	Improving estimates of ecosystem metabolism by reducing effects of tidal advection on dissolved oxygen time series	Jim Hagy	2/2/2015
ord,nrmrl,wswrd, wqmb	ORD-011438	Phosphate Adsorption using Modified Iron Oxide-based Sorbents in Lake Water: Kinetics, Equilibrium, and Column Tests	Mallikarjuna Nadagouda	6/17/2015
ord,nerl,erd	ORD-011442	Agencies Collaborate, Develop a Cyanobacteria Assessment Network	Blake Schaeffer	2/2/2015
ord,nerl,eerd,erb	ORD-011443	Understanding controls on flow permanence in intermittent rivers to aid ecological research: integrating meteorology, geology and land cover	Ken Fritz	7/17/2015

ord,nrmrl,appcd,aptb	ORD-011450	Catalytic Destruction of a Surrogate Organic Hazardous Air Polutant as a Potential Co-benefit for Coal-fired Selective Catalyst Reduction Systems	Chun-Wai Lee	2/24/2015
ord,osa,rafs	ORD-011453	Illustrative Case Using the RISK21 Roadmap and Matrix: Prioritization for Evaluation of Chemicals Found in Drinking Water	Rita Schoeny	3/4/2015
ord,nheerl,wed,pceb	ORD-011459	Development and validation of a habitat suitability model for the non-indigenous seagrass Zostera japonica in North AmericaOF THE INTRODUCED SEAGRASS ZOSTERA JAPONICA	Jim Kaldy	2/3/2015

ord,nerl,eerd,mirb	ORD-011464	Reproductive effects in fathead minnows (Pimphales promelas) following a 21 d exposure to 17α-ethinylestradiol	Jim Lazorchak	6/17/2015
ord,nheerl,ephd,eb	ORD-011490	Epidemiology of nontuberculous mycobacteria isolations among central North Carolina residents, 2006-2010	E Hilborn	6/12/2015
ord,nrmrl,std,sab	ORD-011502	Managing for resilience: an information theory-based approach to assessing ecosystems	Tarsha Eason	2/10/2015
ord,nrmrl,appcd,iemb	ORD-011529	Laboratory study of PCB transport from primary sources to settled dust	Xiaoyu Liu	6/12/2015
ord,nheerl,wed,eeb	ORD-011545	Long-term impacts of land cover changes on stream channel loss	Paul Mayer	3/7/2015

ord,nerl,eerd,mirb	ORD-011550	Evaluating the extent of pharmaceuticals in surface waters of the United States using a national scale rivers and streams assessment survey	Angela Batt	4/28/2016
ord,nheerl,ged	ORD-011553	Future Needs and Recommendations in the Development of Species Sensitivity Distributions: Estimating Toxicity Thresholds for Aquatic Ecological Communities and Assessing Impacts of Chemical Exposures	Mace Barron	2/9/2015
ord,nrmrl,appcd	ORD-011565	Community Air Sensor Network Project: Lower Cost, Continuous Ambient Monitoring Methods	Gayle Hagler	2/23/2015

ord,nheerl,istd,gctb	ORD-011567	Mutagenicity- and Pollutant-Emission Factors of Solid-Fuel Cookstoves: Comparison to Other Combustion Sources	David DeMarini	5/7/2015
ord,nheerl,aed,heb	ORD-011584	Status and Distribution of Wintering Waterfowl in Narragansett Bay, Rhode Island, 2005-2014	Rick Mckinney	2/25/2015
ord,nheerl,istd,sbb	ORD-011592	Chemical and Hormonal Effects on STAT5b-Dependent Sexual Dimorphism of the Liver Transcriptome.	Chris Corton	3/2/2015
ord,nheerl,med	ORD-011597	Fish tissue lipid-C:N relationships for correcting ä13C values and estimating lipid content in aquatic food web studies	Joel Hoffman	4/14/2015
ord,nerl,ced	ORD-011599	Modeling the impact of solid noise barriers on near road air quality	Vlad Isakov	5/8/2017

ord,nerl,eerd,erb	ORD-011600	Delineation and quantification of wetland depressions in the Prairie Pothole Region of North Dakota	Charles Lane	1/7/2016
ord,nrmrl,wswrd,uwmb	ORD-011603	Nutrient Infiltrate Concentrations from Three Permeable Pavement Types	Mike Borst	3/5/2015
ord,nrmrl,std	ORD-011605	Quantifying the Adaptive Cycle	Ahjond Garmestani	2/12/2015
ord,nrmrl,wsd	ORD-011614	Multi-scale quantitative precipitation forecasting using nonlinear and nonstationary teleconnection signals and artificial neural network models - paper	Jeff Yang	3/6/2015
ord,nheerl,aed,mab	ORD-011629	Emergy baseline for the Earth: A historical review of the science and a new calculation	Dan Campbell	4/24/2015

ord,nrmrl,std,cpb	ORD-011630	Ferrate promoted oxidative cleavage of sulfonamides: Kinetics and product formation under acidic conditions	Rajender Varma	3/31/2015
ord,nerl,emmd	ORD-011656	Enantiomer‐specific measurements of current‐ use pesticides in aquatic systems	Elin Ulrich	7/20/2017
ord,nheerl,wed,eeb	ORD-011696	Stream restoration and sanitary infrastructure alter sources and fluxes of water, carbon, and nutrients in urban watersheds	Paul Mayer	10/1/2015
ord,nerl,eerd,merb	ORD-011703	Phylogeny and species diversity of Gulf of California oysters (Ostreidae) inferred from mitochondrial DNA	Erik Pilgrim	11/13/2015

ord,nheerl,tad,nb	ORD-011704	Environmental aging alters Al(OH)3 coating of TiO2 nanoparticles enhancing their photocatalytic and phototoxicity activities	William Boyes	3/6/2015
ord,nheerl,aed,heb	ORD-011715	Comparison of Bottomless Lift Nets and Breder Traps for Sampling Salt-Marsh Nekton	Marty Chintala	3/30/2015
ord,nrmrl,std,seb	ORD-011760	Institutional networks and adaptive water governance in the Klamath River Basin, USA.	Ahjond Garmestani	3/13/2015
ord,nrmrl,wswrd,wqmb	ORD-011789	Measuring nitrification inhibition in wastewater treatment systems: current state of science and fundamental research needs	Jorge Santodomingo	4/24/2015
ord,nerl,heasd,mdab	ORD-011796	Predicting oral relative bioavailability of arsenic in soil from in vitro bioaccessibility	Karen Bradham	5/26/2016

ord,nerl,heasd,emrb	ORD-011800	Reconstructing Exposures from Biomarkers using Exposure-Pharmacokinetic Modeling - A Case Study with Carbaryl	Kathleen Holm	11/2/2015
ord,nrmrl,wswrd,tteb	ORD-011812	An evaluation of sampling methods and supporting techniques for tackling lead in drinking water in Aberta Province	Michael Schock	9/1/2015
ord,nerl,esd	ORD-011815	1DTempPro V2: New Features for Inferring Groundwater/Surface-Water Exchange	D Werkema	8/4/2015
ord,nheerl,wed,eeb	ORD-011823	Nutrient Retention in Restored Streams and Floodplains: A Review and Synthesis	Paul Mayer	11/17/2015
ord,nrmrl,appcd,iemb	ORD-011840	Laboratory evaluation of PCBs encapsulation method	Xiaoyu Liu	5/15/2015

ord,nerl,heasd,emrb	ORD-011845	Developing a Physiologically-Based Pharmacokinetic Model Knowledgebase in Support of Provisional Model Construction	Cecilia Tan	11/25/2015
ord,ncct,N/A	ORD-011859	(Future Medicinal Chemistry) Docking-based classification models for exploratory toxicology studies on high-quality estrogenic experimental data	Richard Judson	6/16/2015
ord,nrmrl,std,cpb	ORD-011860	National Assessment of Tree City USA Participation According to Geography andSocioeconomic Characteristics	Matthew Hopton	3/13/2015
ord,nerl,esd,leb	ORD-011872	Association between Natural Resources for Outdoor Activities and Physical Inactivity: Results from the Contiguous United States	Yongping Yuan	8/22/2016

ord,nheerl,ged	ORD-011887	Effects of Louisiana crude oil on the sheepshead minnow (Cyprinodon variegatus) during a life-cycle exposure to laboratory oiled sediment	Sandy Raimondo	3/11/2015
ord,nheerl,ged	ORD-011888	Linking ecosystem service supply to stakeholder concerns on both land and sea: An example from Guánica Bay watershed, Puerto Rico	Susan Yee	4/24/2015
ord,nheerl,ephd,crb	ORD-011889	Climate change impacts on projections of excess mortality at 2030 using spatially varying ozone-temperature	Ana Rappold	6/12/2015
ord,nerl,esd,leb	ORD-011902	Temporal Trends in Impervious Cover Relative to Stream Location.	James Wickham	8/21/2015

ord,nrmrl,lrpcd,wmb	ORD-011903	An integrated science-based methodology to assess potential risks and implications of engineered nanomaterials	Thabet Tolaymat	5/5/2015
ord,nerl,emmd	ORD-011904	Comparison of fipronil sources in North Carolina surface water and identification of a novel fipronil transformation product in recycled wastewater	Mark Strynar	2/27/2017
ord,ncea,nceacin	ORD-011911	"Bias in the Development of Health and Ecological Assessments and Potential Solutions"	Glenn Suter	4/20/2015
ord,nheerl,med	ORD-011932	Comparisons of soil nitrogen mass balances for an ombrotrophic bog and a minerotrophic fen in northern Minnesota	Brian Hill	4/14/2015

ord,nheerl,istd	ORD-011938	Assessment of the vitro dermal irritation of cerium silver and titanium nanoparticles in a human skin equivalent model	MichaelF Hughes	4/30/2015
ord,nerl,ced	ORD-011952	Estimating Children’s Soil/Dust Ingestion Rates through Retrospective Analyses of Blood Lead Biomonitoring from the Bunker Hill Superfund Site in Idaho	Lindsay Stanek	4/24/2015
ord,nhsrc,tcad	ORD-011985	Considerations for Estimating Microbial Environmental Data Concentrations Collected from a Field Setting	Erin Silvestri	6/30/2015
ord,nrmrl,wswrd	ORD-011988	Multi-scale Quantitative Precipitation Forecasting Using Nonlinear and Nonstationary Teleconnection Signals and Artificial Neural Network Models	Jeff Yang	4/15/2015

ord,nrmrl,wswrd,tteb	ORD-011997	Monochloramine Cometabolism by Nitrifying Biofilm Relevant to Drinking Water	David Wahman	5/18/2015
ord,nheerl,istd	ORD-012004	Biochemical Effects of six Ti02 and four Ce02 Nanomaterials in HepG2 cells	Kirk Kitchin	4/6/2015
ord,nerl,erd	ORD-012025	Isomers/enantiomers of perfluorocarboxylic acids: Method development and detection in environmental samples	John Washington	10/14/2015
ord,nheerl,med	ORD-012030	Pathway-based approaches for assessment of real-time exposure to an estrogenic wastewater treatment plant effluent on fathead minnow reproduction	Gerald Ankley	8/27/2015

ord,nheerl,ephd,eb	ORD-012050	Association of Roadway Proximity with Fasting Plasma Glucose and Metabolic Risk Factors for Cardiovascular Disease in a Cross-Sectional Study of Cardiac Catheterization Patients	Lucas Neas	4/30/2015
ord,nerl,amd,amb	ORD-012055	The Impact of Incongruous Lake Temperatures on Regional Climate Extremes Downscaled from the CMIP5 Archive Using the WRF Model	Tanya Spero	2/5/2016
ord,nrmrl,appcd,iemb	ORD-012074	A Reference Method for Measuring Emissions of SVOCs in Small Chambers	Xiaoyu Liu	5/5/2015
ord,nerl,heasd,ecab	ORD-012092	Near-road measurements for nitrogen dioxide and its association with traffic exposure zones	Shaibal Mukerjee	7/2/2015

ord,nheerl,aed,peb	ORD-012100	Source determination of benzotriazoles in sediment cores from two urban estuaries on the Atlantic Coast of the United States	Mark Cantwell	9/15/2015
ord,nerl,sed,efab	ORD-012121	Review of pathogen treatment reductions for onsite non-potable reuse of alternative source waters	Jay Garland	4/2/2015
ord,nheerl,med	ORD-012137	Prior knowledge-based approach for associating contaminants with biological effects: A case study in the St. Croix river basin, MN, WI, USA.	Dan Villeneuve	9/9/2015
ord,nheerl,med	ORD-012140	Water quality in the St. Louis River Area of Concern (AOC), Lake Superior: An historical perspective with assessment implications	Joel Hoffman	12/10/2015

ord,nerl,ced	ORD-012149	Probabilistic estimation of residential air exchange rates for population-based human exposure modeling	Lisa Baxter	2/27/2017
ord,nheerl,wed,pceb	ORD-012153	Effects of Temperature, Salinity and Seed Age on Induction of Zostera japonica Germination in North America, USA	Jim Kaldy	4/16/2015
ord,nerl,heasd,ecab	ORD-012174	Spatial analysis of volatile organic compounds in South Philadelphia using passive samplers	Shaibal Mukerjee	2/11/2016
ord,nrmrl,wswrd,wqmb	ORD-012213	Transcriptional and physiological responses of nitrifying bacteria to heavy metal inhibition	Jorge Santodomingo	5/29/2015
ord,nheerl,wed,eeb	ORD-012214	Influence of resource availability on Juniperus virginiana expansion in a forest–prairie ecotone	Paul Mayer	4/16/2015

ord,nerl,emmd	ORD-012218	A North American and global survey of perfluoroalkyl substances in surface soils: Distribution patterns and mode of occurrence	John Washington	4/17/2015
ord,nhsrc,dcmd	ORD-012219	Surface Decontaminatio n of Blister Agents Lewisite, Sulfur Mustard and Agent Yellow, a Lewisite and Sulfur Mustard Mixture	Lukas Oudejans	5/27/2015
ord,nerl,amd,aqfr b	ORD-012228	Assessing the Added Value of Dynamical Downscaling Using the Standardized Precipitation Index	Tanya Spero	1/11/2016
ord,nerl,heasd,m dab	ORD-012234	Taxonomic applicability of inflammatory cytokines in adverse outcome pathway (AOP) development	Joachim Pleil	4/27/2015

ord,nrmrl,wswrd,wqmb	ORD-012237	Comparison of satellite reflectance algorithms for estimating chlorophyll-a in a temperate reservoir using coincident hyperspectral aircraft imagery and dense coincident surface observations	Christopher Nietch	4/24/2015
ord,nrmrl,std,cpb	ORD-012241	Micro–mesoporous iron oxides with record efficiency for the decomposition of hydrogen peroxide: morphology driven catalysis for the degradation of organic contaminants	Rajender Varma	4/14/2015
ord,nerl,eerd,mirb	ORD-012261	Are harmful algal blooms becoming the greatest inland water quality threat to public health and aquatic ecosystems?	Jim Lazorchak	5/13/2015

ord,nheerl,wed,eeb	ORD-012263	A dynamic leaf gas-exchange strategy is conserved in woody plants under changing ambient CO2: evidence from carbon isotope discrimination in paleo and CO2 enrichment studies	Reneej Brooks	4/22/2015
ord,nheerl,istd,gctb	ORD-012271	Health Effects of Soy-Biodiesel Emissions: Bioassay-Directed Fractionation for Mutagenicity*	David DeMarini	6/3/2015
ord,ncct,N/A	ORD-012275	(Environmental Health Perspectives) CERAPP: Collaborative Estrogen Receptor Activity Prediction Project	Richard Judson	3/31/2016

ord,ncea,odd,pos	ORD-012278	Using Physiologically Based Pharmacokinetic Modeling and Benchmark Dose Methods to Derive an Occupational Exposure Limit for N-Methylpyrrolidone	Paul Schlosser	6/9/2015
ord,nerl,amd,aspmb	ORD-012326	Updating sea spray aerosol emissions in the Community Multiscale Air Quality (CMAQ) model version 5.0.2	Jesse Bash	11/30/2015
ord,nerl,amd,aspmb	ORD-012335	Evaluation of improved land use and canopy representation in BEIS v3.61 with biogenic VOC measurements in California	Jesse Bash	7/22/2016
ord,nheerl,istd	ORD-012340	Development and Application of a Human PBPK Model for Bromodichloromethane (BDCM) to Investigate Impacts of Multi-Route Exposure	Elaina Kenyon	5/7/2015

ord,nrmrl,lrpcd,wmb	ORD-012342	Estimating Dermal Exposure to Copper Nanoparticles from the Surfaces of Pressure-Treated Lumber and Implications for Toxicity	Todd Luxton	7/10/2015
ord,nrmrl,appcd,ecpb	ORD-012345	A Mobile Sensing Approach for Regional Surveillance of Fugitive Methane Emissions in Oil and Gas Production	Eben Thoma	9/29/2015
ord,nerl,heasd,mdab	ORD-012350	Soil ingestion rates for children under 3 years old in Taiwan	Karen Bradham	9/15/2015
ord,nerl,heasd,mdab	ORD-012358	The Omics Revolution in Agricultural Research	Jeanette VanEmon	11/25/2015
ord,nrmrl,wswrd,mccb	ORD-012367	CHANGES IN BACTERIAL COMPOSITION OF BIOFILM IN A METROPOLITAN DRINKING WATER DISTRIBUTION SYSTEM	Randy Revetta	7/6/2015

ord,nheerl,ged	ORD-012370	Aqueous and Tissue Residue-Based Interspecies Correlation Estimation Models Provide Conservative Hazard Estimates for Aromatic Compounds	Mace Barron	4/24/2015
ord,nheerl,ephd,eb	ORD-012374	The Risk of Cyanobacterial Toxins in Dialysate, What do we Know?	E Hilborn	6/15/2015
ord,nheerl,istd,gctb	ORD-012375	Health Effects of Soy-Biodiesel Emissions: Mutagenicity-Emission Factors	David DeMarini	6/3/2015
ord,nerl,mceard,merb	ORD-012377	The relationship between environmental relative moldiness index values and asthma	Stephen Vesper	10/30/2015
ord,nheerl,aed,peb	ORD-012384	Resident perceptions of natural resources between cities and across scales in the Pacific Northwest	Betty Kreakie	7/29/2015

ord,nheerl,wed,feb	ORD-012385	The Stream-Catchment (StreamCat) Dataset: A database of watershed metrics for the conterminous USA	Scott Leibowitz	4/22/2015
ord,ncct,N/A	ORD-012387	(PLoS ONE) A Liver-centric Multiscale Modeling Framework for Xenobiotics	John Wambaugh	2/12/2016
ord,nheerl,med,wdb	ORD-012403	Mapping ecosystem service indicators in a Great Lakes estuarine Area of Concern	Theodore Angradi	5/27/2015
ord,nheerl,med	ORD-012405	Development of the larval amphibian growth and development assay: Effects of benzophenone-2 exposure in Xenopus laevis from embryo to juvenile	Sigmund Degitz	11/13/2015

ord,nrmrl,appcd,apb	ORD-012408	Role of natural gas in meeting an electric sector emissions reduction strategy and effects on greenhouse gas emissions	Carol Lenox	6/15/2015
ord,nheerl,med	ORD-012412	Toxicokinetics of perfluorooctane sulfonate in rainbow trout (Oncorhynchus mykiss)	John Nichols	6/12/2015
ord,nerl,heasd,emab	ORD-012421	Development and assessment of a physics-based simulation model to investigate residential PM2.5 infiltration across the US housing stock	Ronald Williams	12/22/2015
ord,nheerl,med	ORD-012451	Divergent oviposition preferences of sister species are not driven by nest survival: The evidence for neutrality	Matthew Etterson	4/28/2015

ord,nrmrl,wswrd	ORD-012453	The Full-Scale Implementation of an Innovative Biological Ammonia Treatment Process	Darren Lytle	5/18/2015
ord,nrmrl,std,cpb	ORD-012454	Nanoscale TiO2 films and their application in remediation of organic pollutants	Rajender Varma	5/4/2015
ord,nheerl,med	ORD-012485	Vector analysis of ecoenzyme activities reveal constraints on coupled C, N and P dynamics	Brian Hill	4/28/2015
ord,nheerl,istd	ORD-012494	Dose and Effect Thresholds for Early Key Events in a Mode of PPARa-Mediated Action	Susan Hester	7/27/2015

ord,nheerl,tad,rtb	ORD-012516	Dose addition models based on biologically-relevant reductions in fetal testosterone accurately predict postnatal reproductive tract alterations by a phthalate mixture in rats	Earl Gray	5/28/2015
ord,nhsrc,wipd	ORD-012536	Occurrence and Control of Tularemia in Drinking Water	Gene Rice	5/12/2015
ord,nerl,heasd,mdab	ORD-012537	Immunochemistry for high-throughput screening of human exhaled breath condensate (EBC) media: implementation of automated quanterix SIMOA instrumentation	Joachim Pleil	8/10/2015
ord,nrmrl,std,seb	ORD-012539	Vacant urban lot soils and their potential to support ecosystem services	William Shuster	7/23/2015

ord,nerl,heasd,mdab	ORD-012549	Comparing biomarker measurements to a normal range: when to use standard error of the mean (SEM) or standard deviation (SD) confidence intervals tests	Joachim Pleil	5/26/2016
ord,nheerl,tad,nb	ORD-012554	Neurotoxicological and thyroid evaluations of rats developmentally exposed to tris(1,3-dichloro-2-propyl)phosphate (TDICPP) and tris(2-chloro-2-ethyl)phosphate (TCEP)	Ginger Moser	6/11/2015
ord,nerl,emmd	ORD-012561	Arsenic and Environmental Health: State of the Science and Future Research Opportunities	Karen Bradham	9/21/2015
ord,nrmrl,lrpcd,esmb	ORD-012562	Anaerobic Biodegradation of soybean biodiesel and diesel blends under sulfate-reducing conditions	Robyn Conmy	11/10/2015

ord,nrmrl,lrpcd,wmb	ORD-012564	Non-labile silver species in biosolids remain stable throughout 50 years of weathering and ageing.	Kirk Scheckel	8/17/2015
ord,nheerl,ged	ORD-012566	Assessing variability in chemical acute toxicity of unionid mussels: Influence of intra- and inter-laboratory testing, life stage, and species	Sandy Raimondo	5/7/2015
ord,nheerl,ged	ORD-012567	SWMPr: An R Package for Retrieving, Organizing, and Analyzing Environmental Data for Estuaries	Marcus Beck	5/14/2015
ord,nheerl,ephd	ORD-012570	Association Between Satellite-based Estimates of Long-term PM2.5 Exposure and Coronary Artery Disease	Robert Devlin	7/1/2015

ord,nrmrl,std	ORD-012580	Environmental Assessment of Different Cement Manufacturing Processes Based on Emergy and Ecological Footprint Analysis	Heriberto Cabezas	5/14/2015
ord,nrmrl,std,gcb	ORD-012590	The utilization of forward osmosis for coal tailings dewatering	Vasudevan Namboodiri	5/20/2015
ord,nheerl,istd	ORD-012603	Estimation of Tetrabromobisphenol A (TBBPA)percutaneous uptake in humans using the parallelogram method.	MichaelF Hughes	6/1/2015
ord,nheerl,istd,gctb	ORD-012633	Acute and Developmental Behavioral Effects of Flame Retardants and Related Chemicals in Zebrafish	Stephanie Padilla	6/11/2015
ord,nheerl,istd,sbb	ORD-012635	Use of Alternative Assays to Identify and Prioritize Organophosphorus Flame Retardants for Potential Developmental and Neurotoxicity	William Mundy	6/11/2015

ord,nrmrl,appcd,apb	ORD-012654	Economic and environmental evaluation of coal-and-biomass-to-liquids-and-electricity plants equipped with carbon capture and storage	Dan Loughlin	6/2/2015
ord,nheerl,ephd,eb	ORD-012658	Factors associated with self-reported health: implications for screening level community-based health and environmental studies	Tim Wade	5/20/2015
ord,nerl,sed,eib	ORD-012664	Using ecological production functions to link ecological processes to ecosystem services.	Randy Bruins	5/22/2015
ord,nrmrl,std,cpb	ORD-012679	Continuous flow transfer hydrogenation of nitroarenes, azides and alkenes using maghemite-Pd nanocomposites	Rajender Varma	7/15/2015

ord,nrmrl,std,cpb	ORD-012680	Oxidative degradation of triazine- and sulfonylurea-based herbicides using Fe(VI): The case study of atrazine and iodosulfuron with kinetics and degradation products	Rajender Varma	6/22/2015
ord,nerl,amd,amdb	ORD-012684	Impact of inherent meteorology uncertainty on air quality model predictions	Robert Gilliam	12/21/2015
ord,nrmrl,lrpcd,wmb	ORD-012696	Uranium fate in wetland mesocosms: Effects of plants at two iron loadings with different pH values	Kirk Scheckel	8/17/2015
ord,nerl,mceard,barb	ORD-012715	The evaluation of hollow-fiber ultrafiltration and celite concentration of enteroviruses, adenoviruses and bacteriophage from different water matrices	Eric Rhodes	2/8/2016

ord,nheerl,ephd	ORD-012727	Ambient Air Pollution and Increases in Blood Pressure: Role for biological constituents of particulate matter	Wayne Cascio	5/21/2015
ord,nheerl,istd	ORD-012728	Mining the archives: a cross-platform analysis of gene expression profiles in archival formalin-fixed paraffin-embedded (FFPE) tissue.	Charles Wood	9/24/2015
ord,nheerl,wed,feb	ORD-012744	Do Geographically Isolated Wetlands Influence Landscape Functions?	Scott Leibowitz	6/19/2015
ord,nrmrl,appcd,iemb	ORD-012746	Genome sequence of Stachybotrys chartarum Strain 51-11	Timothy Dean	8/7/2015
ord,ncea,odd	ORD-012749	Advancing the Next Generation of Risk Assessment Multi-Year Study-Highlights of Findings, Applications to Risk Assessment and Future Directions	Ila Cote	6/9/2015

ord,nrmrl,std,cpb	ORD-012805	Cyclic Sulfamidate Enabled Syntheses of Amino Acids, Peptides, Carbohydrates, and Natural Products	Rajender Varma	6/22/2015
ord,nerl,shemfs	ORD-012820	Survival of Manure-borne Escherichia coli and Fecal Coliforms in Soil: Temperature Dependence as Affected by Site-Specific Factors	Gene Whelan	6/16/2015
ord,nheerl,istd,sbb	ORD-012821	Life-Stage Physiologically-Based Pharmacokinetic (PBPK) Model Application to Screen Environmental Hazards Using Adverse Outcome Pathways (AOPs) and Environmental Exposure Models.	Hisham El-Masri	12/17/2015
ord,nheerl,istd,pb	ORD-012827	A physiologically based pharmacokinetic model of vitamin D	Marina Evans	6/2/2015

ord,nerl,amd,amdb	ORD-012834	Assessment of long-term WRF–CMAQ simulations for understanding direct aerosol effects on radiation "brightening" in the United States	Jon Pleim	12/21/2015
ord,nheerl,tad,rtb	ORD-012839	Establishing the Biological Relevance of Dipentyl Phthalate Reductions in Fetal Rat Testosterone Production and Plasma and Testis Testosterone Levels	Earl Gray	8/3/2015
ord,nheerl,ephd,cib	ORD-012858	Ozone Exposure Increases Circulating Stress Hormones and Lipid Metabolites in Humans	Urmila Kodavanti	8/11/2015
ord,ncct,N/A	ORD-012910	(Journal of Applied Toxicology) BMDExpress Data Viewer: A Visualization Tool to Analyze BMDExpress Datasets	Russell Thomas	8/14/2015

ord,nerl,heasd,mdab	ORD-012912	Assessment of the bioaccessibility of micronized copper wood in synthetic stomach fluid	Karen Bradham	12/22/2015
ord,nerl,heasd,emrb	ORD-012927	Air Pollution Exposure Model for Individuals (EMI) in Health Studies: Evaluation for Ambient PM2.5 in Central North Carolina	Michael Breen	12/17/2015
ord,nhsrc,wipd	ORD-012929	Decontamination of Bacillus spores adhered to iron and cement-mortar drinking water infrastructure in a model system using disinfectants	Jeff Szabo	8/31/2015
ord,nerl,erd	ORD-012935	Identification of Unsaturated and 2H Polyfluorocarboxylate Homologous Series and Their Detection in Environmental Samples and as Polymer Degradation Products	John Washington	10/23/2015

ord,nheerl,med	ORD-012945	The non-native faucet snail (Bithynia tentaculata) makes the leap to Lake Superior	Anett Trebitz	11/23/2015
ord,nheerl,aed,peb	ORD-012947	Progress and Challenges in Coupled Hydrodynamic-Ecological Estuarine Modeling	Brenda Rashleigh	6/22/2015
ord,nerl,heasd,pmrb	ORD-012951	Photooxidation of farnesene mixtures in the presence of NOx: Analysis of reaction products and their implication to ambient PM2.5	Michael Lewandowski	12/14/2015
ord,ncea,odd,gcas	ORD-012960	Improving Conservation Outcomes with a New Paradigm for Understanding Species’ Fundamental and Realized Adaptive Capacity [Journal Article]	Jordan West	7/23/2015

ord,nheerl,wed,eeb	ORD-012966	Germination and early plant development of ten plant species exposed to TiO2 and CeO2 nanoparticles	Christian Andersen	6/8/2015
ord,ncea,nceawa	ORD-012974	Science at the Boundaries: Scientific Support for the Clean Water Rule.	Laurie Alexander	9/11/2015
ord,nrmrl,std,cpb	ORD-012976	Maghemite decorated with ultra-small palladium nanoparticles (γ-Fe2O3–Pd): applications in the Heck–Mizoroki olefination, Suzuki reaction and allylic oxidation of alkenes	Rajender Varma	6/29/2015
ord,nrmrl,std,cpb	ORD-012978	Pd@Pt Core–Shell Nanoparticles with Branched Dandelion-like Morphology as Highly Efficient Catalysts for Olefin Reduction	Rajender Varma	6/29/2015

ord,nheerl,ged	ORD-012993	Development of 3D-QSAR model for acetylcholinesterase inhibitors using a combination of fingerprint, molecular docking, and structure-based pharmacophore approaches	Mace Barron	8/26/2015
ord,nheerl,aed,wdb	ORD-013005	Comparing Measures of Estuarine Ecosystem Production in a Temperate New England Estuary	Autumn Oczkowski	7/30/2015
ord,nheerl,aed,heb	ORD-013026	Wetland Loss Patterns and Inundation-Productivity Relationships Prognosticate Widespread Salt Marsh Loss for Southern New England.	Cathleen Wigand	9/10/2015
ord,nerl,sed	ORD-013030	Chemical and non-chemical stressors affecting childhood obesity: a systematic scoping review	Nicolle Tulve	8/17/2017

ord,nheerl,ephd,cib	ORD-013032	Long-Term Toxicity of Naturally Occurring Asbestos in Male Fischer 344 Rats	Stephen Gavett	7/28/2015
ord,nheerl,tad,etb	ORD-013039	Mild Thyroid Hormone Insufficiency During Development Compromises Activity-Dependent Neuroplasticity in the Hippocampus of Adult Make Rats	Mary Gilbert	6/22/2015
ord,nerl,mceard,barb	ORD-013052	Optimization and evaluation of a method to detect adenoviruses in river water	Brian McMinn	3/23/2016
ord,nerl,erd	ORD-013065	Abiotic Hydrolysis of Fluorotelomer-Based Polymers as a Source of Perfluorocarboxylates at the Global Scale	John Washington	7/2/2015

ord,nheerl,aed,mab	ORD-013067	From restoration to adaptation: the changing discourse of invasive species management in coastal New England under global environmental change	Marisa Mazzotta	8/10/2015
ord,nerl,heasd,emab	ORD-013068	The Biomarkers of Exposure and Effect in Agriculture (BEEA) Study: Rationale, design, methods, and participant characteristics	Kent Thomas	9/1/2015
ord,nrmrl,appcd,aptb	ORD-013072	Soot, organics and ultrafine ash from air- and oxy-fired coal combustion	Bill Linak	8/7/2015

ord,nheerl,ephd	ORD-013073	Temporal and Environmental Factors Driving the Vibrio Vulnificus and V. Parahaemolyticus populations and Their Associations with Harmful Algal Blooms in South Carolina Detention Ponds and Receiving Tidal Creeks	E Hilborn	5/24/2017
ord,nheerl,wed,eeb	ORD-013076	The Scientific Basis for Modeling Northern Spotted Owl Habitat: A Response to Loehle, Irwin, Manly, and Merrill	Nathan Schumaker	7/2/2015
ord,nrmrl,wswrd,mccb	ORD-013079	Characterization and optimization of cathodic conditions for H2O2 synthesis in microbial electrochemical cells	Mark Rodgers	8/6/2015

ord,nheerl,med	ORD-013098	A review of Ruffe (Gymnocephalus cernuus) life history in its native versus non-native range (journal article)	Joel Hoffman	11/19/2015
ord,nheerl,tad,nb	ORD-013100	Acute and Subchronic Toxicity of Inhaled Toluene in Male Long-Evans Rats: Oxidative Stress Markers in Brain	Prasada Kodavanti	6/23/2015
ord,nheerl,aed,peb	ORD-013102	pCO2 effects on species composition and growth of an estuarine phytoplankton community.	Jason Grear	6/29/2015
ord,nheerl,med	ORD-013110	Evaluation of whole-mount in situ hybridization as a tool for pathway-based toxicological research with early-life stage fathead minnows	Gerald Ankley	8/7/2015

ord,nheerl,ephd,eb	ORD-013111	Cyanotoxins in Inland Lakes of the United States: Occurrence and Potential Recreational Health Risks in the EPA National Lakes Assessment 2007	E Hilborn	7/16/2015
ord,nheerl,ephd,eb	ORD-013124	The Association between Dust Storms and Daily Non-Accidental Mortality in the United States, 1993-2005.	James Crooks	7/7/2015
ord,nheerl,istd,cb	ORD-013126	Proteomic Assessment of Biochemical Pathways That Are Critical to Nickel-Induced Toxicity Responses in Human Epithelial Cells	Yue Ge	12/30/2016
ord,nrmrl,std,cpb	ORD-013128	Plant-derived nanostructures: types and applications	Rajender Varma	8/14/2015

ord,nerl,emmd,mieb	ORD-013129	Human infective potential of Cryptosporidium spp., Giardia duodenalis and Enterocytozoon bieneusi in urban wastewater treatment plant effluents	Eric Villegas	8/13/2016
ord,nerl,erd	ORD-013130	Characterizing relationships among fecal indicator bacteria, microbial source tracking markers, and associated waterborne pathogen occurrence in stream water and sediments in a mixed land use watershed	Kate Sullivan	6/29/2015

ord,nheerl,tad,nb	ORD-013135	Neurophysiological Assessment of Auditory, Peripheral Nerve, Somatosensory, and Visual System Function After Developmental Exposure to Gasoline, E15 and E85 Vapors	David Herr	6/25/2015
ord,nheerl,aed,mab	ORD-013136	Emergy Synthesis 8 ~ Emergy and environmental accounting: Theories, applications, and methodologies	Dan Campbell	6/24/2015
ord,nerl,esd,cmb	ORD-013145	Linking Management and Riparian Physical Functions to Water Quality and Aquatic Habitat	Daniel Heggem	3/8/2016
ord,nerl,esd	ORD-013176	Autoregressive Spatially-Varying Coefficient Models for Predicting Daily PM2:5 Using VIIRS Satellite AOT	David Holland	12/2/2015

ord,nheerl,ged	ORD-013178	Spatially explicit assessment of estuarine fish after Deepwater Horizon oil spill: trade-off in complexity and parsimony	Jill Awkerman	7/23/2015
ord,nheerl,med	ORD-013188	Evaluation of the scientific underpinnings for identifying estrogenic chemicals in non-mammalian taxa using mammalian test systems	Gerald Ankley	9/10/2015
ord,ncea,nceartp, emag	ORD-013195	Maternal Residential Exposure to Agricultural Pesticides and Birth Defects in a 2003 to 2005 North Carolina Birth Cohort	Tom Luben	8/20/2015
ord,nrmrl,appcd	ORD-013197	Characterization of Gas and Particle Emissions from Laboratory Burns of Peat	Brian Gullett	7/29/2015

ord,nheerl,med	ORD-013205	Demographic analysis demonstrates contrasting abiotic and biotic stressors across a species range	Matthew Etterson	7/2/2015
ord,nerl,ced	ORD-013209	Evaluation of Traffic Density Parameters as an Indicator of Vehicle Emission-Related Near-Road Air Pollution: A Case Study with NEXUS Measurement Data on Black Carbon	Shi Liu	1/5/2018
ord,ncea,odd,gcas	ORD-013215	Assessing the Effects of Climate Change and Air Pollution on Soil Properties and Plant Diversity in Sugar Maple-Beech-Yellow Birch Hardwood Forests in the Northeastern United States: Model Simulations from 1900-2100	Christopher Clark	9/2/2015

ord,nerl,heasd,pmrb	ORD-013221	ZnO Functionalization of Multi-walled Carbon Nanotubes for Methane Sensing at Single Parts Per Million Concentration Levels	Paul Solomon	9/21/2015
ord,nrmrl,wswrd	ORD-013222	Greenhouse Gas Emissions from Reservoir Water Surfaces: A New Global Synthesis - journal	Jake Beaulieu	9/14/2015
ord,nheerl,istd,sbb	ORD-013226	Differential genomic effects of six different TiO2 nanomaterials on human liver HepG2 cells	Sheau-Fung Thai	7/15/2015
ord,nrmrl,std,seb	ORD-013229	"Sustaining the Shrinking City: Concepts, Dynamics and Management"(A special issue of Sustainability) (ISSN 2071-1050).	William Shuster	7/14/2015

ord,nrmrl,wswrd	ORD-013232	Water Quality Modeling in the Dead End Sections of Drinking Water Distribution Networks	Jeff Yang	9/2/2015
ord,nerl,amd,aspmb	ORD-013240	Roadside vegetation barrier designs to mitigate near-road air pollution impacts	Vlad Isakov	1/11/2016
ord,nheerl,istd,pb	ORD-013246	In vivo dermal absorption of pyrethroid pesticides in the rat.	MichaelF Hughes	8/5/2015
ord,nheerl,aed,wdb	ORD-013257	Spatial statistical network models for stream and river temperature in New England, USA	Naomi Detenbeck	10/30/2015
ord,nheerl,ged	ORD-013259	Development of Algal Interspecies Correlation Estimation Models for Chemical Hazard Assessment	Sandy Raimondo	7/8/2015
ord,nheerl,wed,feb	ORD-013271	Hydrologic Landscape Characterization for the Pacific Northwest, USA	Scott Leibowitz	7/9/2015

ord,nheerl,wed,feb	ORD-013277	Continental-scale increase in stream and lake phosphorus: Are oligotrophic systems disappearing in the U.S.?	John Stoddard	7/21/2015
ord,nerl,eerd,merb	ORD-013278	Fish Connectivity Mapping: Linking Chemical Stressors by Their MOA-Driven Transcriptomic Profiles	Rong-Lin Wang	7/24/2015
ord,nheerl,istd,sbb	ORD-013296	Application of Biologically-Based Lumping To Investigate the Toxicological Interactions of a Complex Gasoline Mixture	Hisham El-Masri	9/3/2015
ord,nerl,sed,eib	ORD-013297	Tools to minimize interlaboratory variability in vitellogenin gene expression monitoring programs	Jim Lazorchak	1/4/2017

ord,nrmrl,std,cpb	ORD-013298	Eco-friendly Synthesis of Ceria Foam via Carboxymethylcellulose Gelation: Application for the Epoxidation of Chalcone	Rajender Varma	7/23/2015
ord,nrmrl,std,cpb	ORD-013299	Magnetic graphitic carbon nitride: its applicationin the C–H activation of amines	Rajender Varma	7/30/2015
ord,nheerl,ephd,eb	ORD-013311	Water Recreation and Illness Severity	Tim Wade	7/16/2015
ord,nheerl,ged	ORD-013314	Habitat restoration from an ecosystem goods and services perspective: Application of a spatially explicit individual-based model	Richard Fulford	7/27/2015
ord,nerl,eerd,erb	ORD-013319	Identification of Putative Geographically Isolated Wetlands of the Conterminous United States	Charles Lane	8/24/2015

ord,nerl,eerd,erb	ORD-013329	Macroinvertebrate and organic matter export from headwater tributaries of a Central Appalachian stream	Ken Fritz	6/1/2016
ord,nheerl,aed,peb	ORD-013330	A Random Forest Approach to Predict the Spatial Distribution of Sediment Pollution in an Estuarine System	Diane Nacci	12/17/2015
ord,nerl,amd,aspmb	ORD-013334	Tropospheric Emission Spectrometer (TES) satellite observations of ammonia, methanol, formic acid, and carbon monoxide over the Canadian oil sands: validation and model evaluation	Jesse Bash	1/11/2016
ord,nrmrl,appcd,ecpb	ORD-013339	Effects of cold temperature and ethanol content on VOC emissions from light duty gasoline vehicles	Thomas Long	8/20/2015

ord,nheerl,istd,sbb	ORD-013342	Computational Model of the Fathead Minnow Hypothalamic-Pituitary-Gonadal Axis: Incorporating Protein Synthesis in Improving Predictability of Responses to Endocrine Active Chemicals	Rory Conolly	9/16/2015
ord,nrmrl,wswrd,tteb	ORD-013344	AFM Structural Characterization of Drinking Water Biofilm under Physiological Conditions	David Wahman	9/1/2015
ord,nerl,amd	ORD-013345	Air pollution and climate response to aerosol direct radiative effects: A modeling study of decadal trends across the northern hemisphere	Rohit Mathur	12/17/2015
ord,nrmrl,appcd,apb	ORD-013348	Spring and summer contrast in new particle formation over nine forest areas in North America	Johnt Walker	8/7/2015

ord,nrmrl,std,cpb	ORD-013356	Natural inorganic nanoparticles – formation, fate, and toxicity in the environment.	Rajender Varma	8/26/2015
ord,nrmrl,wswrd,wqmb	ORD-013367	Estimating Potential Increased Bladder Cancer Risk Due to Increased Bromide Concentrations in Sources of Disinfected Drinking Waters	Michael Elovitz	1/6/2016
ord,ncea,nceartp	ORD-013377	Residential metal contamination and potential health risks of exposure in adobe brick houses in Potosí, Bolivia	John Vandenberg	8/26/2015
ord,nerl,amd,aspmb	ORD-013382	Understanding sources of organic aerosol during CalNex-2010 using the CMAQ-VBS	Matthew Woody	5/26/2016

ord,nheerl,med	ORD-013383	In vivo and in vitro neurochemical-based assessments of wastewater effluents from the Maumee River area of concern.	Dan Villeneuve	8/27/2015
ord,nerl,heasd,emab	ORD-013396	Linking high resolution mass spectrometry data with exposure and toxicity forecasts to advance high-throughput environmental monitoring	Jon Sobus	12/14/2015
ord,ncea,nceartp,hpag	ORD-013399	Overview of Chronic Oral Toxicity Values for Chemicals Present in Hydraulic Fracturing Fluids, Flowback and Produced Waters	John Stanek	9/1/2015
ord,nheerl,istd	ORD-013420	Adverse Outcome Pathways – Organizing Toxicological Information to Improve Decision Making	Stephen Edwards	7/31/2015

ord,nheerl,ephd,cib	ORD-013422	Acrolein inhalation alters myocardial synchrony and performance at and below exposure concentrations that cause ventilatory responses	Aimen Farraj	9/22/2015
ord,nerl,esd	ORD-013443	Comparing Vapor Intrusion Mitigation System Performance for VOCs and Radon	JohnH Zimmerman	3/14/2016
ord,nheerl,tad,nb	ORD-013445	A Noninvasive Method to Study Regulation of Extracellular Fluid Volume in Rats Using Nuclear Magnetic Resonance	Christopher Gordon	7/31/2015
ord,nheerl,wed,eeb	ORD-013447	Genetic factors in Threatened Species Recovery Plans on three continents	Nathan Schumaker	8/11/2015

ord,nheerl,istd,sbb	ORD-013460	Estimating Margin of Exposure to Thyroid Peroxidase Inhibitors Using High-throughput In Vitro Data, High-throughput Exposure Modeling, and Physiologically-Based Pharmacokinetic/Pharmacodynamic Modeling	Hisham El-Masri	10/14/2015
ord,nrmrl,std,cpb	ORD-013461	Visible light mediated upgrading of biomass to biofuel	Rajender Varma	8/14/2015
ord,nheerl,med	ORD-013479	Impaired anterior swim bladder inflation following exposure to the thyroid peroxidase inhibitor 2-Mercaptobenzothiazole Part I: Fathead minnow	Dan Villeneuve	8/27/2015

ord,nheerl,med	ORD-013481	Impaired anterior swim bladder inflation following exposure to the thyroid peroxidase inhibitor 2-mercaptobenzothiazole - Part II: zebrafish	Dan Villeneuve	8/27/2015
ord,nerl,eerd,mirb	ORD-013487	Saving freshwater from salts	Jim Lazorchak	8/28/2015
ord,nerl,amd,amdb	ORD-013496	Modeling the current and future role of particulate organic nitrates in the southeastern United States	Havala Pye	11/30/2015
ord,ncct,N/A	ORD-013497	(Toxicological Sciences) High-throughput screening of chemical effects on steroidogenesis using H295R human adrenocortical carcinoma cells	Matt Martin	8/19/2015
ord,nheerl,istd	ORD-013501	Accelerating Adverse Outcome Pathway Development Using Publicly Available Data Sources	Stephen Edwards	8/7/2015

ord,nrmrl,wswrd,uwmb	ORD-013502	Estimates of reservoir methane emissions based on a spatially balanced probabilistic-survey	Jake Beaulieu	9/8/2015
ord,ncct,N/A	ORD-013503	(Carcinogenesis) Bisphenol A activates EGFR and ERK promoting proliferation, tumor spheroid formation and resistance to EGFR pathway inhibition in estrogen receptornegative inflammatory breast cancer cells	Imran Shah	9/18/2015
ord,nrmrl,wsd,dwtdb	ORD-013508	Characterizing Ohio River NOM Variability and Reconstituted-Lyophilized NOM as a Source Surrogate	Jonathan Pressman	9/17/2015
ord,nrmrl,std,cpb	ORD-013524	Prediction of in vitro and in vivo oestrogen receptor activity using hierarchical clustering	Todd Martin	8/18/2015

ord,nrmrl,appcd	ORD-013549	Simulation of rail yard emissions transport to the near-source environment	Gayle Hagler	8/25/2015
ord,nrmrl,wswrd	ORD-013551	Identification of specialists and abundance-occupancy relationships among intestinal bacteria of Aves, Mammalia, and Actinopterygii	Orin Shanks	10/19/2015
ord,nheerl,aed,mab	ORD-013562	Adaptive Management of Urban Ecosystem Restoration: Learning From Restoration Managers in Rhode Island, USA	Marisa Mazzotta	9/1/2015
ord,nerl,esd	ORD-013564	Estimation of Radiative Forcing of Chemicals with Potentially Significant Global Warming Potential	Don Betowski	12/1/2015

ord,nerl,sed,eib	ORD-013607	Boosted Regression Tree Models to Explain Watershed Nutrient Concentrations and Biological Condition	Heather Golden	12/4/2015
ord,nrmrl,wswrd	ORD-013617	Human-Associated Fecal qPCR Measurements and Predicted Risk of Gastrointestinal Illness in Recreational Waters Contaminated with Raw Sewage	Orin Shanks	9/2/2015
ord,nrmrl,wswrd,tteb	ORD-013621	Effect of chlorination on the protein phosphatase inhibition activity for several microcystins	Heath Mash	10/4/2015
ord,nrmrl,lrpcd,wmb	ORD-013637	Assessing the Impact of Removing Select Materials from Coal Mine Overburden, Central Appalachia Region, USA	Souhail Al-Abed	9/10/2015

ord,nerl,heasd,pmrb	ORD-013638	Performance Evaluation and Community Application of Low-Cost Sensors for Ozone and Nitrogen Dioxide	Rachelle Duvall	8/25/2016
ord,nheerl,ephd,cib	ORD-013645	Diesel exhaust worsens cardiac conduction instability in dobutamine-challenged Wistar-Kyoto and spontaneously hypertensive rats	Mehdi Hazari	10/10/2015
ord,nrmrl,appcd,apb	ORD-013646	Scenarios for low carbon and low water electric power plant operations: implications for upstream water use	Rebecca Dodder	9/29/2015
ord,nheerl,med	ORD-013650	Environmental surveillance and monitoring. The next frontiers for high-throughput toxicology	Dan Villeneuve	9/25/2015

ord,nerl,emmd	ORD-013657	Linking field-based metabolomics and chemical analyses to prioritize contaminants of emerging concern in the Great Lakes basin	Drew Ekman	10/6/2015
ord,nhsrc,tcad	ORD-013659	Modeling Rabbit Responses to Single and Multiple Aerosol Exposures of Bacillus anthracis Spores (HS 4.04.02 - 475)	Sarah Taft	7/20/2017
ord,nerl,heasd,ecab	ORD-013661	Source apportionment with uncertainty estimates of fine particulate matter in Ostrava, Czech Republic using Positive Matrix Factorization	Teri Conner	5/19/2016

ord,nrmrl,appcd,iemb	ORD-013664	Biological Responses of Raw 264.7 Macrophage Exposed to Two Strains of Stachybotrys chartarum Spores Grown on Four Different Wallboard Types	Timothy Dean	10/27/2015
ord,nerl,heasd,emab	ORD-013681	Temporal variability of pyrethroid metabolite levels in bedtime, morning, and 24-hr urine samples for 50 adults in North Carolina	Marsha Morgan	11/3/2015
ord,nrmrl,std,gcb	ORD-013682	Emergy Analysis for the Sustainable Utilization of Biosolids Generated in a Municipal Wastewater Treatment Plant	Gerardo Ruiz-Mercado	9/2/2015
ord,ncct,N/A	ORD-013695	(Toxicological Sciences) Analysis of the Effects of Cell Stress and Cytotoxicity on In Vitro Assay Activity Across a Diverse Chemical and Assay Space	Richard Judson	9/2/2015

ord,nrmrl,std,sab	ORD-013708	Conceptual Framework To Extend Life Cycle Assessment Using Near-Field Human Exposure Modeling and High-Throughput Tools for Chemicals	Jane Bare	9/2/2015
ord,nhsrc,wipd	ORD-013709	Enhanced survival but not amplification of Francisella spp. in the presence of free-living amoebae	Gene Rice	9/29/2015
ord,nrmrl,wswrd,wqmb	ORD-013716	Effects of Cr(III) and CR(VI) on nitrification inhibition as determined by SOUR, function-specific gene expression and 16S rRNA sequence analysis of wastewater nitrifying enrichments	Jorge Santodomingo	10/4/2015
ord,nerl,mceard,barb	ORD-013721	Conference Report: The 6th International Symposium on Waterborne Pathogens ISWP 2015	Eric Villegas	10/30/2015

ord,nheerl,aed,peb	ORD-013732	Selected Pharmaceuticals Entering an Estuary: Concentrations, Temporal Trends, Partitioning and Fluxes	Mark Cantwell	10/13/2015
ord,ncct,N/A	ORD-013733	(Reg. Tox. Pharm.) Systematically evaluating read-across prediction and performance using a local validity approach characterized by chemical structure and bioactivity information	Imran Shah	9/10/2015
ord,nerl,sed,efab	ORD-013736	Prioritization of pesticides based on daily dietary exposure potential as determined from the SHEDS model	Lisa Melnyk	7/12/2016
ord,nrmrl,wsd	ORD-013744	Titanium Dioxide-Based Antibacterial Surfaces for Water Treatment	Mallikarjuna Nadagouda	1/5/2016

ord,nheerl,med	ORD-013745	Derivation and evaluation of putative adverse outcome pathways for the effects of cyclooxygenase inhibitors on reproductive processes in female fish	Dan Villeneuve	9/9/2015
ord,nrmrl,appcd,aptb	ORD-013747	Particulate matter and black carbon optical properties and emission factors from prescribed fires in the southeastern United States	Amara Holder	9/28/2015
ord,nerl,heasd,emab	ORD-013748	Contributions of a Child’s Built, Natural, and Social Environments to Their General Cognitive Ability: A Systematic Scoping Review	Nicolle Tulve	12/22/2015
ord,nrmrl,std,cpb	ORD-013750	Oxidative esterification via photocatalytic C-H activation	Rajender Varma	8/28/2015

ord,nerl,heasd,emrb	ORD-013759	A simulation study to quantify the impacts of exposure measurement error on air pollution health risk estimates in copollutant time-series models.	Kathie Dionisio	11/29/2016
ord,nerl,mceard,barb	ORD-013761	SHP-2 Mediates Cryptosporidium parvum Infectivity in Human Intestinal Epithelial Cells	Eunice Varughese	2/8/2016
ord,ncct,N/A	ORD-013762	(Chemical Research in Toxicology) Current and future perspectives on the development, evaluation and application of in silico approaches for predicting toxicity	Grace Tier	10/5/2015

ord,nheerl,istd	ORD-013775	Integrating publicly-available data to generate computationally-predicted adverse outcome pathways for hepatic steatosis	Stephen Edwards	9/28/2015
ord,nheerl,istd	ORD-013776	An Integrative data mining approach to identifying Adverse Outcome Pathway (AOP) Signatures	Stephen Edwards	9/21/2015
ord,nrmrl,std,sab	ORD-013781	Mining Available Data from the United States Environmental Protection Agency to Support Rapid Life Cycle Inventory Modeling of Chemical Manufacturing	David Meyer	9/3/2015
ord,nrmrl,lmmd,lcdsb	ORD-013782	High-throughput exposure modeling to support prioritization of chemicals in personal care products	David Meyer	9/3/2015

ord,nheerl,istd,sbb	ORD-013788	Screening for angiogenic inhibitors in zebrafish to evaluate a predictive model for developmental vascular toxicity	Tamara Tal	10/16/2015
ord,nerl,esd	ORD-013791	Probing the Biological Sources of Soil N2O Emissions by Quantum Cascade Laser-Based 15N Isotopocule Analysis	DavidJ Williams	7/7/2016
ord,nrmrl,wswrd,wqmb	ORD-013792	An innovative zinc oxide-coated zeolite adsorbent for removal of humic acid	Mallikarjuna Nadagouda	5/13/2016
ord,nheerl,istd,sbb	ORD-013797	Comparison of Human Induced PluripotentStem Cell-Derived Neurons and Rat Primary CorticalNeurons as In Vitro Models of Neurite Outgrowth	William Mundy	9/16/2015

ord,nheerl,ephd,eb	ORD-013806	Elevated blood lead and cadmium levels associated with chronic infections among non-smokers in a cross-sectional analysis of NHANES data	Tim Wade	9/2/2015
ord,ncea,nceartp,emag	ORD-013807	The ability of winter grazing to reduce wildfire size, intensity, and fire-induced plant mortality was not demonstrated: A comment on Davies et al. (2015)	Alan Talhelm	11/6/2015
ord,nheerl,ephd,crb	ORD-013808	Heme oxygenase activity correlates with serum indices of iron homeostasis in healthy nonsmokers	Andy Ghio	9/18/2015
ord,nheerl,wed,feb	ORD-013815	Navigating Benefit Transfer for Salmon Improvements in the Western US	Matthew Weber	9/8/2015

ord,nhsrc,wipd	ORD-013817	Sorption of Radionuclides to Building Materials and its Removal Using Simple Wash Solutions	Matthew Magnuson	9/18/2015
ord,nrmrl,lrpcd,wmb	ORD-013818	In situ fixation of metal(loid)s in contaminated soils: a comparison of conventional, by product and engineered soil amendments	Kirk Scheckel	1/14/2016
ord,nrmrl,std,seb	ORD-013822	A tale of two rain gardens: Barriers and bridges to adaptive management of urban stormwater in Cleveland, Ohio	Ahjond Garmestani	9/14/2015
ord,ncea,nceartp,hpag	ORD-013824	Estimating the Potential Toxicity of Chemicals Associated with Hydraulic Fracturing Operations Using Quantitative Structure Activity Relationship Modeling	John Stanek	9/28/2015

ord,nheerl,ephd,cib	ORD-013835	Integrated Decision Strategies for Skin Sensitization Hazard	David Lehmann	10/15/2015
ord,nerl,emmd,mieb	ORD-013843	Applying Quantitative Molecular Tools for Virus Transport Studies: Opportunities and Challenges	Marirosa Molina	10/6/2015
ord,nheerl,med	ORD-013846	Impact of natural organic matter on particle behavior and phototoxicity of titanium dioxide nanoparticles	Dale Hoff	11/16/2015
ord,nerl,ced,amaab	ORD-013855	Comparison of Highly Resolved Model-Based Exposure Metrics for Traffic-Related Air Pollutants to Support Environmental Health Studies	Vlad Isakov	11/5/2015

ord,nerl,heasd,mdab	ORD-013864	Inflammatory Cytokines and White Blood Cell Counts Response to Environmental Levels of Diesel Exhaust and Ozone Inhalation Exposures	Joachim Pleil	3/16/2016
ord,nerl,heasd,ecab	ORD-013899	Volatile organic compounds at oil and natural gas production well pads in Colorado and Texas using passive samplers	Shaibal Mukerjee	2/11/2016
ord,nerl,mceard,merb	ORD-013900	Multi-laboratory survey of qPCR enterococci analysis method performance in U.S. coastal and inland surface waters	Rich Haugland	1/19/2016
ord,nheerl,ephd,crb	ORD-013905	Protein Sulfenylation: A Novel Readout of Environmental Oxidant Stress	James Samet	6/2/2016

ord,nerl,heasd,ecab	ORD-013907	Investigating the impact of local urban sources on total atmospheric mercury wet deposition in Cleveland, Ohio, USA	Matthew Landis	12/22/2015
ord,nheerl,wed,eeb	ORD-013908	Effects of biochar blends on microbial community composition in two coastal plain soils	Markg Johnson	9/29/2015
ord,nheerl,tad,nb	ORD-013919	Effect of High Fructose and High Fat Diets on Pulmonary Sensitivity, Motor Activity, and Body Composition of Brown Norway Rats Exposed to Ozone	Christopher Gordon	9/15/2015
ord,nerl,sed,efab	ORD-013934	Reducing inherent biases introduced during DNA viral metagenome analyses of municipal wastewater	Nichole Brinkman	3/5/2018

ord,nheerl,wed,eeb	ORD-013944	Plant reproduction is altered by simulated herbicide drift toconstructed plant communities	David Olszyk	9/21/2015
ord,nerl,emmd	ORD-013948	An integrated experimental and computational approach for characterizing the kinetics and mechanism of triadimefon racemization.	John Kenneke	10/14/2015
ord,nheerl,ephd,eb	ORD-013952	Gender and Racial/Ethnic Disparities: Cumulative Screening of Health Risk Indicators in 20-50 Year Olds in the United States	Tim Wade	9/15/2015
ord,nerl,mceard,merb	ORD-013963	Application of the Environmental Relative Moldiness Index in Finland	Stephen Vesper	11/12/2015
ord,nheerl,ephd,cib	ORD-013975	U.S. Domestic Cats as Sentinels for Perfluoroalkyl Substances: Possible Linkages with Housing, Obesity and Disease	Janice Dye	9/18/2015

ord,nrmrl,wswrd,mccb	ORD-013977	Draft Genome Sequences of Six Mycobacterium immunogenum, Obtained from a Chloraminated Drinking Water Distribution System Simulator	Randy Revetta	10/19/2015
ord,nrmrl,lrpcd,wmb	ORD-013978	BIOACCESSIBILITY TESTS ACCURATELY ESTIMATE BIOAVAILABILITY OF LEAD TO QUAIL	Kirk Scheckel	12/11/2015
ord,nheerl,ged	ORD-013988	Parameterization of biogeochemical sediment-water fluxes using in-situ measurements and a steady-state diagenetic model	Richard Devereux	9/18/2015
ord,nerl,emmd,mieb	ORD-013996	B-Glucan exacerbates allergic asthma independent of fungal sensitization and promotes steroid-resistant TH2/TH17 responses	Stephen Vesper	1/31/2017

ord,ncea,nceartp, emag	ORD-014035	Maternal exposure to nitrogen dioxide, intake of methyl nutrients and congenital heart defects in offspring	Tom Luben	11/4/2015
ord,nerl,ced	ORD-014052	Regional and hemispheric influences on temporal variability in baseline carbon monoxide and ozone over the Northeast US	Christian Hogrefe	6/20/2017
ord,nheerl,istd,cb	ORD-014059	Tipping the Balance: Hepatotoxicity and the Four Apical Key Events of Hepatic Steatosis	Brian Chorley	9/23/2015
ord,nheerl,ged	ORD-014063	Functional implications of changes in seagrass species composition in two shallow coastal lagoons	John Lehrter	9/23/2015
ord,nrmrl,wswrd	ORD-014069	Removal of Strontium from Drinking Water by Conventional Treatment and Lime Softening	Darren Lytle	3/18/2016

ord,nheerl,ephd,crb	ORD-014079	Effects of environmental pollutants on cellular iron homeostasis and ultimate links to human disease	Dina Schreinemachers	10/2/2015
ord,nerl,esd	ORD-014081	The Development and Evaluation of a High-Resolution Above Ground Biomass Product for the Commonwealth of Puerto Rico (2000)	John Iiames	1/17/2017
ord,nrmrl,wswrd,mccb	ORD-014085	Whole-Genome Sequences of Four Strains Closely Related with Members of the Mycobacterium chelonae group, Isolated from Biofilms in a Drinking Water Distribution System Simulator	Randy Revetta	10/19/2015

ord,nerl,ced	ORD-014089	Soil organic matter content effects on dermal pesticide bioconcentration in American toads (Bufo americanus).	Tom Purucker	10/6/2015
ord,nheerl,istd,gctb	ORD-014090	Metabolomic effects of CeO2, SiO2 and CuO metal oxide nanomaterials on HepG2 cells	Kirk Kitchin	1/13/2017
ord,nerl,amd,amb	ORD-014099	Simulating the phase partitioning of NH3, HNO3, and HCl with size-resolved particles over northern Colorado in winter	Chris Nolte	4/5/2016
ord,nerl,ced	ORD-014105	Polybrominated Diphenyl Ethers in Human Milk and Serum from the U.S. EPA MAMA Study: Modeled Predictions of Infant Exposure and Considerations for Risk Assessment	John Kenneke	10/14/2015

ord,nerl,emmd	ORD-014106	Metabolite profiles of repeatedly sampled urine from male fathead minnows (Pimephales promelas) contain unique lipid signatures following exposure to anti-androgens	Tim Collette	10/14/2015
ord,nerl,ced	ORD-014112	Characterization and prediction of chemical functions and weight fractions in consumer products	Kristin Isaacs	2/8/2017
ord,nrmrl,lrpcd,wmb	ORD-014122	In vivo formation of natural HgSe nanoparticles in the liver and brain of pilot whales	Kirk Scheckel	12/14/2015
ord,nheerl,ephd,cib	ORD-014123	Acute Ozone-Induced Pulmonary and Systemic Metabolic Effects are Diminished in Adrenalectomized Rats#	Urmila Kodavanti	10/15/2015
ord,nhsrc,dcmd	ORD-014129	Efficacy of decontaminant solutions for remediation on TICs on PPE materials	Lukas Oudejans	10/20/2015

ord,nerl,ced	ORD-014133	Unexpected Benefits of Reducing Aerosol Cooling Effects	Rohit Mathur	6/20/2016
ord,nhsrc,dcmd	ORD-014141	Evaluation of the Efficacy of Methyl Bromide in the Decontaminatio n of Building and Interior Materials Contaminated with Bacillus anthracis Spores	Joe Wood	10/13/2015
ord,nrmrl,std,cpb	ORD-014156	Selective oxidation of alcohols using photoactive VO@g-C3N4.	Rajender Varma	10/8/2015
ord,nheerl,wed,eeb	ORD-014165	Douglas-fir displays a range of growth responses to temperature, water, and Swiss needle cast in western Oregon, USA	EHenry Lee	10/9/2015
ord,nerl,mceard,merb	ORD-014175	Mold populations and dust mite allergen concentrations in house dust samples from across Puerto Rico	Stephen Vesper	10/30/2015

ord,ncct,N/A	ORD-014177	(Reproductive Toxicology) Identification of vascular disruptor compounds by a tiered analysis in zebrafish embryos and mouse embryonic endothelial cells	Thomas Knudsen	8/10/2016
ord,nerl,eerd,merb	ORD-014186	Comparison of stationary and personal air sampling with an air dispersion model for children’s ambient exposure to manganese	Florence Fulk	10/13/2015
ord,nerl,sed,efab	ORD-014194	Pathways of inhalation exposure to manganese in children living near a ferromanganese refinery: A structural equation modeling approach	Florence Fulk	12/1/2015

ord,nheerl,ephd	ORD-014195	Differential Expression of pro-inflammatory and oxidative stress mediators induced by nitrogen dioxide and ozone in primary human bronchial epithelial cells	Robert Devlin	10/1/2015
ord,nhsrc,wipd	ORD-014200	Assessing Inhalation Exposures Associated with Contamination Events in Water Distribution Systems	Robert Janke	9/12/2016
ord,nerl,esd	ORD-014211	An Evaluation of Time-Series Smoothing Algorithms for Landcover Classifications Using MODIS-NDVI Multi-Temporal Data	Ross Lunetta	3/1/2016

ord,nrmrl,aemd,dsbb	ORD-014219	NO to NO2 conversion rate analysis and implications for dispersion model chemistry methods using Las Vegas, Nevada near-road field measurements	Sue Kimbrough	11/29/2016
ord,nheerl,istd,sbb	ORD-014233	Moving Toward Integrating Gene Expression Profiling into High-throughput Testing:A Gene Expression Biomarker Accurately Predicts Estrogen Receptor α Modulation in a Microarray Compendium	Chris Corton	11/23/2015
ord,nrmrl,wswrd,wqmb	ORD-014236	Biofilms on Hospital Shower Hoses: Characterization and Implications for Nosocomial Infections	Jorge Santodomingo	10/26/2015

ord,ncct,N/A	ORD-014250	(TOXICOLOGICAL SCIENCES) Tiered High-Throughput Screening Approach to Identify Thyroperoxidase Inhibitors within the ToxCast Phase I and II Chemical Libraries	Steve Simmons	10/9/2015
ord,nrmrl,appcd,apb	ORD-014257	The Increasing Importance of Deposition of Reduced Nitrogen in the United States	Johnt Walker	11/9/2015
ord,nerl,sed	ORD-014258	A Citizen-Science Study Documents Environmental Exposures and Asthma Prevalence in Two Communities	Florence Fulk	12/16/2016
ord,nrmrl,std,cpb	ORD-014262	Photocatalytic C−H Activation of Hydrocarbons over VO@g‐ C3N4	Rajender Varma	10/8/2015

ord,nheerl,tad,nb	ORD-014295	Impact of Genetic Strain on Body Fat Loss, Food Consumption, Metabolism, Ventilation, and Motor Activity in Free Running Female Rats	Christopher Gordon	10/5/2015
ord,nheerl,tad,nb	ORD-014296	Effect of Genetic Strain and Gender on Age-Related Changes in Body Composition of the Laboratory Rat	Christopher Gordon	10/5/2015
ord,nerl,heasd,pmrb	ORD-014304	Characterization of polar organosulfates in secondary organic aerosol from the unsaturated aldehydes 2-E-pentenal, 2-E-hexenal, and 3-Z-hexenal	Michael Lewandowski	7/22/2016
ord,nhsrc,wipd	ORD-014320	Detention Outlet Retrofit Improves the Functionality of Existing Detention Basins by Reducing Erosive Flows in Receiving Channels	James Goodrich	3/14/2016

ord,nrmrl,lrpcd,wmb	ORD-014351	Assessing Metal Mobilization from Industrially Lead-Contaminated Soils Located at an Urban Site	Souhail Al-Abed	9/30/2016
ord,nerl,emmd,mieb	ORD-014352	Use of Medicaid and housing data may help target areas of high asthma prevalence	Stephen Vesper	10/30/2015
ord,nerl,emmd	ORD-014388	Total and Bioaccessible Soil Arsenic and Lead Levels and Plant Uptake in Three Urban Community Gardens in Puerto Rico	Karen Bradham	1/24/2018
ord,nhsrc,wipd	ORD-014392	Enhancing climate Adaptation Capacity for Drinking Water Treatment Facilities	James Goodrich	12/7/2015
ord,nerl,esd	ORD-014396	The Fractured Rock Geophysical Toolbox Method Selection Tool	D Werkema	8/8/2016

ord,nheerl,med,tecb	ORD-014407	Sediment Bioaccumulation Test with Lumbriculus variegatus: Effects of Organism Loading	Lawrence Burkhard	10/20/2015
ord,nrmrl,std,cpb	ORD-014412	Magnetic Fe@g-C3N4: A Photoactive Catalyst for the Hydrogenation of Alkenes and Alkynes	Rajender Varma	10/22/2015
ord,nheerl,ephd,eb	ORD-014435	Estimated Costs of Sporadic Gastrointestinal Illness Associated with Surface Water Recreation: A Combined Analysis of Data from NEEAR and CHEERS Studies	Tim Wade	10/15/2015
ord,nheerl,med	ORD-014437	Estuarine consumers utilize marine, estuarine and terrestrial organic matter and provide connectivity among these food webs	Joel Hoffman	10/20/2015

ord,nheerl,ephd,crb	ORD-014439	Baseline Chromatin Modification Levels May Predict Interindividual Variability in Ozone-Induced Gene Expression	Shaun McCullough	10/30/2015
ord,nerl,emmd,mieb	ORD-014440	Developing a Salivary Antibody Multiplex Immunoassay to Measure Human Exposure to Environmental Pathogens	Swinburne Augustine	4/15/2016
ord,nrmrl,wswrd,uwmb	ORD-014446	Detection of semi-volatile organic compounds in permeable pavement infiltrate	Thomas OConnor	5/17/2016
ord,nheerl,ged	ORD-014449	A Model For Change: An Approach for Forecasting Well-Being From Service-Based Decisions	Kevin Summers	11/12/2015
ord,nheerl,istd,sbb	ORD-014485	Characterization of Early Cortical Neural Network Development in Multiwell Microelectrode Array Plates	Tim Shafer	11/10/2015

ord,nheerl,aed,peb	ORD-014490	Caffeine in Boston Harbor past and present, assessing its utility as a tracer of wastewater contamination in an urban estuary	Mark Cantwell	12/21/2015
ord,nheerl,wed,feb	ORD-014492	Development of a Benthic Macroinvertebrate Multimetric Index (MMI) for Neotropical Savanna Headwater Streams	Phil Kaufmann	1/7/2016
ord,nheerl,aed,peb	ORD-014496	Particle-bound metal transport after removal of a small dam in the Pawtuxet River, Rhode Island, USA	David Katz	5/31/2016
ord,ncea,nceartp,emag	ORD-014499	Estimation of on-road NO2 concentrations, NO2/NOx ratios, and related roadway gradients from near-road monitoring data	Jennifer Richmond-Bryant	11/16/2015

ord,nheerl,aed,adpo	ORD-014502	Emergy evaluation of hierarchically nested systems: application to EU27, Italy and Tuscany and consequences for the meaning of emergy indicators	Dan Campbell	10/22/2015
ord,nheerl,wed,feb	ORD-014506	Disentangling the pathways of land use impacts on the functional structure of fish assemblages in Amazon streams	Phil Kaufmann	11/25/2015
ord,nheerl,ged	ORD-014509	Evaluating the Zebrafish Embryo Toxicity Test for Pesticide Hazard Screening	Mace Barron	10/27/2015
ord,nrmrl,wswrd	ORD-014513	Data Acceptance Criteria for Standardized Human-Associated Fecal Source Identification Quantitative Real-Time PCR Methods	Orin Shanks	12/14/2015

ord,nerl,heasd,emrb	ORD-014514	Completing the Link between Exposure Science and Toxicology for Improved Environmental Health Decision Making: The Aggregate Exposure Pathway Framework	Cecilia Tan	2/11/2016
ord,nheerl,N/A	ORD-014515	One Health - Transdisciplinary Opportunities for SETAC Leadership in Integrating and Improving the Health of People, Animals, and the Environment	William Benson	10/22/2015
ord,nheerl,wed,feb	ORD-014521	Multi-scale assessment of human-induced changes to Amazonian instream habitats	Phil Kaufmann	11/25/2015

ord,nheerl,ephd,cib	ORD-014546	Morning NO2 Exposure Sensitizes Hypertensive Rats to the Cardiovascular Effects of Same Day O3 Exposure in the Afternoon	Aimen Farraj	12/2/2015
ord,nerl,amd,amdb	ORD-014560	New directions: Atmospheric chemical mechanisms for the future	Deborah Luecken	11/30/2015
ord,nheerl,tad,nb	ORD-014564	Pulmonary Sensitivity to Ozone Exposure in Sedentary Versus Chronically Trained, Female Rats	Christopher Gordon	12/3/2015
ord,nheerl,aed,adpo	ORD-014569	Eco-exergy and emergy based self-organization of three forest plantations in lower subtropical China	Dan Campbell	12/10/2015
ord,nheerl,istd,pb	ORD-014574	Human Health Screening and Public Health Significance of Contaminants of Emerging Concern Detected in Public Water Supplies	Jane Simmons	11/24/2015

ord,ioaa,s	ORD-014575	Past, Present and Future Challenges To Science and Sustainability At EPA: A Review	Alan Hecht	12/1/2015
ord,nrmrl,std,sab	ORD-014576	Detailed Life Cycle Assessment of Bounty Paper Towel Operations in the United States	Wesley Ingwersen	11/5/2015
ord,nheerl,wed,eeb	ORD-014589	USDA-ARS and US EPA scientific investigations concerning biochars impact on soil health characteristics, microbial transport, and environmental restoration of mine-impacted soils	Markg Johnson	11/16/2015
ord,nrmrl,std,seb	ORD-014605	Adaptive management for ecosystem services (j/a)	Ahjond Garmestani	10/29/2015
ord,nrmrl,std,seb	ORD-014632	Body size distributions signal a regime shift in a lake ecosystem	Ahjond Garmestani	10/29/2015

ord,nrmrl,appcd	ORD-014642	The Effects of Vegetation Barriers on Near-road Ultrafine Particle Number and Carbon Monoxide Concentrations	Gayle Hagler	12/9/2015
ord,nheerl,ged	ORD-014647	Linking Terrigenous Sediment Delivery to Declines in Coral Reef Ecosystem Services	Susan Yee	10/30/2015
ord,nheerl,ephd,crb	ORD-014679	Persistent Effects of Libby Amphibole and Amosite Asbestos Following Subchronic Inhalation in Rats	Stephen Gavett	11/30/2015
ord,nheerl,aed,mab	ORD-014681	The geobiosphere emergy baseline: A synthesis.	Dan Campbell	12/15/2015

ord,nheerl,istd,gctb	ORD-014687	Progressive Increase in Disinfection Byproducts and Mutagenicity from Sourceto Tap to Swimming Pool and Spa Water: Implications for Public Health	David DeMarini	2/14/2016
ord,nerl,emmd,mieb	ORD-014692	Populations of some molds in water-damaged homes may differ if the home was constructed with gypsum drywall compared to plaster	Stephen Vesper	1/31/2017
ord,nhsrc,wipd	ORD-014693	Sediment Resuspension and Transport in Water Distribution Storage Tanks	Regan Murray	12/15/2015
ord,nrmrl,std,seb	ORD-014694	Adaptive governance of riverine and wetland ecosystem goods and services	Ahjond Garmestani	11/5/2015

ord,nheerl,istd,sbb	ORD-014698	Effects of an Environmentally-relevant Mixture of Pyrethroid Insecticides on Spontaneous Activity in Primary Cortical Networks on Microelectrode Arrays	Tim Shafer	11/10/2015
ord,nerl,emmd,phcb	ORD-014709	Increasing Prevalence Rate of Nontuberculous Mycobacteria Infections in Five States, 2008–2013	Maura Donohue	10/4/2016
ord,nrmrl,appcd,iemb	ORD-014724	Characterization of organophosphorus flame retardants' sorption on building materials and consumer products	Xiaoyu Liu	11/23/2015
ord,nheerl,ephd,eb	ORD-014736	Acute Gastroenteritis and Recreational Water: Highest Burden Among Young US Children	Tim Wade	12/7/2015

ord,nheerl,ged	ORD-014749	Identifying and structuring objectives for a coral reef protection plan at the U.S. Environmental Protection Agency	William Fisher	11/13/2015
ord,nerl,amd	ORD-014766	Assessment of the effects of horizontal grid resolution on long-term air quality trends using coupled WRF-CMAQ simulations	Christian Hogrefe	3/16/2016
ord,nerl,amd,amdb	ORD-014776	Aqueous-phase mechanism for secondary organic aerosol formation from isoprene: application to the southeast United States and co-benefit of SO2 emission controls	Havala Pye	2/9/2016
ord,nerl,heasd,mdab	ORD-014787	Using paired soil and house dust samples in an in vitro assay to assess the post ingestion bioaccessibility of sorbed fipronil	James Starr	4/26/2016

ord,nerl,esd	ORD-014789	Potential Application of VIIRS Day/Night Band for Monitoring Nighttime Surface PM2.5 Air Quality From Space	Jim Szykman	12/23/2015
ord,nrmrl,wswrd	ORD-014798	Copper Nanoparticle Induced Cytotoxicity to Nitrifying Bacteria in Wastewater Treatment: A Mechanistic Copper Speciation Study by X-ray Absorption Spectroscopy	Todd Luxton	12/14/2015
ord,nheerl,aed,adpo	ORD-014886	Interactions among energy consumption, economic development and greenhouse gas emissions in Japan after World War II	Dan Campbell	12/15/2015
ord,nerl,sed	ORD-014887	An Assessment of US Microbiome Research	Jay Garland	12/22/2015

ord,nerl,erd	ORD-014888	Phototransformation-Induced Aggregation of Functionalized Single-Walled Carbon Nanotubes: The Importance of Amorphous Carbon	Richard Zepp	4/7/2016
ord,nrmrl,appcd,ecpb	ORD-014891	Comparison of Field Measurements at a New Landfill to Methane Emissions Models	Eben Thoma	1/11/2016
ord,nheerl,ephd,cib	ORD-014944	Multivariate Models for Prediction of Human Skin Sensitization Hazard#	David Lehmann	12/17/2015
ord,nheerl,ged	ORD-014947	A Mechanism-based 3D-QSAR Approach for Classification and Prediction of Acetylcholinesterase Inhibitory Potency of Organophosphate and Carbamate Analogs	Mace Barron	12/8/2015

ord,nerl,eerd,mirb	ORD-014951	Diploid and triploid African catfish (Clarias gariepinus) differ in biomarker responses to the pesticide chlorpyrifos	Jim Lazorchak	12/14/2015
ord,nrmrl,std,cpb	ORD-014961	A photoactive bimetallic framework for direct aminoformylation of nitroarenes	Rajender Varma	12/9/2015
ord,nheerl,aed,mab	ORD-014966	Optical Models for Remote Sensing of Colored Dissolved Organic Matter Absorption and Salinity in New England, Middle Atlantic and Gulf Coast Estuaries USA	Darryl Keith	3/2/2016
ord,nheerl,med	ORD-014967	The acute toxicity of major ion salts to Ceriodaphnia dubia: I. Influence of background water chemistry	Russell Erickson	6/29/2016

ord,nrmrl,wswrd,mccb	ORD-014969	Applicability of UV resistant Bacillus pumilus endospores as a human adenovirus surrogate for evaluating the effectiveness of virus inactivation in low-pressure UV treatment systems	Laura Boczek	12/23/2015
ord,nrmrl,appcd,aptb	ORD-014970	Dry sorbent injection of trona to control acid gases from a pilot-scale coal-fired combustion facility	Tiffany Yelverton	12/9/2015
ord,nheerl,med	ORD-014971	Optimization of a UDP-glucuronosyltransferase assay for trout liver S9 fractions: Activity enhancement by alamethicin, a pore-forming peptide	John Nichols	2/9/2016
ord,nrmrl,appcd,ecpb	ORD-014973	South Philadelphia Passive Sampler and Sensor Studies	Eben Thoma	12/11/2015

ord,nerl,sed,iemb	ORD-014980	Relative Contributions of Agricultural Drift, Para-Occupational, and Residential Use Exposure Pathways to House Dust Pesticide Concentrations: Meta-Regression of Published Data	Kent Thomas	4/26/2016
ord,nheerl,med	ORD-014981	Quantitative structure - mesothelioma potency model optimization for complex mixtures of elongated particles in rat pleura: A retrospective study	Dale Hoff	3/7/2016
ord,nerl,sed	ORD-014984	Occupational Exposure to Pesticides and the Incidence of Lung Cancer in the Agricultural Health Study	Kent Thomas	4/25/2016
ord,nrmrl,std,sab	ORD-014986	Area of Concern: a new paradigm in life cycle assessment for the development of footprint metrics	Andrew Henderson	1/12/2016

ord,nheerl,ephd,cib	ORD-014996	Age-related differences in pulmonary effects of acute and subchronic episodic ozone exposures in Brown Norway rats	Urmila Kodavanti	5/5/2016
ord,ncea,nceacin	ORD-014997	In Response: Bias in the Science that Supports Environmental Assessments—A Regulatory Assessment Perspective	Glenn Suter	12/2/2015
ord,nrmrl,appcd,apb	ORD-015000	Ecosystem-scale VOC fluxes during an extreme drought in a broad-leaf temperate forest of the Missouri Ozarks (central USA)	Chris Geron	8/11/2016
ord,nheerl,aed,heb	ORD-015001	Eutrophication and Hypoxia Diminish Ecosystem Functions of Benthic Communities in a New England Estuary	Stephen Hale	1/26/2016

ord,nheerl,wed,eeb	ORD-015004	Evidence that higher CO2 increases tree growth sensitivity to temperature: a comparison of modern and paleo oaks	Reneej Brooks	1/9/2016
ord,nheerl,wed,feb	ORD-015009	How Misapplication of the Hydrologic Unit Framework Diminishes the Meaning of Watersheds	Marc Weber	12/14/2015
ord,nheerl,med	ORD-015012	Activation of AhR-mediated toxicity pathway by emerging pollutants polychlorinated diphenyl sulfides	Dan Villeneuve	12/10/2015
ord,nheerl,ephd,crb	ORD-015022	Repeating Cardiopulmonary Health Effects in Rural North Carolina Population During a Second Large Peat Wildfire	Ana Rappold	12/24/2015

ord,nerl,emmd	ORD-015023	Novel Chemoresistive CH4 Sensor with 10 ppm Sensitivity Based on Multi-Walled Carbon Nanotubes (MWCNTs) Functionalized with SnO2nanocrystals	Paul Solomon	1/5/2016
ord,nrmrl,appcd,apb	ORD-015033	Large Drought-Induced Variations in Oak Leaf Volatile Organic Compound Emissions during PINOT NOIR 2012	Chris Geron	12/24/2015
ord,nrmrl,wswrd,mccb	ORD-015034	Draft Genome of Two Sphingopyxis sp. Strains, Dominant Members of the Bacterial Community Associated with a Drinking Water Distribution System Simulator	Randy Revetta	1/11/2016

ord,nrmrl,wsd,wrrb	ORD-015036	Demonstration and Evaluation of Innovative Rehabilitation Technologies for Water Infrastructure Systems	Ariamalar Selvakumar	2/8/2016
ord,nerl,emmd	ORD-015040	International Association of Breath Research 10th Anniversary Conference at the Schoenbrunn Palace in Vienna, Austria	Joachim Pleil	6/3/2016
ord,nheerl,ephd,eb	ORD-015044	County-level environmental quality and associations with cancer incidence#	Danelle Lobdell	1/11/2016
ord,ncea,nceartp	ORD-015048	Expert consensus on an in vitro approach to assess pulmonary fibrogenic potential of aerosolized nanomaterials	Annie Jarabek	4/8/2016

ord,nerl,emmd	ORD-015049	High-Resolution Mass Spectrometry: Basic Principles for Using Exact Mass and Mass Defect for Discovery Analysis of Organic Molecules in Blood, Breath, Urine and Environmental Media	Joachim Pleil	4/4/2016
ord,ncea,nceartp, emag	ORD-015062	Hypospadias and maternal exposure to atrazine via drinking water in the National Birth Defects Prevention Study	Tom Luben	4/28/2016
ord,ncea,nceartp, emag	ORD-015068	Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiologic Literature	Erin Hines	6/23/2016

ord,ncea,nceartp,emag	ORD-015070	The heart as an extravascular target of endothelin-1 in particulate matter-induced cardiac dysfunction	Elizabeth Chan	12/18/2015
ord,ncea,odd,pos	ORD-015077	Unmasking Silent Neurotoxicity Following Developmental Exposure to Environmental Toxicants	Andrew Kraft	1/11/2016
ord,nheerl,tad,nb	ORD-015081	Toluene Inhalation Exposure for 13 Weeks Causes Persistent Changes in Electroretinograms of Long-Evans Rats	William Boyes	12/14/2015
ord,nheerl,aed,peb	ORD-015090	Passive Sampling in Regulatory Chemical Monitoring of Nonpolar Organic Compounds in the Aquatic Environment	Robert Burgess	12/10/2015
ord,nhsrc,wipd	ORD-015098	Advanced Oxidation of Tartrazine and Brilliant Blue with Pulsed Ultraviolet Light Emitting Diodes	Matthew Magnuson	1/28/2016

ord,nerl,sed	ORD-015099	Sensitivities of Summertime Mesoscale Circulations in the Coastal Carolinas to Modifications of the Kain–Fritsch Cumulus Parameterization	Kiran Alapaty	12/11/2015
ord,nheerl,adh,adh	ORD-015113	Age-Dependent Human Hepatic Carboxylesterase 1 (CES1) and Carboxylesterase 2 (CES2) Postnatal Ontogeny	Ronald Hines	12/9/2015
ord,nrmrl,std,cpb	ORD-015115	Sustainable Strategy Utilizing Biomass: Visible-Light-Mediated Synthesis of γ-Valerolactone	Rajender Varma	1/12/2016
ord,ncct,N/A	ORD-015117	(FOOD AND CHEMICAL TOXICOLOGY) Evaluation of food-relevant chemicals in the ToxCast high-throughput screening program	Keith Houck	12/20/2015

ord,nerl,ced	ORD-015118	Characterization of pollutant dispersion near elongated buildings based on wind tunnel simulations	Steven Perry	8/24/2016
ord,nheerl,ged	ORD-015119	Acute toxicity prediction to threatened and endangered species using Interspecies Correlation Estimation (ICE) models	Mace Barron	1/11/2016
ord,nheerl,aed,peb	ORD-015127	Evaluating the Relationship between Equilibrium Passive Sampler Uptake and Aquatic Organism Bioaccumulation	Robert Burgess	3/1/2016
ord,nerl,ced	ORD-015131	Historical Trends in PM2.5-Related Premature Mortality during 1990-2010 across the Northern Hemisphere	Rohit Mathur	4/26/2016

ord,ncea,nceacin	ORD-015133	Advancing environmental risk assessment of regulated products under EFSA’s remit	Glenn Suter	2/9/2016
ord,nheerl,ephd,cib	ORD-015134	Consensus Report of the 2015 Weinman International Conference on Mesothelioma	Stephen Gavett	12/15/2015
ord,nheerl,tad,nb	ORD-015136	Age-and Brain Region-Specific Differences in Mitochondrial Bioenergetics in Brown Norway Rats	Prasada Kodavanti	12/30/2015
ord,nheerl,aed,mab	ORD-015143	Associations between Chlorophyll a and various microcystin-LR health advisory concentrations	Jeff Hollister	1/25/2016
ord,nrmrl,appcd,aptb	ORD-015165	Attrition of a Copper Oxide-Based Oxygen Carrier in Chemical Looping Combustion for CO2 Capture	Bill Linak	12/24/2015

ord,nerl,emmd	ORD-015166	Exposure Science in an Age of Rapidly Changing Climate: Challenges and Opportunities	Jon Sobus	4/20/2016
ord,nerl,emmd,mieb	ORD-015167	Role of Biochar in Degradation of Nonylphenol in Sediment：Microbial Stimulation versus Adsorptive Inhibition	Jingrang Lu	7/24/2017
ord,nheerl,ephd,eb	ORD-015169	The Water Quality in Rio Highlights the Global Public Health Concern Over Untreated Sewage Disposal	Tim Wade	1/30/2016
ord,ncct,N/A	ORD-015175	(Crit. Rev. Tox.) Comparison of rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects	Thomas Knudsen	1/25/2016

ord,nheerl,wed,feb	ORD-015177	Assessment of Disturbance at Three Spatial Scales in Two Large Tropical Reservoirs	Phil Kaufmann	1/7/2016
ord,ncct,N/A	ORD-015178	(Journal of Applied Toxicology) What determines skin sensitization potency: myths, maybes and realities. The 500 molecular weight cut-off: An updated analysis	Grace Patlewicz	2/3/2016
ord,ncct,N/A	ORD-015179	(Crit. Rev. Tox.) Comparing rat and rabbit embryo-fetal developmental toxicity studies for 379 pharmaceuticals : On systemic dose and developmental effects	Thomas Knudsen	1/25/2016

ord,nerl,sed	ORD-015180	Assessing the impact of fine particulate matter (PM2.5) on respiratory-cardiovascular chronic diseases in the New York City Metropolitan area using Hierarchical Bayesian Model estimates	EricS Hall	3/15/2016
ord,nrmrl,std,seb	ORD-015182	Ecology for the shrinking city (JA)	Ahjond Garmestani	1/4/2016
ord,ncea,nceartp	ORD-015195	Spectral indices accurately quantify changes in tree physiology following fire: toward mechanistic assessments of landscape carbon dynamics following wildfire	Alan Talhelm	2/15/2016

ord,ncct,N/A	ORD-015201	(Journal of Applied Toxicology) Is skin penetration a determining factor in skin sensitisation potential and potency? Refuting the notion of a LogKow threshold for Skin Sensitisation	Grace Patlewicz	5/20/2016
ord,nheerl,ephd,cib	ORD-015205	The role of micronutrients in the response to air pollutants: potential mechanisms and suggestions for research design.	Colette Miller	5/24/2016
ord,nerl,sed,eib	ORD-015218	A comparison of biomarker responses in juvenile diploid and triploid African catfish, Clarias gariepinus, exposed to the pesticide butachlor	Jim Lazorchak	1/5/2016

ord,nheerl,wed,eeb	ORD-015222	Uncoupling the complexity of forest soil variation: influence of terrain attributes, spectral indices, and spatial variability	Markg Johnson	1/4/2016
ord,nheerl,wed,eeb	ORD-015225	Gasified grass and wood biochars facilitate plant establishment in acid mine soils	Markg Johnson	1/4/2016
ord,nheerl,ephd,cib	ORD-015244	TRPA1 mediates changes in heart rate variability and cardiac mechanical function in mice exposed to acrolein	Mehdi Hazari	2/16/2016
ord,nheerl,med	ORD-015247	Predicting fecundity of fathead minnows (Pimephales promelas) exposed toeEndocrine-disrupting chemicals using a MATLAB®-based model of oocyte growth dynamics	Gerald Ankley	12/31/2015

ord,nheerl,adh	ORD-015254	Determination of Human Hepatic CYP2C8 and CYP1A2 Age-Dependent Expression to Support Human Health Risk Assessment for Early Ages	Ronald Hines	1/4/2016
ord,ncea,nceartp, emag	ORD-015279	Current Approaches Used in Epidemiologic Studies to Examine Short-term Multipollutant Air Pollution Exposures	Jason Sacks	2/15/2016
ord,nrmrl,wswrd	ORD-015286	Mixing at double-Tee junctions with unequal pipe sizes in water distribution systems	Jeff Yang	3/2/2016
ord,nheerl,aed,adpo	ORD-015287	Emergy analysis of a silvo-pastoral system, a case study in southern Portugal	Dan Campbell	1/25/2016

ord,nheerl,istd,pb	ORD-015289	Estimation of human percutaneous bioavailability for two novel brominated flame retardants, 2-ethylhexyl tetrabromobenzoate (EH-TBB) and bis(2-ethylhexyl) tetrabromophthalate (BEH-TEBP), using the parallelogram approach	MichaelF Hughes	2/17/2016
ord,nheerl,tad	ORD-015290	Search for the Missing lncs: Gene Regulatory Networks in Neural Crest Development and Long Non-coding RNA Biomarkers of Hirschsprung's Disease	John Rogers	1/28/2016
ord,nheerl,istd,cb	ORD-015294	Characterizing "Adversity " of Pathology Findings in Nonclinical Toxicity Studies: Results from the 4th ESTP International Expert Workshop.	Charles Wood	1/12/2016

ord,nheerl,aed	ORD-015297	Assessing and managing multiple risks in a changing world – the Roskilde recommendations.	Wayne Munns	2/19/2016
ord,nrmrl,std,cpb	ORD-015299	Co-constructive development of a green chemistry-based model for the assessment of nanoparticles synthesis	Rajender Varma	8/17/2016
ord,nerl,emmd	ORD-015303	Cellular respiration: replicating in vivo systems biology for in vitro exploration of human exposome, microbiome, and disease pathogenesis biomarkers	Joachim Pleil	3/11/2016
ord,nerl,sed,efab	ORD-015327	Evaluation of near surface ozone and particulate matter in air quality simulations driven by dynamically downscaled historical meteorological fields	Chris Nolte	2/2/2016

ord,nrmrl,std,cpb	ORD-015328	Preparation of Water-Selective Polybutadiene Membranes and Their Use in Drying Alcohols by Pervaporation and Vapor Permeation Technologies	Leland Vane	1/13/2016
ord,nrmrl,wswrd	ORD-015354	Water Quality Modeling in the Dead End Sections of Drinking Water Distribution Networks - journal article	Jeff Yang	6/8/2016
ord,nheerl,med	ORD-015378	Identification of Ruffe larvae (Gymnocephalus cernuus) in the St. Louis River, Lake Superior: Clarification and guidance regarding morphological descriptions	Greg Peterson	1/5/2017
ord,nerl,sed,eib	ORD-015382	An improved representation of geographically isolated wetlands in a watershed-scale hydrologic model	Heather Golden	1/19/2016

ord,nrmrl,lmmd,mmb	ORD-015388	Evaluating weathering of food packaging polyethylene-nano-clay composites: Release of nanoparticles and their impacts	Endalkachew Sahle-Demessie	1/27/2016
ord,nerl,emmd,encb	ORD-015408	The Effect of Equilibration Time and Tubing Material on Soil Gas Measurements	JohnH Zimmerman	5/6/2016
ord,nerl,sed,ehcab	ORD-015414	Effect of land cover change on snow free surface albedo across the continental United States	James Wickham	9/22/2016
ord,nrmrl,wsd,wmb	ORD-015434	Storm Water Management Model (SWMM): Performance Review and Gap Analysis	Christopher Nietch	3/15/2016
ord,nerl,ced	ORD-015438	Considerations of Environmentally Relevant Test Conditions for Improved Evaluation of Ecological Hazards of Engineered Nanomaterials	JohnM Johnston	1/20/2016

ord,ncer,asd	ORD-015440	Invited article summarizing the Science To Achieve Results research portfolio on Black Carbon for the journal EM of the Air and Waste Management Association.	Bryan Bloomer	4/27/2016
ord,nheerl,istd	ORD-015441	Adverse Outcome Pathways: From Research to Regulation - Scientific Workshop Report	Stephen Edwards	1/19/2016
ord,nheerl,istd,sbb	ORD-015444	Developing and applying the adverse outcome pathway concept for understanding and predicting neurotoxicity	Tim Shafer	1/25/2016
ord,nheerl,wed,eeb	ORD-015445	Molecular and physiological responses to titanium dioxide and cerium oxide nanoparticles in arabidopsis	Christian Andersen	2/8/2016

ord,nrmrl,aemd	ORD-015454	Performance Assessment of a Solar-powered Air Quality and Weather Station Placed on a School Roof top in Hong Kong	Gayle Hagler	2/2/2016
ord,nheerl,ephd,crb	ORD-015455	Air pollution particles and iron homeostasis	Andy Ghio	2/17/2016
ord,nheerl,aed,peb	ORD-015458	Effect-directed analysis supporting monitoring of aquatic environments - An in-depth overview	Robert Burgess	2/1/2016
ord,nerl,sed,eib	ORD-015459	Flow intermittence and ecosystem services in rivers of the Anthropocene	Ken Fritz	1/27/2016
ord,nheerl,aed,wdb	ORD-015462	Establishing an Anthropogenic Nitrogen Baseline Using Native American Shell Middens	Autumn Oczkowski	2/15/2016

ord,ncea,nceartp,emag	ORD-015468	Associations between maternal water consumption and birth defects in the National Birth Defects Prevention Study(2000-2005)	Tom Luben	2/15/2016
ord,nheerl,ephd,crb	ORD-015472	Live-cell Imaging Approaches for the Investigation of Xenobiotic-Induced Oxidant Stress	James Samet	2/16/2016
ord,nrmrl,lrpcd,wmb	ORD-015473	State of the Science Review: Potential for Beneficial Use of Waste By-Products for <I>In-situ</I> Remediation of Metal-Contaminated Soil and Sediment	Kirk Scheckel	3/9/2016
ord,ncea,nceartp	ORD-015475	Concentrations of individual fine particulate matter components in the United States around July 4th	Elizabeth Chan	4/14/2016

ord,nerl,sed	ORD-015483	Pharmaceuticals and the Environment (PiE): Evolution and impact of the published literature revealed by bibliometric analysis	Christian Daughton	4/19/2016
ord,nrmrl,std,seb	ORD-015487	Nerve-gas destruction with metal organic frameworks	John Glaser	2/18/2016
ord,nrmrl,std,sab	ORD-015490	Multi-pathway exposure modelling of chemicals in cosmetics with application to shampoo	Andrew Henderson	2/18/2016
ord,nheerl,aed,wdb	ORD-015494	Quantifying contributions to light attenuation in estuaries and coastal embayments: Application to Narragansett Bay, Rhode Island	Mohamed Abdelrhman	4/4/2016

ord,ncea,nceacin, brab	ORD-015497	Improving predictive models of in-stream phosphorus based on nationally-available spatial data coverages in a Southwestern Ohio watershed	Michael McManus	2/24/2016
ord,nheerl,aed,mab	ORD-015498	Optimal Groundwater Extraction under Uncertainty and a Spatial Stock Externality	Nathaniel Merrill	3/4/2016
ord,nerl,sed,ehcab	ORD-015502	Marine invasions enter the genomic era: three lessons from the past, and the way forward	John Darling	2/16/2016
ord,nerl,emmd	ORD-015504	Performance of Passive Samplers Analyzed by Computer Controlled Scanning Electron Microscopy to Measure PM10-2.5	Robert Willis	10/13/2016

ord,ncea,nceartp, emag	ORD-015511	Effects of perfluorinated chemicals on thyroid function, markers of ovarian reserve, and natural fertility	Erin Hines	4/28/2016
ord,nrmrl,wswrd, wqmb	ORD-015518	Inhibitory effect of cyanide on wastewater nitrification determined using SOUR and RNA-based gene-specific assays	Jorge Santodomingo	3/18/2016
ord,nheerl,istd,pb	ORD-015520	Environmentally relevant mixing ratios in cumulative assessments: a study on the correlation of blood and brain concentrations of a mixture of pyrethroid insecticides to neurotoxicity in the rat	MichaelF Hughes	3/31/2016
ord,nrmrl,lrpcd	ORD-015533	Anaerobic Toxicity of Cationic Silver Nanoparticles	Thabet Tolaymat	4/13/2016

ord,nheerl,tad,nb	ORD-015542	Esterase detoxification of acetylcholinesterase inhibitors using human liver samples in vitro	Ginger Moser	2/10/2016
ord,nerl,emmd	ORD-015553	U.S. Domestic Cats as Sentinels for Perfluoroalkyl Substances: Associations with Housing, Obesity and Chronic Disease	Mark Strynar	10/13/2016
ord,nerl,emmd	ORD-015554	Effects of O2 Plasma and UV-O3 Assisted Surface Activation on High Sensitivity Metal Oxide Functionalized Multi-Walled Carbon Nanotube CH4 Sensors	Paul Solomon	5/23/2017
ord,nheerl,ephd,eb	ORD-015556	Associations between environmental quality and mortality in the contiguous United States 2000-2005	Danelle Lobdell	3/13/2016

ord,ncct,N/A	ORD-015575	(ALTEX) CAAT Altex workshop paper entitled "Towards Good Read-Across Practice (GRAP) Guidance"	Grace Tier	2/14/2016
ord,nrmrl,appcd,ecpb	ORD-015577	Community Air Sensor Network (CAIRSENSE) project: Evaluation of low-cost sensor performance in a suburban environment in the southeastern United States	Gayle Hagler	3/18/2016
ord,nerl,emmd	ORD-015587	Initial Development of a Multigene Omics-Based Exposure Biomarker for Pyrethroid Pesticides	Susan Glassmeyer	9/26/2016
ord,nheerl,ged	ORD-015589	Bio-optical water quality dynamics observed from MERIS in Pensacola Bay, Florida	John Lehrter	2/2/2016

ord,ncct,N/A	ORD-015591	(Biomaterials) Human iPSC-Derived Endothelial Cell Sprouting Assay in Synthetic Hydrogel Arrays	Thomas Knudsen	2/12/2016
ord,nheerl,aed,heb	ORD-015593	Diagnosis of potential stressors adversely affecting benthic invertebrate communities in Greenwich Bay, Rhode Island, USA	Peg Pelletier	3/3/2016
ord,nheerl,ged	ORD-015610	Satellite-based empirical models linking river plume dynamics with hypoxic area andvolume	John Lehrter	3/10/2016
ord,nrmrl,std,cpb	ORD-015633	Sustainable Application of Pecan Nutshell Waste: Greener Synthesis of Pd-based Nanocatalysts for Electro-oxidation of Methanol	Rajender Varma	2/24/2016

ord,nerl,ced	ORD-015658	Improved meteorology from an updated WRF/CMAQ modeling system with MODIS vegetation and albedo	Jon Pleim	2/8/2016
ord,nheerl,ephd,cib	ORD-015674	Atypical Microglial Response to Biodiesel Exhaust in Healthy and Hypertensive Rats	Urmila Kodavanti	2/16/2016
ord,nheerl,ephd,cib	ORD-015675	Stretching the Stress Boundary: Linking Air Pollution Health Effects to a Neurohormonal Stress Response	Urmila Kodavanti	5/24/2016
ord,nhsrc,tcad	ORD-015676	Hyperspectral Analysis for Standoff Detection of Dimethyl Methylphosphonate on Building Materials [HS7.52.01]	Stuart Willison	2/25/2016
ord,nrmrl,wswrd	ORD-015681	An approach to measure parameter sensitivity in watershed hydrologic modeling	Jeff Yang	3/22/2016

ord,nheerl,istd,cb	ORD-015685	MicroRNA Biomarkers of Toxicity in Biological Matrices	Brian Chorley	2/19/2016
ord,nrmrl,std,sab	ORD-015688	A comparison of major petroleum life cycle models	Wesley Ingwersen	2/23/2016
ord,nerl,ced	ORD-015698	Evaluating the Impact of Uncertainties in Clearance and Exposure When Prioritizing Chemicals Screened in High-Throughput Assays	Cecilia Tan	5/9/2016
ord,nerl,ced	ORD-015701	Technical note: Examining ozone deposition over seawater	Golam Sarwar	7/1/2016
ord,nheerl,wed,eeb	ORD-015702	Intrinsic and extrinsic drivers of source-sink dynamics	Nathan Schumaker	3/7/2016
ord,nheerl,wed,eeb	ORD-015703	Habitat degradation and loss as key drivers of regional population extinction	Nathan Schumaker	3/7/2016

ord,nerl,ced	ORD-015709	Connecting the Dots: Linking Environmental Justice Indicators to Daily Dose Model Estimates	Timothy Barzyk	9/27/2016
ord,nheerl,tad,dtb	ORD-015710	Perfluoroalky acids-induced liver steatosis: Effects on genes controlling lipid homeostasis	Christopher Lau	3/16/2016
ord,nheerl,aed,peb	ORD-015718	Growth, morphometrics and nutrient content of farmed eastern oysters, Crassostrea virginica (Gmelin), in New Hampshire, USA	Mark Cantwell	2/15/2016
ord,nerl,sed	ORD-015721	Phylogenetic relationships of North American Gomphidae and their close relatives	Erik Pilgrim	5/13/2016

ord,nerl,ced	ORD-015727	Development and evaluation of the R-LINE model algorithms to account for chemical transformation in the near-road environment	David Heist	4/20/2018
ord,nheerl,med	ORD-015743	The influence of control group reproduction on the statistical power of the Environmental Protection Agency’s medaka Extended One-Generation Reproduction Test (MEOGRT)	Kevin Flynn	8/10/2016
ord,nheerl,wed,eeb	ORD-015749	Zostera marina root demography in an intertidal estuarine environment measured using minirhizotron technology	Markg Johnson	2/25/2016
ord,nrmrl,std,seb	ORD-015756	Transformative environmental governance	Ahjond Garmestani	2/23/2016

ord,nheerl,istd,cb	ORD-015757	Proteomic Responses of BEAS-2B Cells to Nontoxic and Toxic Chromium: Protein Indicators of Cytotoxicity Conversion	Yue Ge	2/22/2016
ord,nrmrl,lrpcd,wmb	ORD-015758	Assessment of arsenic speciation and bioaccessibility in mine-impacted materials	Kirk Scheckel	7/8/2016
ord,nheerl,istd	ORD-015759	Computational modeling of dynamic alteration of plasma vitellogenin in response to aromatase CYP19 inhibition in fathead minnows	Rory Conolly	2/22/2016
ord,nheerl,med	ORD-015767	Reconstructing fish movements between coastal wetland and nearshore habitats of the Great Lakes	Michael Sierszen	2/16/2016
ord,nrmrl,lrpcd,wmb	ORD-015772	Iron Mineralogy and Uranium-Binding Environment in the Rhizosphere of a Wetland Soil	Kirk Scheckel	7/8/2016

ord,nerl,ced	ORD-015776	Representing the effects of stratosphere–troposphere exchange on 3-D O3 distributions in chemistry transport models using a potential vorticity-based parameterization	Rohit Mathur	2/10/2017
ord,nrmrl,lrpcd,esmb	ORD-015782	Characterizing light attenuation within Northwest Florida Estuaries: Implications for RESTORE Act water quality monitoring	Robyn Conmy	3/15/2016
ord,nerl,sed	ORD-015793	Significance of dissolved methane in effluents of anaerobically treated low strength wastewater and potential for recovery as an energy product: A review	Jay Garland	3/7/2016

ord,nrmrl,lrpcd,esmb	ORD-015800	Methods of Oil Detection in Response to the Deepwater Horizon Oil spill	Robyn Conmy	3/15/2016
ord,nrmrl,wswrd,mccb	ORD-015801	Resilience of microbial communities in a simulated drinking water distribution system subjected to disturbances: role of conditionally rare taxa and potential implications for antibiotic-resistant bacteria	Randy Revetta	3/10/2016
ord,nheerl,istd,cb	ORD-015811	SIX1 Oncoprotein as a Biomarker in a Model of Hormonal Carcinogenesis and in Human Endometrial Cancer.	Charles Wood	3/2/2016
ord,nerl,sed	ORD-015817	Does temperature nudging overwhelm aerosol radiative effects in regional integrated climate models?	Kiran Alapaty	3/27/2017

ord,nhsrc,wipd	ORD-015834	The Effect of Malathion on the Activity, Performance, and Microbial Ecology of Activated Sludge- journal	Matthew Magnuson	3/24/2016
ord,nerl,emmd,mieb	ORD-015836	Effect of rice-straw biochar on isomer-specific biodegradation of nonylphenols in isomer-specificity	Jingrang Lu	6/22/2017
ord,nerl,sed	ORD-015839	Characterization and Placement of Wetlands for Integrated Conservation Practice Planning	Yongping Yuan	3/23/2016
ord,ncct,N/A	ORD-015840	(Chemical Research in Toxicology) The ToxCast Chemical Landscape - Paving the Road to 21st Century Toxicology	Ann Richard	4/12/2016

ord,nrmrl,wswrd	ORD-015845	Copper-silver ionization at a US hospital: interaction of treated drinking water with plumbing materials, aesthetics and other considerations	Darren Lytle	5/10/2016
ord,nerl,ced	ORD-015854	Contribution of regional-scale fire events to ozone and PM2.5 air quality estimated by photochemical modeling approaches	Matthew Woody	5/6/2016
ord,nheerl,wed,eeb	ORD-015866	Seasonal patterns of bole water content in old growth Douglas-fir (Pseudotsuga menziesii (Mirb.) Franco)	Peter Beedlow	2/23/2016
ord,nrmrl,std,gcb	ORD-015870	A framework for multi-stakeholder decision-making and conflict resolution	Gerardo Ruiz-Mercado	3/10/2016

ord,nrmrl,std,cpb	ORD-015873	Advancing Sustainable Catalysis with Magnetite Surface Modification and Synthetic Applications	Rajender Varma	4/6/2016
ord,nheerl,ephd	ORD-015875	Proposed Pathophysiologic Framework to Explain Some Excess Cardiovascular Death Associated with Ambient Air Particle Pollution: Insights for Public Health Translation	Wayne Cascio	2/27/2016
ord,nheerl,aed,peb	ORD-015881	Integrating Monitoring and Genetic Methods To Infer Historical Risks of PCBs and DDE to Common and Roseate Terns Nesting Near the New Bedford Harbor Superfund Site (Massachusetts, USA)	Diane Nacci	4/27/2016

ord,nheerl,ephd,eb	ORD-015908	Comparison of gestational dating methods and implications for exposure-outcome associations: an example with PM2.5 and preterm birth	Kristen Rappazzo	3/10/2016
ord,ncea,nceacin,crab	ORD-015914	DISINFECTION BY-PRODUCT EXPOSURES AND THE RISK OF SPECIFIC CARDIAC BIRTH DEFECTS Journal Article	Michael Wright	3/10/2016
ord,nheerl,aed,peb	ORD-015918	Statistical evaluation of biogeochemical variables affecting spatiotemporal distributions of multiple free metal ion concentrationsin an urban estuary	Robert Burgess	3/1/2016
ord,nheerl,istd,cb	ORD-015922	Developing a gene biomarker at the tipping point of adaptive and adverse responses in human bronchial epithelial cells	Brian Chorley	3/15/2016

ord,nerl,sed,efab	ORD-015954	Mineralizing urban net-zero water treatment: Phase II field results and design recommendations	Nichole Brinkman	3/7/2016
ord,nerl,emmd,mieb	ORD-015957	Annual variations and effects of temperature on Legionella spp. and other potential opportunistic pathogens in tap and shower water	Jingrang Lu	10/26/2016
ord,nheerl,tad,dtb	ORD-015964	Engineering stromal-epithelial interactions in vitro for toxicology assessment	Barbara Abbott	3/21/2016
ord,nerl,emmd	ORD-015969	Functionalized Multi-Walled Carbon Nanotube Based Sensors for Distributed Methane LeakDetection	Paul Solomon	2/21/2017

ord,ncct,N/A	ORD-015992	(Green Chemistry) A Probablistic Diagram to Guide Chemical Design with Reduced Potency to Incur Cytotoxicity	Richard Judson	5/23/2016
ord,nrmrl,io	ORD-016005	Connecting Toxicology and Chemistry to Ensure Safer Chemical Design	Nicholas Anastas	3/25/2016
ord,ncea,nceartp, hpag	ORD-016039	A Decision Analysis Framework for Estimating the Potential Hazards for Drinking Water Resources of Chemicals Used in Hydraulic Fracturing Fluids	John Stanek	6/3/2016
ord,nerl,emmd	ORD-016063	Estimating Central Tendency From a Single Spot Measure: A Closed-Form Solution for Lognormally Distributed Biomarker Data for Risk Assessment at the Individual Level	Joachim Pleil	5/25/2016

ord,nerl,sed,ehcab	ORD-016070	Use of Pathogen-Specific Antibody Biomarkers to Estimate Waterborne Infections in Population-Based Settings	Shannon Griffin	6/6/2016
ord,nerl,ced	ORD-016072	Environmental effects of ozone depletion and its interactions with climate change: progress report, 2015	Richard Zepp	5/3/2016
ord,nerl,emmd	ORD-016091	Surfactant-Wrapped Multiwalled Carbon Nanotubes in Aquatic Systems: Surfactant Displacement in the Presence of Humic Acid	Dermont Bouchard	8/19/2016
ord,nheerl,med	ORD-016102	Comparison of trout hepatocytes and liver S9 fractions as in vitro models for predicting hepatic clearance in fish	John Nichols	4/7/2016

ord,nheerl,aed,heb	ORD-016103	Subtidal Benthic Invertebrates Shifting Northward Along the U.S. Atlantic Coast	Stephen Hale	7/8/2016
ord,nheerl,aed,heb	ORD-016108	Sea level rise, drought and the decline of Spartina patens in New England marshes	Cathleen Wigand	3/29/2016
ord,nheerl,aed,heb	ORD-016109	Contrasting Decadal-Scale Changes in Elevation and Vegetation in Two Long Island Sound Salt Marshes	Cathleen Wigand	3/21/2016
ord,nheerl,aed,heb	ORD-016110	Varying Inundation Regimes Differentially Affect Natural and Sand-Amended Marsh Sediments	Cathleen Wigand	6/18/2016
ord,nrmrl,std,gcb	ORD-016126	Development of Chemical Process Design and Control for Sustainability	Gerardo Ruiz-Mercado	4/6/2016
ord,nheerl,rpcs	ORD-016129	Influence of exposure differences on city-to-city heterogeneity in PM2.5-mortality associations in US cities	Lisa Baxter	4/12/2016

ord,ncea,nceacin	ORD-016132	Weighing Evidence and Assessing Uncertainties	Glenn Suter	3/24/2016
ord,nheerl,wed,feb	ORD-016133	Bridge over troubled waters: A Synthesis Session to connect scientific and decision making sectors	Michael Papenfus	4/7/2016
ord,nrmrl,std,seb	ORD-016134	The Role of Law in Adaptive Governance	Ahjond Garmestani	3/22/2016
ord,nheerl,wed,feb	ORD-016136	Basin-Scale Variation in the Spatial Pattern of Fall Movement of Juvenile Coho Salmon in the West Fork Smith River, Oregon	Joe Ebersole	3/21/2016
ord,nheerl,wed,feb	ORD-016137	Valuing instream-related services of wastewater	Matthew Weber	3/18/2016
ord,nerl,emmd	ORD-016155	Actively Heated High-Resolution Fiber-Optic Distributed Temperature Sensing to Quantify Flow Dynamics in Zones of Strong Groundwater Upwelling	D Werkema	12/12/2016

ord,nrmrl,wswrd,mccb	ORD-016157	Ohmic resistance affects microbial community and electrochemical kinetics in a multi-anode microbial electrochemical cell	Mark Rodgers	5/23/2016
ord,nrmrl,wsd,dwsb	ORD-016158	The Roles of Biofilm Conductivity and Donor Substrate Kinetics in a Mixed-Culture Biofilm Anod	Mark Rodgers	5/23/2016
ord,nheerl,aed,heb	ORD-016161	Burrowing and foraging activity of marsh crabs under different inundation regimes	Rick Mckinney	5/31/2016
ord,nerl,emmd,mieb	ORD-016176	Concentration and Quantification of Somatic and F+ Coliphage from Recreational Waters	Brian McMinn	7/12/2017

ord,ncea,nceartp, emag	ORD-016177	A Systematic Review of Cardiovascular Emergency Department Visits, Hospital Admissions and Mortality Associated with Ambient Black Carbon	Tom Luben	5/16/2016
ord,nheerl,med	ORD-016182	Sensitivity and accuracy of high-throughput metabarcoding methods for early detection of invasive fish species	Chelsea Hatzenbuhler	4/12/2016
ord,nerl,emmd	ORD-016183	Breath Biomonitoring in National Security Assessment, Forensic THC Testing, Biomedical Technology and Quality Assurance Applications: Report from PittCon 2016	Joachim Pleil	4/18/2016
ord,nheerl,ced	ORD-016185	Mechanistic modeling of insecticide risks to breeding birds in North American agroecosystems	Matthew Etterson	6/10/2016

ord,nrmrl,appcd,ecpb	ORD-016188	Joint measurements of black carbon and particle mass for heavydutydiesel vehicles using a portable emission measurement system	Richard Baldauf	4/21/2016
ord,nrmrl,aemd	ORD-016194	Characterizing emissions from open burning of military food waste and ration packaging compositions	Brian Gullett	8/11/2016
ord,nheerl,ephd,crb	ORD-016196	Alterations in airway microbiota in patients with PaO2/FiO2 ratio ≤ 300 after burn and inhalation injury	David Diaz-Sanchez	3/23/2016
ord,nheerl,ephd,crb	ORD-016208	A novel approach for measuring residential socioeconomic factors associated with cardiovascular and metabolic health	David Diaz-Sanchez	4/9/2016
ord,nrmrl,std,seb	ORD-016215	The role of trees for urban stormwater management	Matthew Hopton	4/6/2016

ord,nrmrl,std,cpb	ORD-016220	Sustainable pathway to furanics from biomass via heterogeneous organo-catalysis	Rajender Varma	10/27/2016
ord,nrmrl,std,seb	ORD-016225	Balancing stability and flexibility in adaptive governance: an analysis of tools available in U.S. environmental law	Ahjond Garmestani	4/7/2016
ord,nerl,ced	ORD-016226	Development of the crop residue and rangeland burning in the 2014 National Emissions Inventory using information from multiple sources	George Pouliot	3/8/2017
ord,ncct,N/A	ORD-016237	(Environmental Health Perspectives) Prioritizing Environmental Chemicals for Obesity and Diabetes Outcomes Research: A Screening Approach Using ToxCast High Throughput Data	Richard Judson	3/29/2016

ord,nrmrl,std,seb	ORD-016240	Green Net Value Added as a Sustainability Metric Based on Life Cycle Assessment: An Application to Bounty® Paper Towel	Bayou Demeke	4/27/2016
ord,nerl,sed	ORD-016242	Planning for community resilience to future United States domestic water demand	Megan Mehaffey	11/17/2016
ord,nheerl,med	ORD-016247	A depth-adjusted ambient distribution approach for setting numeric removal targets for a Great Lakes Area of Concern beneficial use impairment: Degraded benthos	Theodore Angradi	4/27/2016
ord,nrmrl,gwerd, artsb	ORD-016259	Environmental implications and applications of engineered nanoscale magnetite and its hybrid nanocomposites : A review of recent literature	Chunming Su	7/28/2016

ord,nheerl,ged	ORD-016270	Numerical and Qualitative Contrasts of Two Statistical Models for Water Quality Change in Tidal Waters	Marcus Beck	5/17/2016
ord,nheerl,tad	ORD-016277	A demonstration of the uncertainty in predicting the estrogenic activity of individual chemicals and mixtures from an in vitro estrogen receptor transcriptional activation assay (T47D-KBluc) to the in vivo uterotrophic assay using oral exposure	Earl Gray	5/13/2016
ord,nerl,emmd	ORD-016285	Blood-borne Biomarkers and Bioindicators for Linking Exposure to Health Effects inEnvironmental Health Science	Joachim Pleil	6/1/2016

ord,nerl,ced	ORD-016288	Alternative futures of dissolved inorganic nitrogen export from the Mississippi River Basin: influence of crop management, atmospheric deposition, and population growth	Ellen Cooter	4/6/2016
ord,nheerl,med	ORD-016290	How adverse outcome pathways can aid the development and use of computational prediction models for regulatory toxicology	Dan Villeneuve	4/7/2016
ord,nheerl,aed,heb	ORD-016293	Anthropocene Survival of Southern New England’s Salt Marshes	Cathleen Wigand	4/19/2016
ord,nheerl,aed,peb	ORD-016301	The Challenge: Microplastics in the aquatic environment - Perspectives on the scope of the problem	Robert Burgess	4/4/2016

ord,nrmrl,std,cpb	ORD-016309	Room temperature synthesis of biodiesel using sulfonated graphitic carbon nitride	Rajender Varma	4/6/2016
ord,nerl,sed	ORD-016336	Challenges, developments and perspectives in intermittent river ecology	Ken Fritz	4/15/2016
ord,nheerl,ephd,crb	ORD-016346	Inflammatory Cell signaling following Exposures to Particulate Matter and Ozone	James Samet	5/5/2016
ord,nheerl,aed,peb	ORD-016351	Aggregation, sedimentation, dissolution and bioavailability of quantum dots in estuarine systems.	Kay Ho	8/23/2016
ord,nhsrc,wipd	ORD-016354	Sorbent Materials for Rapid Remediation of Washwater during Radiological Event Relief	Matthew Magnuson	4/28/2016
ord,nerl,emmd	ORD-016358	Coastal Observations from a New Vantage Point: The NASA GEO-CAPE Ocean Mission	Blake Schaeffer	12/13/2016

ord,nheerl,wed,eeb	ORD-016359	Phosphorus retention in stormwater control structures across streamflow in urban and suburban watersheds	Paul Mayer	5/24/2016
ord,nerl,emmd	ORD-016364	The Bioaccessibility of Polychlorinated Biphenyls (PCBs) and Polychlorinated Dibenzo-P-Dioxins/Furans (PCDD/Fs) in Cooked Plant and Animal Origin Foods	James Starr	5/18/2016
ord,nrmrl,wsd	ORD-016366	Role of Biofilm in Disinfection Byproduct Formation in Drinking Water Distribution Systems - A Reactive Transport Model - journal article	Jeff Yang	6/8/2016
ord,nheerl,aed,heb	ORD-016374	Contributions of organic and inorganic matter to sediment volume and accretion in tidal wetlands at steady state	Cathleen Wigand	4/18/2016

ord,nrmrl,wswrd,tteb	ORD-016375	Regeneration of a Full-Scale Arsenic Removal Adsorptive Media System,Part 1: The Regeneration Process	Thomas Sorg	6/8/2016
ord,nrmrl,std,seb	ORD-016378	News: Synthetic biology leading to specialty chemicals	John Glaser	4/27/2016
ord,nheerl,ephd,crb	ORD-016385	Efffect of Aeroallergen Sensitization on Asthma Control in African-American Teens with Persistent Asthma	David Diaz-Sanchez	4/19/2016
ord,nerl,sed	ORD-016394	Exploring Global Exposure Factors Resources for Use in Consumer Exposure Assessments	Peter Egeghy	4/12/2016
ord,nheerl,istd,cb	ORD-016403	Dose-Response Analysis of RNA-Seq Profiles in Archival Formalin-Fixed Paraffin-Embedded (FFPE) Samples.	Charles Wood	5/12/2016

ord,nerl,emmd	ORD-016419	Assessing the Impact of Anthropogenic Pollution on Isoprene-Derived Secondary OrganicAerosol Formation in PM2.5 Collected from the Birmingham, Alabama Ground Site During the 2013 Southern Oxidant and Aerosol Study	John Offenberg	2/7/2017
ord,nrmrl,std,cpb	ORD-016421	Interaction of engineered nanomaterials with hydrophobic organic pollutants.	Endalkachew Sahle-Demessie	5/20/2016
ord,nerl,emmd	ORD-016436	Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Dinking Water: Linked to Industrial Sites, Military fire Training Areas and Wastewater Treatment Plants	Andrew Lindstrom	8/26/2016

ord,nrmrl,wswrd,tteb	ORD-016438	Regeneration of a Full-Scale Arsenic Removal Adsorptive Media System,Part 2: The Performance and Cost	Thomas Sorg	6/7/2016
ord,nheerl,wed,eeb	ORD-016447	A likelihood-based time series modeling approach for application in dendrochronology to examine the growth-climate relations and forest disturbance history	EHenry Lee	4/18/2016
ord,nerl,sed,ehcab	ORD-016449	Changes in Landscape Greenness and Climatic Factors over 25 Years (1989–2013) in the USA	Maliha Nash	12/5/2016
ord,nrmrl,appcd,iemb	ORD-016451	Particulate polycyclic aromatic hydrocarbon emissions from burning kerosene, liquid petroleum gas, and wood fuels in household cookstoves	Jim Jetter	6/14/2016

ord,nheerl,wed,feb	ORD-016470	Intermittent Surface Water Connectivity: Fill and Spill vs. Fill and Merge Dynamics	Scott Leibowitz	5/3/2016
ord,nerl,emmd,mieb	ORD-016482	Towards Universal Screening for Toxoplasmosis: Rapid, Cost-effective and Simultaneous Detection of Toxoplasma Anti-IgG, IgM and IgA Antibodies Using Very Small Serum Volumes	Swinburne Augustine	5/4/2016
ord,nheerl,med	ORD-016485	The Great Lakes Hydrography Dataset: Consistent, binational watersheds for the Laurentian Great Lakes Basin	Tom Hollenhorst	11/7/2016
ord,nerl,sed,eib	ORD-016486	Enhancing protection for vulnerable waters	Charles Lane	4/22/2016

ord,ncct,N/A	ORD-016488	(Environment International) Refining high-throughput prioritization of environmental chemicals to include inter-individual variability across subpopulations	John Wambaugh	2/28/2017
ord,nrmrl,wsd	ORD-016496	Analysis of human mitochondrial DNA sequences from fecally polluted environmental waters as a tool to study population diversity	Jorge Santodomingo	8/17/2016
ord,nrmrl,wswrd, wqmb	ORD-016498	Clades of Candidatus Accumulibacter phosphatis enriched under cyclic anaerobic and microaerobic conditions simultaneously use different electron acceptors	Jorge Santodomingo	9/28/2016

ord,ncct,N/A	ORD-016499	(ENVIRONMENT INTERNATIONAL) From the exposome to mechanistic understanding of chemical-induced adverse effects	John Wambaugh	5/4/2016
ord,nrmrl,gwerd,srb	ORD-016507	Potential Aquifer Vulnerability in Regions Down-Gradient from Uranium In Situ Recovery (ISR) Sites	Rick Wilkin	8/24/2016
ord,nerl,sed	ORD-016510	Pyrethroid insecticides and their environmental degradates in repeated duplicate-diet solid food samples of 50 adults	Marsha Morgan	5/10/2016
ord,nrmrl,wswrd,wqmb	ORD-016518	Corexit 9500 Enhances Oil Biodegradation and Changes Active Bacterial Community Structure of Oil-Enriched Microcosms	Jorge Santodomingo	9/30/2016

ord,nerl,emmd	ORD-016519	Ubiquitous Low-cost Functionalized Multi-Walled Carbon Nanotube Sensors for Distributed Methane Leak Detection	Paul Solomon	5/23/2016
ord,nheerl,aed,peb	ORD-016520	Adaptive Significance of ERα Splice Variants in Killifish (Fundulus heteroclitus) Resident in an Estrogenic Environment	Diane Nacci	4/28/2016
ord,nrmrl,wsd,dwsb	ORD-016523	Evaluating UV-C LED disinfection performance and investigating potential dual-wavelength synergy	Hodon Ryu	7/8/2016
ord,nheerl,ged	ORD-016529	Impact of Satellite Remote Sensing Data on Simulations of Coastal Circulation and Hypoxia on the Louisiana Continental Shelf	John Lehrter	4/27/2016

ord,nheerl,ephd,crb	ORD-016532	Dietary and Pharmacological Intervention to Mitigate the Cardiopulmonary Effects of Air Pollution Toxicity	Haiyan Tong	5/9/2016
ord,nheerl,ged	ORD-016549	Storms do not alter long-term watershed development influences on coastal water quality	John Lehrter	5/2/2016
ord,nheerl,istd,pb	ORD-016554	Role of complex organic arsenicals in food in aggregate exposure to arsenic	David Thomas	5/24/2016
ord,nerl,emmd	ORD-016555	Perspective: Crowd-based breath analysis: assessing behavior, activity, exposures, and emotional response of people in groups	Joachim Pleil	5/26/2016

ord,nheerl,tad,etb	ORD-016557	Thyroid Hormone-Dependent Formation of a Subcortical Band Heterotopia (SBH) in the Neonatal Brain is not Exacerbated Under Conditions of Low Dietary Iron (FeD)	Mary Gilbert	5/5/2016
ord,nheerl,N/A	ORD-016577	Developmental Exposure to an Environmental PCB Mixture Delays the Propagation of Kindling in the Amygdala	Mary Gilbert	6/2/2016
ord,nheerl,ephd,eb	ORD-016580	Additive interaction between heterogeneous environmental quality domains (air, water, land, sociodemographic and built environment) on preterm birth	Danelle Lobdell	6/8/2016

ord,nheerl,ged	ORD-016584	Residues of organochlorine pesticides in surface soil and raw foods from rural areas of the Republic of Tajikistan	Mace Barron	5/2/2016
ord,nerl,sed,eib	ORD-016586	Factors Influencing Farmers’ Adoption of Best Management Practices: A Review and Synthesis	Randy Bruins	5/24/2016
ord,ncct,N/A	ORD-016588	(Archives of Toxicology) Recommended approaches in the application of toxicogenomics to derive points of departure for chemical risk assessment	Russell Thomas	5/20/2016
ord,nheerl,ephd,eb	ORD-016589	Exposure to human-associated fecal indicators and self-reported illness among swimmers at recreational beaches: A cohort study	Tim Wade	6/2/2016

ord,nerl,ced	ORD-016595	Multiscale predictions of aviation-attributable PM2.5 for U.S. airports modeled using CMAQ with plume-in-grid and an aircraft-specific 1-D emission model	Matthew Woody	5/31/2016
ord,nhsrc,dcmd	ORD-016610	A Simple Decontaminatio n Approach Using Hydrogen Peroxide Vapor for Bacillus anthracis Spore Inactivation	Joe Wood	6/13/2016
ord,nrmrl,wswrd, uwmb	ORD-016615	Watershed Land Use and Seasonal Variation Constrain the Influence of Riparian Canopy Cover on Stream Ecosystem Metabolism	Jake Beaulieu	8/5/2016
ord,nheerl,tad,rtb	ORD-016617	Uncertainties in biological responses that influence hazard and risk approaches to the regulation of endocrine active substances	Earl Gray	5/18/2016

ord,nerl,sed	ORD-016620	Development of a Conceptual Framework Depicting a Childs Total (Built, Natural, Social) Environment in Order to Optimize Health and Well-Being	Nicolle Tulve	10/14/2016
ord,nerl,emmd,mieb	ORD-016626	Human virus and microbial indicator occurrence in public-supply groundwater systems: meta-analysis of international studies	Shay Fout	2/15/2017
ord,nerl,emmd	ORD-016627	QQ-plots for assessing distributions of biomarker measurements and generating defensible summary statistics	Joachim Pleil	6/29/2016
ord,nerl,rpdis	ORD-016631	Inhibition of the Human ABC Efflux Transporters P-gp and BCRP by the BDE-47 Hydroxylated Metabolite 6-OH-BDE-47: Considerations for Human Exposure	John Kenneke	7/11/2016

ord,nheerl,ephd,crb	ORD-016638	Ultrafine Particulate Matter Exposure Impairs Vasorelaxant Response in Superoxide Dismutase 2 Deficient Murine Aortic Rings	Haiyan Tong	5/13/2016
ord,nerl,emmd	ORD-016640	Nitrogen dioxide observations from the Geostationary Trace gas and Aerosol Sensor Optimization (GeoTASO) airborne instrument: Retrieval algorithm and measurements during DISCOVER-AQ Texas 2013	Jim Szykman	7/11/2016
ord,nrmrl,lmmd,mmb	ORD-016646	Effects of source and seasonal variations of natural organic matters on the fate and transport of CeO2 nanoparticles in the environment	Endalkachew Sahle-Demessie	5/17/2016

ord,nrmrl,std,seb	ORD-016648	Understanding and applying principles of social cognition and decision making in adaptive environmental governance	Ahjond Garmestani	6/9/2016
ord,nrmrl,std,seb	ORD-016651	Legal and Institutional Foundations of Adaptive Environmental Governance	Ahjond Garmestani	5/11/2016
ord,nerl,rpdis	ORD-016660	The influence of incubation time on adenovirus quantitation in A549 cells by most probable number	Jennifer Cashdollar	7/11/2016
ord,nrmrl,std,cpb	ORD-016690	Aerobic oxidation of alcohols in visible light on Pd-grafted Ti cluster	Rajender Varma	5/17/2016
ord,ncct,N/A	ORD-016691	(BIOINFORMATICS) tcpl: The ToxCast Pipeline for High-Throughput Screening Data	Matt Martin	6/20/2016

ord,nheerl,aed,mab	ORD-016698	Can Better Accounting and Finance Methods Chart a Path toward a More Sustainable World System?	Dan Campbell	5/27/2016
ord,nheerl,wed,eeb	ORD-016701	The role of stable isotopes in understanding rainfall interception processes: a review	Reneej Brooks	5/12/2016
ord,nheerl,ephd,cib	ORD-016711	Systemic Metabolic Derangement, Pulmonary Effects, and Insulin Insufficiency following subchronic ozone exposure in rats	Urmila Kodavanti	5/26/2016
ord,nerl,ced	ORD-016716	Informing the Human Plasma Protein Binding of Environmental Chemicals by Machine Learning in the Pharmaceutical Space: Applicability Domain and Limits of Predictability	Brandall Ingle	5/24/2016

ord,nheerl,ephd,crb	ORD-016717	Short-term effects of air temperature on plasma metabolite concentrations in patients undergoing cardiac cattheterization.	David Diaz-Sanchez	6/1/2016
ord,nerl,emmd	ORD-016723	Detection and Quantification of Silver Nanoparticles at Environmentally Relevant Concentrations Using Asymmetric Flow Field–Flow Fractionation Online with Single Particle Inductively Coupled Plasma Mass Spectrometry	Ed Heithmar	5/26/2016
ord,nerl,emmd	ORD-016761	Evaluation and Comparison of Methods for Measuring Ozone and NO2 Concentrations in Ambient Air during DISCOVER-AQ	Andrew Whitehill	7/5/2016

ord,nheerl,ephd,eb	ORD-016770	Association of land use and its change with beach closure in the United States, 2004-2013	Jianyong Wu	5/24/2016
ord,nheerl,ged	ORD-016779	Attributes of Successful Actions to Restore Lakes and Estuaries Degraded by Nutrient Pollution-	Jim Hagy	6/29/2016
ord,nheerl,istd,pb	ORD-016796	The impact of variation in scaling factors on the estimation of internal dose metrics: a case study using bromodichloro methane (BDCM).1	Elaina Kenyon	7/19/2016
ord,nerl,emmd	ORD-016798	Combustion-Related Organic Species in Temporally Resolved Urban Airborne Particulate Matter	Matthew Landis	5/15/2017

ord,nheerl,med,esab	ORD-016806	Functional toxicogenomic assessment of triclosan in human HepG2 cells using genome-wide CRISPR-Cas9 screen	Dan Villeneuve	6/9/2016
ord,nheerl,med	ORD-016811	Toxicogenomic assessment of 6-OH-BDE47 induced developmental toxicity in chicken embryo	Dan Villeneuve	6/9/2016
ord,nheerl,istd,sbb	ORD-016816	Editor's highlight: Evaluation of a Microelectrode Array-based Assay for Neural Network Ontogeny using Training Set Chemicals	Tim Shafer	6/15/2016

ord,ncct,N/A	ORD-016848	(Toxicology) Identifying Environmental Chemicals as Agonists of the Androgen Receptor by Applying a Quantitative High-throughput Screening Platform	Keith Houck	2/28/2017
ord,nheerl,ged	ORD-016853	Quantifying seagrass light requirements using an algorithm to spatially resolve depth of colonization_	Marcus Beck	7/22/2016
ord,nerl,ced	ORD-016867	Near-road enhancement and solubility of fine and coarse particulate matter trace elements near a major interstate in Detroit, Michigan	Janet Burke	9/26/2016
ord,nheerl,ephd,crb	ORD-016869	A paler shade of green? The toxicology of biodiesel emissions: recent findings from studies with this alternative fuel	Michael Madden	5/27/2016

ord,nerl,ced	ORD-016876	A simple lightning assimilation technique for improving retrospective WRF simulations.	Nicholas Heath	6/10/2016
ord,nheerl,tad,dtb	ORD-016877	The role of hepatocyte nuclear factor 4-alpha in perfluorooctanoic and perfluorooctane sulfonic acid-induced hepatocellular dysfunction	Christopher Lau	6/9/2016
ord,nerl,sed	ORD-016889	The effectiveness of Light Rail transit in achieving regional CO2 emissions targets is linked to building energy use: insights from system dynamics modeling	Rochelle Araujo	4/11/2017
ord,nerl,sed,ehcab	ORD-016890	An inventory of continental U.S. terrestrial candidate ecological restoration areas based on landscape context	James Wickham	2/27/2017

ord,nrmrl,gwerd,srb	ORD-016919	Evidence of sulfate-dependent anaerobic methane oxidation within an area impacted by coalbed methane-related gas migration	Rick Wilkin	11/10/2016
ord,nerl,sed,iemb	ORD-016922	Air Pollution Control and Waste Management	Daniel Vallero	6/27/2016
ord,nerl,emmd	ORD-016932	Atmospheric Mercury Concentrations Observed at Ground-Based Monitoring Sites Globally Distributed in the Framework of the GMOS Network	Matthew Landis	2/7/2017
ord,nerl,emmd	ORD-016944	Measurement of pyrethroids and their environmental degradation products in fresh fruits and vegetables using a modification of the quick easy cheap effective rugged safe (QuEChERS) method	James Starr	6/1/2016

ord,nheerl,wed,eeb	ORD-016948	Cross-scale interactions affect tree growth and intrinsic water use efficiency and highlight the importance of spatial context in managing forests under global change	Reneej Brooks	6/8/2016
ord,nrmrl,wswrd	ORD-016959	Differential Decomposition of Bacterial and Viral Fecal Indicators in Common Human Pollution Types	Orin Shanks	7/19/2016
ord,nrmrl,wsd	ORD-016978	Integrating Land Use and Socioeconomic Factors into Scenario-Based Travel Demand and Carbon Emission Impact Study	Jeff Yang	8/25/2016

ord,ncea,nceacin, crab	ORD-016980	A METHOD TO ASSESS THE CONTRIBUTION OF COMPONENTS TO THE TOXICITY OF COMPLEX MIXTURES: ASSESSMENT OF PUBERTY ACQUISITION IN RATS EXPOSED TO DISINFECTION BYPRODUCTS	Glenn Rice	1/27/2017
ord,nheerl,istd,gctb	ORD-017004	Mutagenicity and Oxidative Damage Induced by an Organic Extract of the Particulate Emissions from a Simulation of the Deepwater Horizon Surface Oil Burns	David DeMarini	10/13/2016
ord,nrmrl,lrpcd,wmb	ORD-017029	Nanosilver as a disinfectant in dental unit waterlines: Assessment of the physiochemical transformations of the AgNPs	Souhail Al-Abed	8/18/2016

ord,nhsrc,tcad	ORD-017045	Optimization of a Sample Processing Protocol for Recovery of Bacillus anthracis Spores from Soil [HS7.52.02 - 514]	Erin Silvestri	6/30/2016
ord,nerl,sed,efab	ORD-017046	Statistical Survey of Persistent Organic Pollutants: Risk Estimations to Humans and Wildlife through Consumption of Fish from U.S. Rivers	Angela Batt	10/10/2016
ord,nrmrl,wsd	ORD-017061	Assessment of variation in microbial community amplicon sequencing by the Microbiome Quality Control (MBQC) project consortium	Orin Shanks	9/27/2016
ord,ioaa,N/A	ORD-017069	Rethinking Environmental Protection: Meeting the Challenges of a Changing World	Kathleen Deener	6/9/2016

ord,nrmrl,appcd	ORD-017073	Characterization of Emissions and Residues from Simulations of the Deepwater Horizon Surface Oil Burns	Brian Gullett	1/23/2017
ord,nerl,ced	ORD-017074	Enhanced representation of soil NO emissions in the Community Multiscale Air Quality (CMAQ) model version 5.0.2	Ellen Cooter	8/8/2016
ord,nerl,emmd,encb	ORD-017085	Novel contaminants identified in fish kills in the Red River watershed, 2011–2013	Tammy Jones-Lepp	9/21/2017
ord,nheerl,tad,etb	ORD-017106	Adult Hippocampal Neurogenesis is Impaired by Transient and Moderate Developmental Thyroid Hormone Disruption	Mary Gilbert	8/25/2016

ord,nheerl,med	ORD-017107	Current limitations and recommendations to improve testing for the environmental assessment of endocrine active substances	Gerald Ankley	8/16/2016
ord,nheerl,med	ORD-017110	Recommended approaches to the scientific evaluation of environmental hazards and risks of endocrine-active substances	Gerald Ankley	8/16/2016
ord,ncea,nceacin, crab	ORD-017113	Swine exposure and methicillin-resistant Staphylococcus aureus infection and colonization among hospitalized patients with skin and soft tissue infections in Illinois: a ZIP code level analysis	Michael Wright	2/13/2017

ord,nerl,emmd	ORD-017120	Complex conductivity response to silver nanoparticles in partially saturated sand columns	D Werkema	2/7/2017
ord,nheerl,ephd,eb	ORD-017121	Coliphages and gastrointestinal illness in recreational waters: pooled analysis of six coastal beach cohorts	Tim Wade	7/27/2016
ord,nheerl,ephd,eb	ORD-017126	Is human fecundity changing? A discussion of research and data gaps precluding us from having an answer.	Danelle Lobdell	6/16/2016
ord,nheerl,med	ORD-017129	Avoiding false positives and optimizing identification of true negatives in estrogen receptor binding and agonist/antagonist assays	Michael Hornung	8/8/2016

ord,nheerl,ged	ORD-017137	Representing causal knowledge in environmental policy interventions: Advantages and opportunities for qualitative influence diagram applications	William Benson	7/27/2016
ord,nerl,ced	ORD-017143	Insights into the deterministic skill of air quality ensembles from the analysis of AQMEII data	Christian Hogrefe	6/21/2016
ord,nrmrl,aemd,dsbb	ORD-017154	Near-Port Air Quality Assessment Utilizing a Mobile Monitoring Approach	Jonathan Steffens	9/22/2016
ord,nrmrl,lrpcd,wmb	ORD-017171	Alterations of lead speciation by sulfate from addition of flue gas desulfurization gypsum (FGDG) in two contaminated soils	Souhail Al-Abed	9/30/2016

ord,nheerl,ephd,cib	ORD-017203	Chemical Composition and Source Apportionment of Size Fractionated Particulate Matter in Cleveland, Ohio, USA	Ian Gilmour	6/22/2016
ord,nheerl,ged	ORD-017213	Bayesian networks improve causal environmental assessments for evidence-based policy	Mace Barron	6/22/2016
ord,nheerl,wed,eeb	ORD-017216	Human-accelerated weathering increases salinization, major ions, and alkalinization in fresh water across land use	Paul Mayer	7/14/2016
ord,nerl,ced	ORD-017217	A photosynthesis-based two-leaf canopy stomatal conductance model for meteorology and air quality modeling with WRF/CMAQ PX LSM	Limei Ran	8/8/2016
ord,nerl,emmd	ORD-017222	Breath Biomarkers in Toxicology	Joachim Pleil	10/26/2016

ord,nrmrl,std,seb	ORD-017224	Avoiding Decline: Fostering Resilience and Sustainability in Midsize Cities	Ahjond Garmestani	7/13/2016
ord,nrmrl,std,seb	ORD-017234	Panarchy use in environmental science for risk and resilience planning	Ahjond Garmestani	7/5/2016
ord,nrmrl,appcd,apb	ORD-017241	Using satellite-based measurements to explore spatiotemporal scales and variability of drivers of new particle formation	Johnt Walker	7/27/2016
ord,nerl,ced	ORD-017242	A Reduced Form Model for Ozone Based on Two Decades of CMAQ Simulations for the Continental United States	Christian Hogrefe	9/20/2016

ord,nheerl,aed,heb	ORD-017250	BOOK REVIEW: OPENING SCIENCE, THE EVOLVING GUIDE ON HOW THE INTERNET IS CHANGING RESEARCH, COLLABORATION, AND SCHOLARLY PUBLISHING	Walter Berry	7/6/2016
ord,nheerl,med	ORD-017261	A study of temporal effects of the model anti-androgen flutamide on components of the hypothalamic-pituitary-gonadal axis in adult fathead minnows	Gerald Ankley	7/22/2016
ord,nerl,emmd	ORD-017266	Characteristics and distributions of atmospheric mercury emitted from anthropogenic sources in Guiyang, southwestern China	Matthew Landis	7/12/2016
ord,nheerl,aed,wdb	ORD-017268	Modeling Water Clarity and Light Quality in Oceans	Mohamed Abdelrhman	7/15/2016

ord,nerl,ced	ORD-017272	Chemical transport model simulations of organic aerosol in southern California: model evaluation and gasoline and diesel source contributions	Matthew Woody	8/9/2016
ord,nhsrc,dcmd	ORD-017288	Review of Emerging Membranes for Potable Water Reuse - Materials Section	Anne Mikelonis	9/21/2016
ord,nerl,ced	ORD-017289	Assessing Exposure to Household Air Pollution: A Systematic Review and Pooled Analysis of Carbon Monoxide as a Surrogate Measure of Particulate Matter	Kathie Dionisio	7/1/2016
ord,nheerl,ephd,crb	ORD-017292	Asthma as a disruption in iron homeostasis	Andy Ghio	8/1/2016

ord,nerl,ced	ORD-017300	Evaluation and development of tools to quantify the impacts of roadside vegetation barriers on near-road air quality.	Vlad Isakov	5/9/2017
ord,ncct,N/A	ORD-017304	(Toxicological Sciences) FutureTox III: Bridges for Translation	Thomas Knudsen	7/7/2016
ord,nerl,ced	ORD-017311	Dermal permeation data and models for the prioritization and screening-level exposure assessment of organic chemicals	Peter Egeghy	7/12/2016
ord,nrmrl,std,sab	ORD-017314	Using Fisher information to track stability in multivariate systems	Tarsha Eason	7/25/2016
ord,nrmrl,std,sab	ORD-017315	Detecting spatial regimes in ecosystems	Tarsha Eason	7/18/2016

ord,nrmrl,wsd	ORD-017339	Occurrence of host-associated fecal markers on child hands, household soil, and drinking water in rural Bangladeshi households	Orin Shanks	8/15/2016
ord,nrmrl,std,cpb	ORD-017347	Titanium-based zeolitic imidazolate framework for chemical fixation of carbon dioxide	Rajender Varma	7/25/2016
ord,nrmrl,lrpcd,wmb	ORD-017350	Soil solution interactions may limit Pb remediation using P amendments in an urban soil	Kirk Scheckel	10/14/2016
ord,nheerl,aed,peb	ORD-017357	Temporal and spatial behavior of pharmaceuticals in Narragansett Bay, Rhode Island, United States.	Mark Cantwell	8/23/2016

ord,nheerl,ged	ORD-017368	A Bayesian network model for predicting aquatic toxicity mode of action using two dimensional theoretical molecular descriptors	Mace Barron	7/18/2016
ord,nerl,ced	ORD-017370	Reduction of air pollution levels downwind of a road with an upwind noise barrier	David Heist	3/2/2017
ord,nerl,ced	ORD-017372	Laboratory simulations of the atmospheric mixed-layer in flow over complex topography	Steven Perry	8/9/2016
ord,nheerl,med	ORD-017374	The acute toxicity of major ion salts to Ceriodaphnia dubia. II. Empirical relationships in binary salt mixtures	Russell Erickson	11/28/2016

ord,nheerl,med	ORD-017375	Alternative approaches for vertebrate ecotoxicity tests in the 21st century: A review of developments over the last 2 decades and current status	Teresa Norberg-King	8/24/2016
ord,nerl,ced,amdbr	ORD-017379	On the influence of viaduct and ground heating on pollutant dispersion in 2D street canyons and toward single-sided ventilated buildings	David-C Wong	7/27/2016
ord,nheerl,wed,feb	ORD-017386	Partitioning taxonomic diversity of aquatic insect assemblages and functional feeding groups in Neotropical Savanna headwater streams	Phil Kaufmann	8/12/2016
ord,nerl,sed,ehcab	ORD-017388	Thematic Accuracy Assessment of the 2011 National Land Cover Database (NLCD)	James Wickham	11/29/2016

ord,nrmrl,std,cpb	ORD-017390	Greener and Sustainable Trends in Synthesis of Organics and Nanomaterials	Rajender Varma	8/12/2016
ord,nerl,emmd	ORD-017400	Temporary vs. Permanent Sub-slab Ports: A Comparative Performance Study	JohnH Zimmerman	5/3/2017
ord,ncct,N/A	ORD-017401	(DRUG DISCOVERY TODAY) Towards a 21st century roadmap for biomedical research and drug discovery: Consensus report and recommendations	Kevin Crofton	8/3/2016
ord,nrmrl,lrpcd	ORD-017416	An Ultra-Sensitive Method for the Analysis of Perfluorinated Alkyl Acids in Drinking Water using a Column Switching High-Performance Liquid Chromatography Tandem Mass Spectrometry	Marc Mills	10/11/2016

ord,nerl,emmd	ORD-017432	Sea surface temperature variation linked to elemental mercury concentrations measured on Mauna Loa	Matthew Landis	7/18/2016
ord,nrmrl,appcd	ORD-017434	Emissions from prescribed burning of timber slash piles in Oregon.	Brian Gullett	8/15/2016
ord,nerl,ced	ORD-017436	Highlights from the Coordinating Research Council’s 2016 Air Quality Research Needs Workshop: Top 11 Research Needs	Rohit Mathur	7/28/2016
ord,nrmrl,lrpcd,wmb	ORD-017448	Mechanisms and Effectivity of Sulfate Reducing Bioreactors using a Chitinous Substrate in Treating Mining Influenced Water	Souhail Al-Abed	10/14/2016

ord,nrmrl,appcd	ORD-017453	A small, lightweight multipollutant sensor system for ground-mobile and aerial emission sampling from open area sources	Brian Gullett	8/15/2016
ord,nerl,emmd	ORD-017468	Imputing Defensible Values for Left-Censored "Below Level of Quantitation” (LoQ) Biomarker Measurements	Joachim Pleil	9/1/2016
ord,nrmrl,gwerd,artsb	ORD-017498	Release and toxicity comparison between industrial- and sunscreen-derived nano-ZnO particles	Chunming Su	8/19/2016
ord,nheerl,ephd,eb	ORD-017504	A Genome-wide Trans-ethnic Interaction Study Links the PIGR-FCAMR Locus to Coronary Atherosclerosis Via Interactions Between Genetic Variants and Residential Exposure to Traffic	Robert Devlin	7/28/2016

ord,nerl,ced	ORD-017507	The Impact of Iodide-Mediated Ozone Deposition and Halogen Chemistry on Surface Ozone Concentrations Across the Continental United States	Golam Sarwar	2/22/2017
ord,nerl,emmd	ORD-017509	Biomarker analysis of liver cells exposed to surfactant-wrapped and oxidized multi-walled carbon nanotubes (MWCNTs)	Matt Henderson	7/22/2016
ord,nheerl,ged	ORD-017511	Novel Analyses of Long-Term Data Provide a Scientific Basis for Chlorophyll-a Thresholds in San Francisco Bay	Jim Hagy	8/8/2016
ord,nerl,emmd	ORD-017526	Predicted phototoxicities of carbon nano-material by quantum mechanical calculations	Don Betowski	4/27/2017

ord,nheerl,aed,wdb	ORD-017527	Biogeography of dinoflagellate cysts in northwest Atlantic estuaries	Jim Latimer	8/3/2016
ord,ncea,nceartp	ORD-017530	Long-Term Simulated Atmospheric Nitrogen Deposition Alters Leaf and Fine Root Decomposition	Alan Talhelm	10/7/2016
ord,nerl,emmd	ORD-017560	NanoRelease: Pilot interlaboratory comparison of a weathering protocol applied to resilient and labile polymers with and without embedded carbon nanotubes	Richard Zepp	2/7/2017
ord,nheerl,ephd,cib	ORD-017572	Early-Life Persistent Vitamin D Deficiency Alters Cardiopulmonary Responses to Particulate Matter-Enhanced Atmospheric Smog in Adult Mice	Mehdi Hazari	10/11/2016

ord,nrmrl,lrpcd,wmb	ORD-017576	Water-level fluctuations influence sediment porewater chemistry and methylmercury production in a flood-control reservoir.	Todd Luxton	12/12/2016
ord,nerl,ced	ORD-017579	Biomarker analysis of American toad (Anaxyrus americanus) and grey tree frog (Hyla versicolor) tadpoles following exposure to atrazine.	Tom Purucker	8/2/2016
ord,nerl,emmd	ORD-017581	Identification of Biomarkers of Exposure to FTOHs and PAPs in Humans Using a Targeted and Non-targeted Analysis Approach	Mark Strynar	10/4/2016
ord,nerl,emmd,ieib	ORD-017584	Estimating virus occurrence using Bayesian modeling in multiple drinking water systems of the United States	Eunice Varughese	8/10/2017

ord,nheerl,istd,pb	ORD-017587	The biological fate of decabromodiphenyl ethane following oral, dermal or intravenous administration	MichaelF Hughes	10/7/2016
ord,nhsrc,wipd	ORD-017617	Inactivation of Bacillus Spores in Wash Waters Using Dilute Chlorine Bleach Solutions at Different Temperatures and pH Levels	Vincente Gallardo	9/6/2016
ord,nerl,ced	ORD-017622	Evaluation and error apportionment of an ensemble of atmospheric chemistry transport modeling systems: multivariable temporal and spatial breakdown	Christian Hogrefe	8/19/2016
ord,nrmrl,std,cpb	ORD-017628	Sustainable hybrid photocatalysts: titania immobilized on carbon materials derived from renewable and biodegradable resources	Rajender Varma	8/17/2016

ord,nheerl,aed,mab	ORD-017635	The Application and Usefulness of Economic Analyses for Water Quality Management in Coastal Areas	Marisa Mazzotta	11/16/2016
ord,nheerl,tad,rtb	ORD-017673	Cumulative effects of antiandrogenic chemical mixtures and their relevance to human health risk assessment	Earl Gray	8/9/2016
ord,nerl,ced	ORD-017699	On the implications of aerosol liquid water and phase separation for organic aerosol mass	Havala Pye	8/9/2016
ord,nrmrl,lrpcd,wmb	ORD-017701	Decision Support for Environmental Management of Industrial Non-Hazardous Secondary Materials: New Analytical Methods Combined with Simulation and Optimization Modeling	Souhail Al-Abed	9/26/2016

ord,nerl,sed,efab	ORD-017709	Simulation of enteric pathogen concentrations in locally-collected greywater and wastewater for microbial risk assessments	Jay Garland	8/29/2016
ord,nerl,sed	ORD-017715	An overview of the model integration process: From pre-integration assessment to testing	Gerry Laniak	8/23/2016
ord,nheerl,ged	ORD-017734	Satellite observation of particulate organic carbon dynamics in two river-dominated estuaries	John Lehrter	8/22/2016
ord,nrmrl,std,sab	ORD-017749	Understanding the LCA and ISO water footprint: A response to Hoekstra (2016) “A critique on the water-scarcity weighted water footprint in LCA”	Andrew Henderson	9/23/2016

ord,nerl,emmd	ORD-017752	Sample integrity evaluation and EPA Method 325B interlaboratory comparison for select volatile organic compounds collected diffusively on Carbopack X sorbent tubes	Shaibal Mukerjee	5/25/2017
ord,nheerl,ephd,eb	ORD-017756	Validity of Self-Reported Concentration and Memory Problems: Relationship with Neuropsychological Assessment and Depression	Danelle Lobdell	9/13/2016
ord,nheerl,wed,feb	ORD-017767	Rivers and Streams in the Media: Evaluating New Sources for Ecosystem Services Content	Matthew Weber	8/19/2016

ord,nheerl,tad,nb	ORD-017778	Locomotor activity and tissue levels following acute administration of lambda- and gamma-cyhalothrin in rats	Ginger Moser	8/22/2016
ord,nrmrl,wswrd,uwmb	ORD-017798	Influence of urban infrastructure on water quality and greenhouse gas dynamics in streams	Jake Beaulieu	2/2/2017
ord,nerl,sed,eib	ORD-017804	IRBAS: An online database to collate, analyze, and synthesize data on the biodiversity and ecology of intermittent rivers worldwide	Ken Fritz	9/11/2016
ord,nheerl,wed,feb	ORD-017808	Assessing the accuracy and stability of variable selection methods for random forest modeling in ecology	Scott Leibowitz	8/24/2016

ord,nrmrl,aemd,ensb	ORD-017845	Effects of recent energy system changes on CO2 projections for the United States	Carol Lenox	11/23/2016
ord,nheerl,tad	ORD-017849	A DEVICE THAT ALLOWS RODENTS TO BEHAVIORALLY THERMOREGULATE WHEN HOUSED IN VIVARIUMS	Christopher Gordon	8/22/2016
ord,nrmrl,lrpcd,wmb	ORD-017850	Quantification of Carbon Nanotubes in Different Environmental Matrices by a Microwave Induced Heating Method	Souhail Al-Abed	10/14/2016
ord,nrmrl,lrpcd,wmb	ORD-017859	Metals contamination in environmental media in residential areas around Romanian mining sites	John McKernan	11/30/2016
ord,nheerl,ephd,crb	ORD-017860	Heme oxygenase activity increases after exercise in healthy volunteers	Andy Ghio	9/30/2016

ord,nheerl,med	ORD-017864	A synoptic survey of microbial respiration, organic matter decomposition, and carbon efflux in U.S. streams and rivers	Brian Hill	9/12/2016
ord,nerl,sed,efab	ORD-017866	Risk-based enteric pathogen reduction targets for non-potable and direct potable use of roof runoff, stormwater, and greywater	Jay Garland	9/7/2016
ord,nrmrl,wsd	ORD-017871	GIFMod: A Flexible Modeling Framework For Hydraulic and Water Quality Performance Assessment of Stormwater Green Infrastructure	Christopher Nietch	9/12/2016
ord,nheerl,tad,nb	ORD-017875	Editor's Highlight: Genetic Targets of Acute Toluene Inhalation in Drosophila melanogaster	David Herr	8/30/2016

ord,nerl,emmd	ORD-017877	Estimating the melting point, entropy of fusion, and enthalpy of fusion of organic compounds via SPARC	Said Hilal	2/28/2017
ord,nheerl,wed,feb	ORD-017882	Impacts to ecosystem services from aquatic acidification: using FEGS-CS to understand the impacts of air pollution	Dixon Landers	10/19/2016
ord,nheerl,wed,feb	ORD-017883	A Framework to Quantify the Strength of the Ecological Links Between an Environmental Stressor and Final Ecosystem Services	Dixon Landers	9/29/2016
ord,nerl,sed,ehcab	ORD-017892	Recreational freshwater fishing drives non-native aquatic species richness patterns at a continental scale (journal)	John Darling	8/28/2017
ord,nerl,sed,ehcab	ORD-017920	Predictors of Urinary 3-Phenoxybenzoic Acid Levels in 50 North Carolina Adults	Marsha Morgan	11/3/2016

ord,nerl,ced	ORD-017922	Development and evaluation of a physics-based windblown dust emission scheme implemented in the CMAQ modeling system	Hosein Foroutan	9/20/2016
ord,nerl,ced	ORD-017924	Associations between socio-demographic characteristics and chemical concentrations contributing to cumulative exposures in the United States	Timothy Barzyk	9/12/2016
ord,ncea,nceartp, emag	ORD-017943	Estimated Maternal Pesticide Exposure from Drinking Water and Heart Defects in Offspring	Tom Luben	2/2/2017
ord,nerl,sed,eib	ORD-017958	Integrating geographically isolated wetlands into land management decisions	Heather Golden	9/11/2016

ord,nrmrl,lrpcd,wmb	ORD-017981	Understanding Arsenic Dynamics in Agronomic Systems to Predict and Prevent Uptake by Crop Plants	Kirk Scheckel	10/5/2016
ord,nerl,ced	ORD-017999	Exploring a United States Maize Cellulose Biofuel Scenario Using an Integrated Energy and Agricultural Markets Solution Approach	Ellen Cooter	9/12/2016
ord,nheerl,ged	ORD-018000	Structure-based Understanding of Binding Affinity and Mode of Estrogen Receptor α Agonists and Antagonists.	Mace Barron	8/26/2016
ord,nheerl,aed,wdb	ORD-018002	Patterns in Stable Isotope Values of Nitrogen and Carbon in Particulate Matter from the Northwest Atlantic Continental Shelf, from the Gulf of Maine to Cape Hatteras	Autumn Oczkowski	9/6/2016

ord,nhsrc,wipd	ORD-018010	A SOFTWARE FRAMEWORK FOR ASSESSING THE RESILIENCE OF DRINKING WATER SYSTEMS TO DISASTERS WITH AN EXAMPLE EARTHQUAKE CASE STUDY	Regan Murray	10/16/2016
ord,nheerl,wed,feb	ORD-018016	Mapping watershed integrity for the conterminous United States..	Scott Leibowitz	9/22/2016
ord,ncea,nceartp,emag	ORD-018022	Framework for assessing causality of air pollution-related health effects for reviews of the National Ambient Air Quality Standards	Steven Dutton	12/30/2016
ord,nheerl,wed,eeb	ORD-018029	MOESHA: A genetic algorithm for automatic calibration and estimation of parameter uncertainty and sensitivity of hydrologic models	Brad Barnhart	9/13/2016

ord,nheerl,wed,feb	ORD-018031	Predictive Mapping of the Biotic Condition of Conterminous-USA Rivers and Streams	Scott Leibowitz	9/22/2016
ord,nrmrl,lmmd,lcdsb	ORD-018039	A quantitative framework for assessing ecological resilience	Ahjond Garmestani	8/31/2016
ord,nheerl,ephd,crb	ORD-018041	Linking the Epigenome with Exposure Effects and Susceptibility: The Epigenetic Seed and Soil Model.	Shaun McCullough	8/25/2016
ord,nheerl,wed,feb	ORD-018043	Simulated juvenile salmon growth and phenology respond to altered thermal regimes and stream network shape	Joe Ebersole	9/7/2016
ord,nerl,emmd	ORD-018059	Predicting Thermal Behavior of Secondary Organic Aerosols	Michael Lewandowski	7/19/2017
ord,nheerl,ephd,crb	ORD-018060	Particle exposure and the historical loss of Native American lives to infections	Andy Ghio	9/6/2016

ord,nheerl,ephd,crb	ORD-018061	The biological effect of asbestos exposure is dependent on changes in iron homeostasis	Andy Ghio	9/6/2016
ord,nheerl,ged	ORD-018063	Acute sensitivity of a broad range of freshwater mussels to chemicals with different modes of toxic action	Sandy Raimondo	8/25/2016
ord,nheerl,med	ORD-018066	An integrated approach for identifying priority contaminant in the Great Lakes Basin - Investigations in the Lower Green Bay/Fox River and Milwaukee Estuary areas of concern	Gerald Ankley	9/22/2016
ord,nrmrl,gwerd,artsb	ORD-018067	Effects of titanium dioxide nanoparticles derived from consumer products on the marine diatom Thalassiosira pseudonana	Chunming Su	9/21/2016

ord,nheerl,ephd,crb	ORD-018076	Community vulnerability to health impacts of wildland fire smoke exposure	Ana Rappold	9/19/2016
ord,ncea,nceartp	ORD-018079	Impacts of fire radiative flux on mature Pinus ponderosa growth and vulnerability to secondary mortality agents	Alan Talhelm	10/7/2016
ord,nerl,emmd	ORD-018086	Review of the of EPA's High-Volume Total Size Selective Performance (Hi-Vol TSP) Sampler	Jonathan Krug	5/15/2017
ord,nheerl,wed,eeb	ORD-018092	The influence of lithology on surface water sources	Reneej Brooks	9/7/2016
ord,nrmrl,lmmd,eceb	ORD-018097	A framework for an alternatives assessment dashboard for evaluating chemical alternatives applied to flame retardants for electronic applications	Todd Martin	9/13/2016

ord,nerl,emmd	ORD-018104	Metabolomics for Informing Adverse Outcome Pathways: Androgen Receptor Activation and the Pharmaceutical Spironolactone	John Davis	5/16/2017
ord,nheerl,med	ORD-018108	Benthic food webs support the production of sympatric flatfish larvae in estuarine nursery habitat	Joel Hoffman	11/28/2016
ord,nerl,sed	ORD-018118	Prediction of Hydrolysis Products of Organic Chemicals under Environmental pH Conditions	Caroline Stevens	5/16/2017
ord,nrmrl,gwerd, artsb	ORD-018123	Role of solution chemistry on the deposition and release of graphene oxide nanoparticles in uncoated and iron oxide-coated sand	Chunming Su	9/21/2016

ord,nheerl,wed,eeb	ORD-018139	Regional patterns of increasing Swiss needle cast impacts on Douglas-fir growth with warming temperatures.	EHenry Lee	9/13/2016
ord,nerl,emmd	ORD-018159	Preservation, Cleanup, and Analysis of the Biomarker Cyanuric Acid in Human Urine	Alfred Dufour	7/31/2017
ord,nhsrc,wipd	ORD-018160	A novel broth medium for enhanced growth of Francisella tularensis	Vincente Gallardo	11/8/2016
ord,nrmrl,wsd,dwsb	ORD-018165	The Role of Anaerobic Digestion in Wastewater Management	Cissy Ma	9/26/2016
ord,nerl,sed,efab	ORD-018169	Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals	Susan Glassmeyer	9/13/2016

ord,nerl,ced	ORD-018177	Description and evaluation of the Community Multiscale Air Quality (CMAQ) modeling system version 5.1	Wyat Appel	9/23/2016
ord,nrmrl,std,sab	ORD-018194	Coupling Computer-Aided Process Simulation and Estimations of Emissions and Land Use for Rapid Life Cycle Inventory Modeling	Raymond Smith	9/7/2016
ord,nerl,ced	ORD-018199	High-throughput dietary exposure predictions for chemical migrants from food contact substances for use in chemical prioritization	Kristin Isaacs	9/7/2017
ord,nheerl,tad,nb	ORD-018201	ACTIVE VS. SEDENTARY LIFESTYLE FROM WEANING TO ADULTHOOD AND SUSCEPTIBILITY TO OZONE IN RATS	Christopher Gordon	9/7/2016

ord,nrmrl,aemd,dsbb	ORD-018210	Roadside vegetation design characteristics that can improve local, near road air quality	Richard Baldauf	10/18/2016
ord,nheerl,aed,peb	ORD-018215	The genomic landscape of rapid repeated evolutionary adaptation to toxic pollution in wild fish	Diane Nacci	10/25/2016
ord,ncct,N/A	ORD-018216	(SAR AND QSAR IN ENVIRONMENTAL RESEARCH) An automated curation procedure for addressing chemical errors and inconsistencies in public datasets used in QSAR modeling	Richard Judson	2/21/2017
ord,nerl,ced,hedmb	ORD-018218	High-throughput screening of chemicals as functional substitutes using structure-based classification models	Katherine Phillips	9/19/2016

ord,ncct,N/A	ORD-018220	(ENVIRONMENTAL HEALTH PERSPECTIVES) Identifying Prevalent Chemical Mixtures in the US Population	Woodrow Setzer	12/19/2016
ord,nerl,sed,ehcab	ORD-018222	Nucleic acids-based tools for ballast water surveillance, monitoring, and research	John Darling	3/29/2018
ord,nrmrl,std,seb	ORD-018227	Sustainability for Shrinking Cities	William Shuster	9/27/2016
ord,ncct,N/A	ORD-018232	(Chemical Research in Toxicology) Development and Validation of a Computational Model for Androgen Receptor Activity	Richard Judson	9/12/2016
ord,nheerl,wed,feb	ORD-018235	Designing Visualization Software for Super-wicked Problems	Paul Ringold	9/29/2016

ord,nerl,emmd,mieb	ORD-018236	Immunoprevalence to Six Waterborne Pathogens in Beachgoers at Boquerón Beach, Puerto Rico: Application of a Microsphere-Based Salivary Antibody Multiplex Immunoassay	Swinburne Augustine	4/1/2017
ord,nrmrl,aemd	ORD-018239	Critical factors affecting life cycle assessments of material choice for vehicle mass reduction	Rebecca Dodder	11/28/2016
ord,ncct,N/A	ORD-018255	(Analytical and Bioanalytical Chemistry) Identifying known unknowns using the US EPAs CompTox Chemistry Dashboard	Antony Williams	12/19/2016
ord,nheerl,tad,etb	ORD-018264	Development of a Screening Approach to Detect Thyroid Disrupting Chemicals that Inhibit the Human Sodium/Iodide Symporter (NIS)	Susan Laws	9/29/2016

ord,ncct,N/A	ORD-018279	(CHEMICAL RESEARCH IN TOXICOLOGY) Computational Model of Secondary Palate Fusion and Disruption	Thomas Knudsen	2/28/2017
ord,nrmrl,std,gcb	ORD-018281	Using Green Chemistry and Engineering Principles to Design, Assess, and Retrofit Chemical Processes for Sustainability	Heriberto Cabezas	9/26/2016
ord,nrmrl,lmmd,eceb	ORD-018289	Valuation of Water and Emissions in Energy Systems	Gerardo Ruiz-Mercado	9/27/2016
ord,nerl,emmd,mieb	ORD-018292	Comparison of mold populations in water-damaged homes in Australia and the United States	Stephen Vesper	5/24/2017
ord,nerl,ced	ORD-018294	A web-based screening tool for near-port air quality assessments	Vlad Isakov	8/11/2017
ord,ioaa,s	ORD-018342	Responding to Mega Trends for Resilient and Sustainable Cities	Alan Hecht	9/28/2016

ord,nheerl,med	ORD-018346	Weight of evidence evaluation of a network of adverse outcome pathways linking activation of the nicotinic acetylcholine receptor in honey bees to colony death	Carlie LaLone	1/5/2017
ord,nheerl,wed,eeb	ORD-018350	Modular and Spatially Explicit: A Novel Approach to System Dynamics	Allen Brookes	9/22/2016
ord,nheerl,ged	ORD-018359	Conceptualizing Holistic Community Resilience to Climate Events: Foundation for a Climate Resilience Screening Index	Kevin Summers	10/26/2016
ord,nerl,sed	ORD-018361	Examining the impacts of increased corn production on groundwater quality using a coupled modeling system	Val Garcia	3/1/2017

ord,nheerl,tad,nb	ORD-018367	A comprehensive framework for evaluating the environmental health and safety implications of engineered nanomaterials	William Boyes	10/19/2016
ord,nheerl,wed,eeb	ORD-018368	Intergenerational responses of wheat (Triticum aestivum L.) to cerium oxide nanoparticles exposure	Christian Andersen	9/22/2016
ord,nheerl,med	ORD-018376	Practical approaches to adverse outcome pathway (AOP) development as illustrated by ecological case studies	Gerald Ankley	10/13/2016
ord,nheerl,ged	ORD-018381	Calcification continues in Caribbean reef-building corals at high pCO2 levels in a recirculating ocean acidification exposure system	Mace Barron	9/30/2016

ord,nerl,sed	ORD-018382	Energy and greenhouse gas life cycle assessment and cost analysis of aerobic and anaerobic membrane bioreactor systems: Influence of scale, population density, climate, and methane recovery	Jay Garland	9/23/2016
ord,nrmrl,lrpcd,wmb	ORD-018385	Complete transformation of ZnO and CuO nanoparticles in culture medium and lymphocyte cells during toxicity testing	Kirk Scheckel	12/13/2016
ord,nrmrl,lrpcd,wmb	ORD-018386	Lead and Arsenic Bioaccessibility and Speciation as a Function of Soil Particle Size	Kirk Scheckel	12/12/2016

ord,nerl,sed,eib	ORD-018390	Benthic macroinvertebrate field sampling effort required to produce a sample adequate for the assessment of rivers and streams of Neuquén Province, Argentina	Joseph Flotemersch	10/10/2016
ord,ncea,nceacin, brab	ORD-018392	Application of Gene Set Enrichment Analysis for Identification of Chemically Induced, Biologically Relevant Transcriptomic Networks and Potential Utilization in Human Health Risk Assessment	Scott Wesselkamper	9/16/2016
ord,nerl,ced	ORD-018419	Nitrate radicals and biogenic volatile organic compounds: oxidation, mechanisms, and organic aerosol	Deborah Luecken	9/27/2016

ord,nerl,sed,eib	ORD-018422	A framework for predicting impacts on ecosystem services from (sub)organismal responses to chemicals	Randy Bruins	10/13/2016
ord,nerl,sed,eib	ORD-018423	Building multi-country collaboration on watershed management: lessons on linking environment and public health from the Western Balkans	Maryann Cairns	10/10/2016
ord,nheerl,ged	ORD-018452	Photoenhanced Toxicity of Petroleum to Aquatic Invertebrates and Fish	Mace Barron	9/22/2016
ord,nerl,emmd	ORD-018454	Observation and Monitoring of Mangrove Forests Using Remote Sensing: Opportunities and Challenges	Chandra Giri	11/8/2016
ord,nerl,sed,ehcab	ORD-018459	Southwestern Intermittent and Ephemeral Stream Connectivity	William Kepner	1/29/2018

ord,ncct,N/A	ORD-018477	(Reg. Tox. Pharm.) Retrospective Mining of Toxicology Data to Discover Multispecies and Chemical Class Effects: Anemia as a Case Study	Richard Judson	2/28/2017
ord,nerl,ced,hedmb	ORD-018478	Characterizing the impact of projected changes in climate and air quality on human exposures to ozone	Kathie Dionisio	9/26/2016
ord,ncea,nceawa,earc	ORD-018483	Critical Lake Temperature Response to Climate Change across the United States	Thomas Johnson	10/31/2016
ord,nhsrc,tcad	ORD-018505	Evaluation of Exposure to Brevundimonas diminuta and Pseudomonas aeruginosa during Showering [HS7.44.02]	Tonya Nichols	11/2/2016

ord,nerl,emmd	ORD-018507	Novel Polyfluorinated Compounds Identified Using High Resolution Mass Spectrometry Downstream of Manufacturing Facilities near Decatur, Alabama	Mark Strynar	1/25/2017
ord,nerl,ced	ORD-018518	Advanced Monitoring Technology: Opportunities and Challenges - A Path Forward for EPA and States	Tim Watkins	9/26/2016
ord,nerl,emmd	ORD-018522	A Citizen Science and Government Collaboration: Developing Tools to Facilitate Community Air Monitoring	Ron Williams	6/12/2017
ord,nrmrl,wswrd	ORD-018525	Fine-Tuning ADAS Algorithm Parameters for Optimizing Traffic Safety and Mobility in Connected Vehicle Environment	Jeff Yang	1/24/2017

ord,nerl,sed	ORD-018542	Exploring synergies between transit investment and dense redevelopment: A scenario analysis in a rapidly urbanizing landscape	Rochelle Araujo	9/5/2017
ord,nhsrc,wipd	ORD-018543	Modeling Fate and Transport of Arsenic in a Chlorinated Distribution System	Regan Murray	11/8/2016
ord,nerl,ced	ORD-018545	Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed of North Carolina	Andrew Lindstrom	10/7/2016
ord,nheerl,med	ORD-018593	Early detection monitoring for aquatic non-indigenous species: optimizing surveillance, incorporating advanced technologies, and identifying research needs	Anett Trebitz	11/18/2016

ord,nerl,emmd	ORD-018614	Evaluation of the Immunomodulatory Effects of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate (“GenX”) in C57BL/6 Mice	Mark Strynar	10/12/2016
ord,nrmrl,std,seb	ORD-018616	New plastic recycling technology	John Glaser	12/13/2016
ord,nheerl,aed,heb	ORD-018625	Trends in nitrogen isotope ratios of juvenile winter flounder reflect changing nitrogen inputs to Rhode Island, USA estuarine systems	Richard Pruell	11/22/2016
ord,nheerl,tad,etb	ORD-018664	Effects of Chronic Exposure to Triclosan on Reproductive and Thyroid Endpoints in the Adult Wistar Female Rat	Tammy Stoker	11/1/2016

ord,ncct,N/A	ORD-018679	(Chemical Research in Toxicology) Predicting organ toxicity using in vitro bioactivity data and chemical structure	Imran Shah	7/5/2017
ord,nheerl,wed,pceb	ORD-018690	Development of an epiphyte indicator of nutrient enrichment. A critical evaluation of observational and experimental studies	Walt Nelson	10/3/2016
ord,nheerl,wed,pceb	ORD-018696	Development of an epiphyte indicator of nutrient enrichment: Threshold values for seagrass epiphyte load	Walt Nelson	10/3/2016
ord,nheerl,wed,eeb	ORD-018697	Spatially-explicit modelling model for assessing wild dog control strategies in Western Australia	Nathan Schumaker	10/11/2016

ord,nheerl,med,stb	ORD-018720	Rapid effects of the aromatase inhibitor fadrozole on steroid production and gene expression in the ovary of female fathead minnows (Pimephales promelas)	Dan Villeneuve	2/1/2017
ord,nrmrl,lrpcd,wmb	ORD-018723	Characterizing the Uptake, Accumulation and Toxicity of Silver Sulfide Nanoparticles in Plants	Kirk Scheckel	12/13/2016
ord,nheerl,wed,eeb	ORD-018768	Basal area growth, carbon isotope discrimination, and intrinsic water use efficiency after fertilization of Douglas-fir in the Oregon Coast Range	Reneej Brooks	10/11/2016

ord,nerl,sed	ORD-018780	Comparison of soil sampling and analytical methods for asbestos at the Sumas Mountain Asbestos Site—Working towards a toolbox for better assessment	Daniel Vallero	10/28/2016
ord,nheerl,aed,mab	ORD-018788	Dynamics of ecosystem services provided by subtropical forests in Southeast China during succession as measured by donor and receiver value	Dan Campbell	10/26/2016
ord,nheerl,med,ttb	ORD-018798	Measurement of kinetic parameters for biotransformation of polycyclic aromatic hydrocarbons by trout liver S9 fractions: Implications for bioaccumulation assessment	John Nichols	1/17/2017

ord,nerl,sed,eib	ORD-018820	People and water: Exploring the social-ecological condition of watersheds of the United States	Joseph Flotemersch	10/28/2016
ord,nerl,emmd	ORD-018825	Heat as a Hydrologic Tracer in Shallow and Deep Heterogeneous Media: Analytical Solution, Spreadsheet Tool, and Field Applications	D Werkema	1/31/2017
ord,nheerl,ephd,crb	ORD-018849	Using Chromatin Immunoprecipitation in Toxicology: A Step-by-Step Guide to Increasing Efficiency, Reducing Variability, and Expanding Applications	Shaun McCullough	10/11/2016

ord,ncer,ased	ORD-018860	"Technical note. Harmonization of the multi-scale multi-model activities HTAP, AQMEII and MICS-Asia: simulations, emission inventories, boundary conditions and output formats." For submission to ACP Special Issue on "Global and regional a	Terry Keating	10/20/2016
ord,nerl,emmd	ORD-018870	Methods for Monitoring Cyanobacterial Harmful Algal Bloom Frequency in Recreational Waters and Drinking Water Sources with Satellites	Blake Schaeffer	3/27/2017
ord,nrmrl,std,cpb	ORD-018876	Robustness analysis of a green chemistry-based model for the classification of silver nanoparticles synthesis processes	Rajender Varma	10/21/2016

ord,nheerl,istd,sbb	ORD-018901	PPARα-independent transcriptional targets of perfluoroalkyl acids revealed by transcript profiling	Chris Corton	2/14/2017
ord,nheerl,istd,sbb	ORD-018902	Transcriptome profiling reveals bisphenol A alternatives activate estrogen receptor alpha in human breast cancer cells	Chris Corton	3/21/2017
ord,nerl,sed,ehcab	ORD-018927	Building a Potential Wetland Restoration Indicator for the Contiguous United States.	Megan Mehaffey	8/4/2017
ord,nrmrl,appcd,iemb	ORD-018933	Emission factors, number size distributions and morphology of ultrafine particles in cookstove smoke: A laboratory comparison of different household stove-fuel systems	Jim Jetter	11/17/2016

ord,nrmrl,std,cpb	ORD-018944	Photocatalytic oxidation of aromatic amines using MnO2@g-C3N4	Rajender Varma	10/20/2016
ord,ncct,N/A	ORD-018966	(Life Sciences) Health Effects of Toxicants: Online Knowledge Support	Richard Judson	3/21/2017
ord,nheerl,wed,pceb	ORD-018972	Model application niche analysis: Assessing the transferability and generalizability of ecological models	Ted DeWitt	10/21/2016
ord,nrmrl,std,cpb	ORD-018977	Biofiltration of Chloroform in a Trickle Bed Air Biofilter Under Acidic Conditions	Endalkachew Sahle-Demessie	12/5/2016
ord,nerl,emmd	ORD-018978	Meeting Report: IABR Breath Summit 2016 in Zurich, Switzerland	Joachim Pleil	11/28/2016

ord,nerl,emmd	ORD-018980	Canine olfaction as an alternative to analytical instruments for disease diagnosis: understanding 'dog personality' to achieve reproducible results	Joachim Pleil	12/15/2016
ord,nheerl,istd,cb	ORD-018997	Metabolic Disruption Early in Life is Associated With Latent Carcinogenic Activity of Dichloroacetic Acid in Mice	Charles Wood	12/12/2016
ord,nheerl,istd,sbb	ORD-019001	Compensatory changes in CYP expression in three different toxicology mouse models: CAR-null, Cyp3a-null, and Cyp2b9/10/13-null mice	Chris Corton	2/3/2017
ord,nrmrl,std,seb	ORD-019058	Regime shifts and panarchies in regional scale social-ecological water systems	Ahjond Garmestani	10/24/2016

ord,nheerl,wed,eeb	ORD-019179	Can Biochar Covers Reduce Emissions from Manure Lagoons While Capturing Nutrients?	Markg Johnson	10/31/2016
ord,nrmrl,lmmd,lcdsb	ORD-019206	Critical Review of Elementary Flows in LCA data	Wesley Ingwersen	12/5/2016
ord,ncea,nceacin,crab	ORD-019210	Associations Between Disinfection By-Product Exposures and Craniofacial Birth Defects	Michael Wright	11/29/2016
ord,nerl,sed,eib	ORD-019239	Physical and Chemical Connectivity of Streams and Riparian Wetlands to Downstream Waters: A Synthesis	Ken Fritz	12/13/2016

ord,nerl,sed,eib	ORD-019259	In some places, in some cases, and at some times, harmful algal blooms are the greatest threat to inland water quality	Jim Lazorchak	12/15/2016
ord,nheerl,med	ORD-019266	Which molecular features affect the intrinsic hepatic clearance rate of ionizable organic chemicals in fish?	John Nichols	11/18/2016
ord,nheerl,wed,feb	ORD-019271	Assessing the Social and Environmental Costs of Institutional Nitrogen Footprints	Jana Compton	11/14/2016

ord,nheerl,wed,feb	ORD-019272	The nitrogen footprint tool network: a multi-institution program to reduce nitrogen pollution	Jana Compton	11/14/2016
ord,nheerl,aed,heb	ORD-019279	Using diverse expertise to advance climate change fisheries science	Kate Mulvaney	12/30/2016
ord,nheerl,ephd,crb	ORD-019283	Associations among plasma metabolite levels and short-term exposure to PM2.5 and ozone in a cardiac catheterization cohort.	David Diaz-Sanchez	12/2/2016
ord,nerl,emmd,mieb	ORD-019287	Bacteriophages as indicators of faecal pollution and enteric virus removal	Brian McMinn	3/8/2017
ord,nerl,emmd	ORD-019292	Is the Geographic Range of Mangrove Forests in the Conterminous United States Really Expanding?	Chandra Giri	11/8/2016

ord,nheerl,tad	ORD-019294	SETAC: Nonmonotonic dose response curves (NMDRCs) are common after Estrogen or Androgen signaling pathway disruption. Fact or Falderal?	Earl Gray	11/1/2016
ord,nheerl,aed,mab	ORD-019312	Emergy evaluation of benthic ecosystems influenced by upwelling in northern Chile: Contributions of the ecosystems to the regional economy	Dan Campbell	12/2/2016
ord,nheerl,med,wdb	ORD-019313	Evaluation of a wetland classification system devised for management in a region with a high cover of peatlands: an example from the Cook Inlet Basin, Alaska	Mary Moffett	11/7/2016

ord,nerl,emmd,mieb	ORD-019314	12 Community structures of phytoplankton with emphasis of toxic cyanobacteria in an Ohio inland lake during bloom season	Jingrang Lu	10/16/2017
ord,nheerl,wed,feb	ORD-019317	Comparing Institution Nitrogen Footprints: Metrics for Assessing and Tracking Environmental Impact	Jana Compton	11/14/2016
ord,nerl,sed,ehcab	ORD-019329	A Decision Support Tool for Sustainable Land Use, Transportation, Buildings/Infrastructure, and Materials Management	EricS Hall	11/8/2016
ord,nheerl,aed,mab	ORD-019352	Ecological restoration should be redefined for the twenty-first century	DavidM Martin	3/2/2017

ord,nerl,emmd	ORD-019360	.A method for examining temporal changes in cyanobacterial harmful algal bloom spatial extent using satellite remote sensing	Erin Urquhart	5/25/2017
ord,nerl,sed,efab	ORD-019365	Draft Genome Sequence of Mycobacterium chimaera Type Strain FI-0169	Stacy Pfaller	11/12/2016
ord,nerl,emmd	ORD-019382	Estimating Methylmercury Intake for the General Population of South Korea Using Physiologically Based Pharmacokinetic Modeling	Jon Sobus	2/8/2017
ord,nheerl,ephd	ORD-019384	Ultrafine Particulate Matter Increases Cardiac Ischemia/Reperfusion Injury via Mitochondrial Permeability Transition Pore.	Robert Devlin	11/19/2016

ord,nheerl,wed,pceb	ORD-019387	A mangrove creek restoration plan utilizing hydraulic modeling	Darryl Marois	12/1/2016
ord,nerl,ced	ORD-019419	Simulating Aqueous-Phase Isoprene-Epoxydiol (IEPOX) Secondary Organic Aerosol Production During the 2013 Southern Oxidant and Aerosol Study (SOAS)	Havala Pye	5/2/2017
ord,nheerl,wed,pceb	ORD-019421	Patterns of shading tolerance determined from experimental light reduction studies of seagrasses	Walt Nelson	11/21/2016
ord,nheerl,med	ORD-019460	Assessing the bioaccumulation potential of ionizable organic compounds: Current knowledge and research priorities	Russell Erickson	11/18/2016

ord,nerl,ced	ORD-019499	Southeast Atmosphere Studies: learning from model-observation syntheses	Havala Pye	11/23/2016
ord,nheerl,aed,mab	ORD-019501	Integrated emergy and economic evaluation of lotus-root production systems on reclaimed wetlands surrounding the Pearl River Estuary, China	Dan Campbell	12/12/2016
ord,nheerl,med	ORD-019505	The role of omics in the application of adverse outcome pathways for chemical risk assessment	Gerald Ankley	11/18/2016
ord,nerl,emmd	ORD-019521	An overview of geophysical technologies appropriate for characterization and monitoring at fractured-rock sites	D Werkema	2/21/2017

ord,nheerl,wed,eeb	ORD-019527	Spatial demographic models to inform conservation planning of golden eagles in renewable energy landscapes.	Nathan Schumaker	12/1/2016
ord,nerl,emmd	ORD-019569	Hydroxy-fipronil is a new urinary biomarker of exposure to fipronil	Mark Strynar	8/17/2017
ord,nerl,sed	ORD-019571	Capturing microbial sources distributed in a mixed-use watershed within an integrated environmental modeling workflow	Gene Whelan	8/17/2017
ord,nheerl,tad,nb	ORD-019580	Perinatal exposure to organohalogen pollutants decreases vasopressin content and its mRNA expression in magnocellular neuroendocrine cells activated by osmotic stress in adult rats	Prasada Kodavanti	11/29/2016

ord,nerl,ced	ORD-019583	Persistence of initial conditions in continental scale air quality simulations	Christian Hogrefe	12/20/2016
ord,nerl,emmd,mieb	ORD-019585	Fungal Microbiomes Associated with Green and Non-Green Building Materials	Stephen Vesper	8/22/2017
ord,nerl,ced	ORD-019605	A framework for expanding aqueous chemistry in the Community Multiscale Air Quality (CMAQ) model version 5.1	Kathleen Fahey	3/13/2017
ord,nheerl,tad,rtb	ORD-019606	Occurrence and in vitro bioactivity of estrogen, androgen, and glucocorticoid compounds in a nationwide screen of United States stream waters	Vickie Wilson	11/23/2016

ord,nheerl,aed,peb	ORD-019611	When evolution is the solution to pollution: Key principles, and lessons from rapid repeated adaptation of killifish (Fundulus heteroclitus) populations	Diane Nacci	2/22/2017
ord,nheerl,ephd,cib	ORD-019614	Respiratory Effects and Systemic Stress Response Following Acute Acrolein Inhalation in Rats#	Urmila Kodavanti	2/10/2017
ord,osa,rafs	ORD-019619	A Topical Overview of Cumulative Risk Assessment Concepts, Methods, and Applications (2007–2016)	Lawrence Martin	12/2/2016
ord,nerl,emmd	ORD-019620	Fluorinated Compounds in U.S. Fast Food Packaging	Mark Strynar	12/2/2016

ord,nrmrl,lmmd,mmb	ORD-019640	Water recovery from brines and salt-saturated solutions: operability and thermodynamic efficiency considerations for desalination technologies	Leland Vane	11/30/2016
ord,nheerl,aed,peb	ORD-019645	Towards the review of the European Union Water Framework management of chemical contamination in European surface water resources	Robert Burgess	12/2/2016
ord,nrmrl,lmmd,mmb	ORD-019659	Performance of Anaerobic Biotrickling Filter and Its Microbial Diversity for the Removal of Stripped Disinfection By-products	Endalkachew Sahle-Demessie	12/5/2016
ord,nrmrl,wsd,dwsb	ORD-019663	High Biofilm Conductivity Maintained Despite Anode Potential Changes in a Geobacter-Enriched Biofilm	Hodon Ryu	1/24/2017

ord,nheerl,aed,heb	ORD-019666	The Role of Shellfish Aquaculture in Reduction of Eutrophication in an Urban Estuary	Suzanne Ayvazian	12/22/2016
ord,nheerl,istd,cb	ORD-019680	Chemical-agnostic hazard prediction: statistical inference of in vitro toxicity pathways from proteomics responses to chemical mixtures	Jeffrey Ross	12/12/2016
ord,nrmrl,std,sab	ORD-019684	USEEIO: A new and transparent United States environmentally extended input-output model	Wesley Ingwersen	1/5/2017
ord,nrmrl,lrpcd,wmb	ORD-019686	Aging of Dissolved Copper and Copper-based Nanoparticles in Five Different Soils: Short term Kinetics vs. Long term Fate	Kirk Scheckel	1/5/2017

ord,nrmrl,wsd,dwsb	ORD-019698	Quantification of the methane concentration using anaerobic oxidation of methane coupled to extracellular electron transfer	Hodon Ryu	1/24/2017
ord,ncct,N/A	ORD-019700	(REPRODUCTIVE TOXICOLOGY) EMBRYONIC VASCULAR DISRUPTION ADVERSE OUTCOMES: LINKING HIGH THROUGHPUT SIGNALING SIGNATURES WITH FUNCTIONAL CONSEQUENCES	Thomas Knudsen	7/5/2017
ord,nerl,ced	ORD-019739	Using exposure bands for rapid decision making in the RISK21 tiered exposureassessment	Peter Egeghy	12/14/2016
ord,nrmrl,std,cpb	ORD-019752	Photocatalytic C–H Activation of Hydrocarbons over VO@g-C3N4	Rajender Varma	12/13/2016

ord,nerl,sed	ORD-019757	Air Pollution Monitoring Changes to Accompany the Transition from a Control to a Systems Focus	Daniel Vallero	4/16/2018
ord,nerl,emmd	ORD-019758	An Artificial Turf-Based Surrogate Surface Collector for the Direct Measurement of Atmospheric Mercury Dry Deposition	Matthew Landis	2/6/2017
ord,nrmrl,lrpcd	ORD-019767	People, Planet and Profit: Unintended Consequences of Legacy Building Materials	Anthony Zimmer	1/31/2017
ord,nhsrc,dcmd	ORD-019794	Evaluation of standardized sample collection, packaging, and decontaminatio n procedures to assess cross-contamination potential during Bacillus anthracis incident response operations	Worth Calfee	2/8/2017

ord,nerl,ced	ORD-019799	Life cycle assessment of a commercial rainwater harvesting system compared with a municipal water supply system	JohnM Johnston	12/15/2016
ord,nheerl,istd,cb	ORD-019808	Procedure and Key Optimization Strategies for an Automated Capillary Electrophoretic-based Immunoassay Method	Brian Chorley	12/19/2016
ord,nerl,emmd	ORD-019814	In vitro bioaccessibility of copper azole following simulated dermal transfer from pressure-treated wood	Kim Rogers	12/15/2016
ord,nrmrl,appcd,ecpb	ORD-019819	Assessment of Uinta Basin Oil and Natural Gas Well Pad Pneumatic Controller Emissions	Eben Thoma	1/25/2017

ord,nerl,sed	ORD-019828	Children's Lead Exposure: A Multimedia Modeling Analysis to Guide Public Health Decision-Making	Valerie Zartarian	5/22/2017
ord,nheerl,wed,feb	ORD-019833	Carbon storage in US wetlands	Amanda Nahlik	12/19/2016
ord,nheerl,wed,pceb	ORD-019853	Effect of Green Macroalgal Blooms on the Behavior, Growth, and Survival of Cockles (Clinocardium nuttallii) in Pacific NW Estuaries	Ted DeWitt	12/23/2016
ord,nheerl,istd	ORD-019885	Quantitative Adverse Outcome Pathways and Their Application to Predictive Toxicology	Rory Conolly	3/24/2017
ord,nheerl,ephd,eb	ORD-019897	Vegetated land cover near residence is associated with reduced allostatic load and improved biomarkers of neuroendocrine, metabolic and immune functions	Andrey Egorov	2/7/2017

ord,ioaa,N/A	ORD-019898	Chemical Risk Assessment: Traditional vs Public Health Perspectives	Maureen Gwinn	1/3/2017
ord,nerl,sed,ehcab	ORD-019899	Biota: Providing Often-overlooked Connections among Freshwater Systems	Jay Christensen	11/14/2017
ord,nerl,ced	ORD-019908	Spatiotemporal modeling of ecological and sociological predictors of West Nile virus in Suffolk County, NY, mosquitoes	JohnM Johnston	2/8/2017
ord,nrmrl,aemd,ensb	ORD-019920	Chromatography related performance of the Monitor for Aerosols and Gases in Ambient Air (MARGA): laboratory and field based evaluation	Johnt Walker	2/3/2017
ord,nrmrl,io	ORD-019923	A Farewell to Harms: The Audacity to Design Safer Products	Nicholas Anastas	4/10/2017

ord,nrmrl,wsd,wrrb	ORD-019925	Managing Uncertainty in Runoff Estimation with the U.S. Environmental Protection Agency National Stormwater Calculator.	William Shuster	1/30/2017
ord,nheerl,aed,wdb	ORD-019928	Impacts of 25 years of groundwater extraction on subsidence in the Mekong delta, Vietnam	Laura Erban	1/24/2017
ord,nheerl,aed,mab	ORD-019936	Monitoring algal blooms in drinking water reservoirs using the Landsat-8 Operational Land Imager	Darryl Keith	2/7/2017
ord,nrmrl,std,cpb	ORD-019957	A sustainable approach to empower the bio-based future: upgrading of biomass via process intensification	Rajender Varma	1/5/2017

ord,nerl,emmd	ORD-019961	Linking physiological parameters to perturbations in the human exposome: Environmental exposures modify blood pressure and lung function via inflammatory cytokine pathway	Joachim Pleil	7/26/2017
ord,ncea,nceacin, brab	ORD-019963	Using extirpation to evaluate ionic tolerance of freshwater fish	Michael Griffith	5/31/2017
ord,nerl,emmd	ORD-019977	Satellite sensor requirements for monitoring essential biodiversity variables of coastal ecosystems	Blake Schaeffer	12/11/2017
ord,nerl,sed,eib	ORD-019978	The Significant Surface-Water Connectivity of “Geographically Isolated Wetlands”	Charles Lane	1/30/2017

ord,nheerl,med,esb	ORD-019979	Comprehensive target-chemical assessment reveals extensive mixed-organic-contaminant exposure in USA streams	Dan Villeneuve	1/4/2017
ord,nheerl,ged	ORD-019983	Acute Sensitivity of the Vernal Pool Fairy Shrimp, Branchinecta Lynchi (Anostraca; Branchinectidae), and Surrogate Species to 10 Chemicals	Sandy Raimondo	1/18/2017
ord,nheerl,med,stb	ORD-019984	Ecdysone receptor agonism leading to lethal molting disruption in arthropods: Review and adverse outcome pathway development	Dan Villeneuve	1/4/2017
ord,nrmrl,wsd,wrrb	ORD-019987	Organism Detection in Permeable Pavement Parking Lot Infiltrates at the Edison Environmental Center, NJ	Ariamalar Selvakumar	2/8/2017

ord,nheerl,med,stb	ORD-020000	Ecosystem services in the Great Lakes	Theodore Angradi	1/4/2017
ord,nrmrl,wsd	ORD-020010	Urban infrastructure influences dissolved organic matter quality and bacterial metabolism in an urban stream network	Jake Beaulieu	2/8/2017
ord,nheerl,ged	ORD-020014	Seasonal Oxygen Dynamics in a Warm Temperate Estuary: Effects of Hydrologic Variability on Measurements of Primary Production, Respiration, and Net Metabolism	Michael Murrell	1/10/2017
ord,nrmrl,lrpcd,wmb	ORD-020024	Modification of an Existing In vitro Method to Predict Relative Bioavailable Arsenic in Soils	Kirk Scheckel	3/1/2017

ord,nheerl,ephd,eb	ORD-020049	Child environmental exposures to water and sand at the beach: Findings from studies of over 68,000 subjects at 12 beaches	Tim Wade	2/13/2017
ord,nheerl,med,esb	ORD-020103	Reevaluating the significance of estrone as an environmental estrogen (article)	Gerald Ankley	1/31/2017
ord,nrmrl,gwerd,tass	ORD-020112	Uptake of Nickel by Synthetic Mackinawite	David Jewett	1/31/2017
ord,nhsrc,tcad	ORD-020113	Sample Processing Approach for Detection of Ricin in Surface Samples [HS7.52.04 - 0671]	Sanjiv Shah	4/17/2017
ord,nheerl,ephd,crb	ORD-020127	Investigating Mitochondrial Dysfunction in Human Lung Cells Exposed to Redox-Active PM Components	James Samet	2/10/2017
ord,nheerl,wed,feb	ORD-020147	Linking terrestrial phosphorus inputs to riverine export across the United States	Jana Compton	1/30/2017

ord,nrmrl,aemd	ORD-020148	Light-absorbing organic carbon from prescribed and laboratory biomass burning and gasoline vehicle emissions	Amara Holder	2/23/2017
ord,nrmrl,std,cpb	ORD-020150	A supplementary tool to existing approaches for assessing ecosystem community structure	Matthew Hopton	2/3/2017
ord,ncct,N/A	ORD-020177	(SAR AND QSAR IN ENVIRONMENTAL RESEARCH) Application of IATA - A case study in evaluating the global and local performance of a Bayesian Network model for Skin Sensitization	Grace Patlewicz	2/28/2017
ord,nhsrc,wipd	ORD-020179	Sorption of cesium onto the mineral phases and cement of concrete and desorption into simple salt solutions	Matthew Magnuson	3/2/2017

ord,nrmrl,aemd	ORD-020189	Marginal abatement cost curve for NOx incorporating controls, renewable electricity, energy efficiency and fuel switching	Dan Loughlin	3/13/2017
ord,nrmrl,aemd,ensb	ORD-020191	Exploring the role of natural gas power plants with carbon capture and storage as a bridge to a low-carbon future	Dan Loughlin	8/24/2017
ord,nheerl,ephd	ORD-020192	Ozone exposure is associated with acute changes in inflammation, fibrinolysis, and endothelial cell function in coronary artery disease patients	Robert Devlin	5/23/2017
ord,nheerl,ephd,eb	ORD-020197	Extreme Precipitation and Emergency Room Visits for Influenza in Massachusetts: A Case-Crossover Analysis	E Hilborn	3/21/2018

ord,ncct,N/A	ORD-020198	(Archives of Toxicology) Predicting In Vivo Effect Levels for Repeat Dose Systemic Toxicity using Chemical, Biological, Kinetic and Study Covariates	Richard Judson	5/2/2017
ord,nheerl,tad,nb	ORD-020207	IMPACTS OF MATERNAL DIET AND EXERCISE ON OFFSPRING BEHAVIOR AND GROWTH	Christopher Gordon	3/1/2017
ord,nheerl,aed	ORD-020226	Ecosystem Services Deserve Better than “Dirty Paper”	Wayne Munns	2/7/2017
ord,nerl,sed,eib	ORD-020228	Delineating wetland catchments and modeling hydrologic connectivity using lidar data and aerial imagery	Charles Lane	2/23/2017

ord,nheerl,ged	ORD-020229	Eco-Health Linkages: Assessing the Role of Ecosystem Goods and Services on Human Health Using Causal Criteria Analysis	Rebeca DeJesus-Crespo	2/7/2017
ord,nrmrl,lmmd,lcdsb	ORD-020233	LCIA framework and cross-cutting issues guidance within the UNEP/SETAC Life Cycle Initiative	Jane Bare	6/12/2017
ord,nrmrl,aemd	ORD-020243	Emissions from Prescribed Burning of Agricultural Fields in the Pacific Northwest	Brian Gullett	4/28/2017
ord,nrmrl,aemd,ssb	ORD-020245	Characterization of Emissions from Liquid Fuel and Propane Open Burns	Brian Gullett	2/28/2017
ord,nheerl,med,ttb	ORD-020252	Testicular oocytes in smallmouth bass in Northeastern Minnesota in relation to presumed exposure to endocrine disrupting compounds	Dave Mount	4/26/2017

ord,nheerl,wed,eeb	ORD-020266	A sprinkling experiment to quantify celerity-velocity differences at the hillslope scale	Reneej Brooks	2/1/2017
ord,nerl,ced,hedmb	ORD-020279	Using exposure prediction tools to link exposure and dosimetry for risk-based decisions: A case study with phthalates	Katherine Phillips	6/30/2017
ord,nrmrl,lmmd,lcdsb	ORD-020281	The creation, management, and use of data quality information for life cycle assessment	Wesley Ingwersen	3/17/2017
ord,ncct,N/A	ORD-020294	(Journal of Chemical Information and Modeling) In Silico Prediction of Physicochemical Properties of Environmental Chemicals Using Molecular Fingerprints and Machine Learning	Richard Judson	7/28/2017

ord,nerl,emmd	ORD-020302	Integrating exhaled breath diagnostics by disease-sniffing dogs with instrumental laboratory analysis	Joachim Pleil	4/18/2017
ord,nheerl,med,ttb	ORD-020320	Impaired swim bladder inflation in early-life stage fathead minnows exposed to a deiodinase inhibitor, iopanoic acid (article)	Dan Villeneuve	3/3/2017
ord,nheerl,ephd,cib	ORD-020342	Adrenal-derived stress hormones modulate ozone-induced lung injury and inflammation	Urmila Kodavanti	2/21/2017
ord,ncea,nceartp,emag	ORD-020345	Factors associated with NO2 and NOx concentration gradients near a highway	Jennifer Richmond-Bryant	3/24/2017

ord,nheerl,med,stb	ORD-020369	Summary of the development the US Environmental Protection Agency’s Medaka Extended One Generation Reproduction Test (MEOGRT) using data from 9 multigenerational medaka tests	Kevin Flynn	5/16/2017
ord,nrmrl,wsd	ORD-020373	Pilot Plant Demonstration of Stable and Efficient High Rate Biological Nutrient Removal with Low Dissolved Oxygen Conditions	Jorge Santodomingo	3/7/2017
ord,nheerl,ged	ORD-020374	Relative Sensitivity of Arctic Species to Physically and Chemically Dispersed Oil Determined from Three Hydrocarbon Measures of Aquatic Toxicity	Mace Barron	2/10/2017

ord,nheerl,istd,sbb	ORD-020382	Evaluation of estrogen receptor alpha activation by glyphosate-based herbicide constituents	Chris Corton	4/6/2017
ord,nerl,emmd	ORD-020388	Particulate-phase mercury emissions from biomass burning and impact on resulting deposition: a modelling assessment	Matthew Landis	2/17/2017
ord,nerl,emmd	ORD-020406	Comparison of mouse and swine bioassays for determination of soil arsenic relative bioavailability	Karen Bradham	9/12/2017
ord,nheerl,ephd,crb	ORD-020416	Impact of Work Task-Related Acute Occupational Smoke Exposures on Select Proinflammatory Immune Parameters in Wildland Firefighters	David Diaz-Sanchez	3/6/2017
ord,nrmrl,wsd,wrrb	ORD-020417	Oxidative C-H activation of amines using protuberant lychee-like goethite	Rajender Varma	3/17/2017

ord,nrmrl,std,cpb	ORD-020419	Fixation of carbon dioxide into dimethyl carbonate over titanium-based zeolitic thiophene-benzimidazolate framework	Rajender Varma	3/17/2017
ord,nheerl,istd,sbb	ORD-020420	Developmental Neurotoxicants Disrupt Activity in Cortical Networks on Microelectrode Arrays: Results of Screening 86 Compounds During Neural Network Formation	Tim Shafer	3/20/2017
ord,nrmrl,lrpcd	ORD-020430	Bayesian Monte Carlo and Maximum Likelihood Approach for Uncertainty Estimation and Risk Management: Application to Lake Oxygen Recovery Model	Mohamed Hantush	2/22/2017
ord,nrmrl,aemd,dsbb	ORD-020446	Measuring and Modeling Surface Sorption Dynamics of Organophosphate Flame Retardants in Chambers	Xiaoyu Liu	3/13/2017

ord,nheerl,aed	ORD-020450	The value of nature: Economic, intrinsic, or both?	Anne Rea	2/27/2017
ord,nerl,ced,amaab	ORD-020469	Dynamic evaluation of two decades of WRF-CMAQ ozone simulations over the contiguous United States	Christian Hogrefe	3/2/2017
ord,nerl,emmd,ieib	ORD-020471	Harmful Algae Bloom Occurrence in Urban Ponds: Relationship of Toxin Levels with Cell Density and Species Composition	Armah Delacruz	4/10/2017
ord,nheerl,ephd,eb	ORD-020472	Inverse Relationship Between Urban Green Space and Childhood Autism in California Elementary School Districts	Laura Jackson	2/17/2017
ord,nheerl,ged	ORD-020474	A keyword approach to finding common ground in community-based definitions of human well-being	Richard Fulford	2/21/2017

ord,nrmrl,std,cpb	ORD-020485	Hydroxylation of Benzene via C-H Activation Using Bimetallic CuAg@g-C3N4	Rajender Varma	3/17/2017
ord,ncea,nceacin	ORD-020491	A WEIGHT OF EVIDENCE FRAMEWORK FOR ECOLOGICAL ASSESSMENTS: INFERING QUALITIES	Glenn Suter	3/28/2017
ord,ncea,nceacin	ORD-020492	A WEIGHT OF EVIDENCE FRAMEWORK FOR ENVIRONMENTAL ASSESSMENTS: INFERING QUANTITIES	Glenn Suter	3/28/2017
ord,nrmrl,lmmd,eceb	ORD-020503	Prediction of pesticide acute toxicity using two-dimensional chemical descriptors and target species classification	Todd Martin	3/17/2017
ord,nheerl,med,esb	ORD-020504	Advancing the adverse outcome pathway framework - An international horizon scanning approach	Carlie LaLone	3/29/2017

ord,nerl,ced	ORD-020512	Modeled Full-Flight Aircraft Emissions Impacts on Air Quality and Their Sensitivity to Grid Resolution	Rohit Mathur	3/7/2017
ord,nheerl,med,esb	ORD-020517	First generation annotations for the fathead minnow (Pimephales promelas) genome	Dan Villeneuve	3/24/2017
ord,nerl,emmd	ORD-020527	Relationship Between Total and Bioaccessible Lead on Children’s Blood Lead Levels in Urban Residential Philadelphia Soils	Karen Bradham	9/12/2017
ord,nerl,ced	ORD-020569	Improving the simulation of convective dust storms in regional-to-global models	Hosein Foroutan	8/30/2017
ord,nerl,emmd	ORD-020572	Effects of triclosan on bacterial community composition and Vibrio populations in natural seawater microcosms	Matt Henderson	4/7/2017

ord,nheerl,med,esb	ORD-020599	An "EAR" on environmental surveillance and monitoring: A case study on the use of exposure-activity ratios to prioritize sites, chemicals, and bioactivities of concern in Great Lakes waters	Dan Villeneuve	3/29/2017
ord,ncct,N/A	ORD-020608	(Computational Toxicology) Navigating through the minefield of read-across tools: A review of in silico tools for grouping	Grace Patlewicz	3/30/2017
ord,nheerl,wed,pceb	ORD-020620	Effects of microtopographic variation and macroalgal cover on morphometrics and survival of the annual form of eelgrass (Zostera marina)	Walt Nelson	2/24/2017

ord,ncea,nceartp	ORD-020627	Chronic nitrogen deposition influences the chemical dynamics of leaf litter and fine roots during decomposition	Alan Talhelm	3/24/2017
ord,nrmrl,aemd,dsbb	ORD-020633	Roadside vegetation design characteristics that can improve local, near-road air quality	Richard Baldauf	4/6/2017
ord,nheerl,aed,mab	ORD-020647	Developing qualitative ecosystem service relationships with the Driver-Pressure-State-Impact-Response framework: A case study on Cape Cod, Massachusetts	DavidM Martin	3/6/2017
ord,nerl,emmd	ORD-020648	Agglomeration Determines Effects of Carbonaceous Nanomaterials on Soybean Nodulation, Dinitrogen Fixation Potential, and Growth in Soil	Dermont Bouchard	12/20/2017

ord,nrmrl,aemd	ORD-020668	Air Pollution Abatement Performances of Green Infrastructure in Different Urban Environments – A Review	Richard Baldauf	4/25/2017
ord,nheerl,tad,nb	ORD-020669	EFFECTS OF MATERNAL HIGH FAT DIET AND SEDENTARY LIFESTYLE ON SUSCEPTIBILITY OF ADULT OFFSPRING TO OZONE EXPOSURE IN RATS	Christopher Gordon	3/8/2017
ord,ncea,nceacin, brab	ORD-020670	Risks to Fish Habitats and Populations Associated with a Transportation Corridor for Proposed Mine Operations in a Salmon-rich Watershed	Michael Kravitz	8/23/2017

ord,nerl,emmd	ORD-020680	Altmetric: 165More detail Article | OPEN Climate change-induced increases in precipitation are reducing the potential for solar ultraviolet radiation to inactivate pathogens in surface waters	Richard Zepp	11/22/2017
ord,nerl,ced	ORD-020682	Impacts of aerosol direct effects on tropospheric ozone through changes in atmospheric dynamics and photolysis rates	Rohit Mathur	3/14/2017
ord,nhsrc,dcmd	ORD-020691	Inactivation of Bacillus anthracis spores to decontaminate subway railcar and related materials via the fogging of peracetic acid and hydrogen peroxide sporicidal liquids	Joe Wood	5/31/2017

ord,nerl,sed	ORD-020724	Developing and applying metamodels of high resolution process-based simulations for high throughput exposure assessment of organic chemicals in riverine ecosystems	Craig Barber	3/27/2017
ord,nerl,emmd	ORD-020756	Constraints on primary and secondary particulate carbon sources using chemical tracer and 14C methods during CalNex-Bakersfield	Michael Lewandowski	8/14/2017
ord,nrmrl,std,cpb	ORD-020759	Agroecology for the Shrinking City	Matthew Hopton	3/17/2017
ord,nrmrl,wsd,wrrb	ORD-020778	Situating Green Infrastructure in Context: A Framework for Adaptive Socio-Hydrology in Cities	Dustin Herrmann	4/25/2017

ord,nheerl,med,stb	ORD-020780	Prioritization of contaminants of emerging concern in wastewater treatment plant discharges using chemical: Gene interactions in caged fish	Dan Villeneuve	3/7/2017
ord,nerl,emmd	ORD-020790	Environmental effects of ozone depletion and its interactions with climate change: Progress report, 2016	Richard Zepp	5/22/2017
ord,nheerl,ged	ORD-020792	Oil Spill Research in the Bulletin	Mace Barron	3/8/2017
ord,nrmrl,wsd,dwtdb	ORD-020808	Scale Formation under Blended Phosphate Treatment for a Utility with Lead Pipes	Michael Schock	4/14/2017
ord,nrmrl,wsd,wrrb	ORD-020816	A global database of nitrogen and phosphorus excretion rates of aquatic animals	Matthew Hopton	3/17/2017

ord,nerl,sed	ORD-020838	High reduction of ozone and particulate matter during the 2016 G-20 summit in Hangzhou by forced emission controls of industry and traffic	Kiran Alapaty	9/19/2017
ord,nheerl,aed,mab	ORD-020850	Integrating watershed hydrology and economics to establish a local market for water quality improvement: A field experiment	Nathaniel Merrill	4/13/2017
ord,nheerl,wed,pceb	ORD-020859	Macrophyte Community Response to Nitrogen Loading and Thermal Stressors in Rapidly Flushed Mesocosm Systems	Jim Kaldy	3/17/2017

ord,nheerl,ged	ORD-020863	A Conceptual Model to Assess Stress-Associated Health Effects of Multiple Ecosystem Services Degraded by Disaster Events in the Gulf of Mexico and Elsewhere	Lisam Smith	3/16/2017
ord,ioaa,N/A	ORD-020877	Overcoming Global Pressures to Achieve a Healthy, Resilient and Sustainable Society	Alan Hecht	3/17/2017
ord,nerl,ced	ORD-020879	Semivolatile POA and parameterized total combustion SOA in CMAQv5.2: impacts on source strength and partitioning	Benjamin Murphy	4/3/2017
ord,nerl,ced,amaab	ORD-020887	Interaction between Soil Moisture and Air Temperature in the Mississippi River Basin	Chunling Tang	8/23/2017

ord,nheerl,ged	ORD-020896	Framework for Optimizing Selection of Interspecies Correlation Estimation Models to Address Species Diversity and Toxicity Gaps in an Aquatic Database	Mace Barron	3/20/2017
ord,nerl,ced,amaab	ORD-020899	Advanced error diagnostics of the CMAQ and Chimere modelling systems within the AQMEII3 model evaluation framework	Christian Hogrefe	9/29/2017
ord,nerl,ced	ORD-020909	Basin-wide impacts of climate change on ecosystem services in the Lower Mekong Basin	JohnM Johnston	3/23/2017

ord,nheerl,tad,etb	ORD-020910	Neurodevelopment and Thyroid Hormone Synthesis Inhibition in the Rat: Quantitative Understanding Within the Adverse Outcome Pathway Framework	Mary Gilbert	8/23/2017
ord,nerl,ced,hedmb	ORD-020911	Consumer product chemical weight fractions from ingredient lists	Kristin Isaacs	12/4/2017
ord,nerl,emmd	ORD-020918	Influences of Coal Ash Leachates and Emergent Macrophytes on Water Quality in Wetland Microcosms	Clay Nelson	9/25/2017
ord,nrmrl,lmmd,lcdsb	ORD-020921	Enhancing quantitative approaches for assessing community resilience	Ahjond Garmestani	3/31/2017
ord,nheerl,wed,feb	ORD-020926	A Nitrogen Physical Input-Output Table (PIOT) Model for Illinois	Jana Compton	3/23/2017

ord,nheerl,med,ttb	ORD-020930	Factors that influence vital rates of Seaside and Saltmarsh sparrows in coastal New Jersey, USA	Matthew Etterson	3/29/2017
ord,nerl,emmd	ORD-020933	Is biochar-manure co-compost a better solution for soil health improvement and N2O emissions mitigation?	DavidJ Williams	9/14/2017
ord,nerl,emmd	ORD-020934	Simulating Multiwalled Carbon Nanotube Transport in Surface Water Systems Using the Water Quality Analysis Simulation Program (WASP)	Dermont Bouchard	9/13/2017
ord,nerl,emmd	ORD-020949	A Comparison of Simulated and Field-Derived Leaf Area Index (LAI) and Canopy Height Values from Four Forest Complexes in the Southeastern USA	John Iiames	4/27/2017

ord,nerl,sed,ehcab	ORD-020961	Spatial Patterns of NLCD Land Cover Change Thematic Accuracy (2001 - 2011)	James Wickham	11/9/2017
ord,nheerl,istd,sbb	ORD-020969	Genomic effects of androstenedione and sex-specific liver cancer susceptibility in mice	Chris Corton	4/19/2017
ord,nrmrl,std,cpb	ORD-021041	Measuring urban tree loss dynamics across residential landscapes	Matthew Hopton	4/14/2017
ord,nheerl,aed	ORD-021047	A Marketing Plan for Scientists: Building Effective Products and Connecting with Stakeholders in Meaningful Ways	Marisa Mazzotta	5/22/2017
ord,nheerl,tad,nb	ORD-021055	THE MOUSE THERMOREGULATORY SYSTEM: ITS IMPACT ON TRANSLATING BIOMEDICAL DATA TO HUMANS	Christopher Gordon	3/29/2017

ord,nerl,sed,ehcab	ORD-021102	Recommendations for developing and applying genetic tools to assess and manage biological invasions in marine ecosystems	John Darling	6/16/2017
ord,nerl,emmd,mieb	ORD-021107	Opportunistic Pathogens and Microbial Communities and their Associations with Sediment Physical Parameters in Drinking Water Storage Tank Sediments	Jingrang Lu	10/10/2017
ord,nerl,emmd,mieb	ORD-021108	Campylobacter jejuni Colonization in the Crow Gut reveals High Deletion Within Cytolethal Distending Toxin Gene Cluster	Jingrang Lu	1/17/2018
ord,nerl,ced	ORD-021111	Ecohydrological index, native fish, and climate trends and relationships in the Kansas River basin	Muluken Muche	8/28/2017

ord,nheerl,istd,sbb	ORD-021112	Screening the ToxCast phase II libraries for alterations in network function using cortical neurons grown on multi-well microelectrode array (mwMEA) plates	Tim Shafer	5/1/2017
ord,nheerl,ged	ORD-021115	Parameter sensitivity and identifiability for a biogeochemical model of hypoxia in the northern Gulf of Mexico	Marcus Beck	5/2/2017
ord,nerl,emmd	ORD-021126	Chemical characterization and sources of PM2.5 at 12-h resolution in Guiyang, China	Matthew Landis	11/16/2017
ord,nheerl,ephd,crb	ORD-021137	The health impacts and economic value of wildland fire episodes in the U.S.: 2008-2012	Neal Fann	4/17/2017

ord,nerl,emmd	ORD-021144	Evaluating a Space-Based Indicator of Surface Ozone-NOx-VOC Sensitivity Over Midlatitude Source Regions and Application to Decadal Trends	Lukas Valin	12/11/2017
ord,nerl,sed,eib	ORD-021145	Hydrological, Physical, and Chemical Functions and Connectivity of Non‐Floodplain Wetlands to Downstream Waters: A Review	Charles Lane	5/5/2017
ord,nerl,ced,amdbr	ORD-021153	Evaluation of the Community Multiscale Air Quality Model for Simulating Winter Ozone Formation in the Uinta Basin.	Deborah Luecken	5/22/2017
ord,nerl,ced,amaab	ORD-021158	Assessing Model Characterization of Single Source Secondary Pollutant Impacts Using 2013 SENEX Field Study Measurements	Matthew Woody	4/7/2017

ord,nrmrl,aemd,dsbb	ORD-021161	Temperature and driving cycle significantly affect semi-volatile organic compound emissions from diesel trucks	Michael Hays	4/28/2017
ord,ncct,N/A	ORD-021164	(REGULATORY TOXICOLOGY AND PHARMACOLOGY) On Selecting a Minimal Set of In Vitro Assays to Reliably Determine Estrogen Agonist Activity	Richard Judson	4/14/2017
ord,nerl,emmd	ORD-021171	Monoterpenes are the largest source of summertime organic aerosol in the southeastern United States	John Offenberg	1/29/2018
ord,nheerl,tad,dtb	ORD-021174	Engineering human cell spheroids to model embryonic tissue fusion in vitro.	Barbara Abbott	4/26/2017
ord,nerl,emmd	ORD-021181	A statistical framework for applying RNA profiling to chemical hazard detection	Mitchell Kostich	8/29/2017

ord,nerl,ced	ORD-021191	Extending the Community Multiscale Air Quality (CMAQ) Modeling System to Hemispheric Scales: Overview of Process Considerations and Initial Applications	Rohit Mathur	8/31/2017
ord,nhsrc,wipd	ORD-021215	Microbial Toxicity Following Boron-Doped Diamond Electrochemical Advanced Oxidation Treatment of Contaminated Waters	Matthew Magnuson	7/11/2017
ord,nerl,emmd	ORD-021221	Scenario Evaluator for Electrical Resistivity Survey Pre-modeling Tool	D Werkema	12/20/2017
ord,nerl,emmd	ORD-021222	Cellular respiration, metabolomics and the search for illicit drug biomarkers in breath: report from PittCon 2017	Joachim Pleil	5/8/2017

ord,nheerl,wed,eeb	ORD-021225	Longitudinal thermal heterogeneity in rivers and refugia for coldwater species: effects of scale and climate change	Joe Ebersole	4/24/2017
ord,nhsrc,wipd	ORD-021227	Full Scale Drinking Water System Decontamination at the Water Security Test Bed	Jeff Szabo	5/1/2017
ord,nheerl,wed,eeb	ORD-021258	Estimating wetland connectivity to streams in the Prairie Pothole Region: an isotopic and remote sensing approach	Reneej Brooks	4/26/2017
ord,nrmrl,aemd	ORD-021261	Field determination of multipollutant, open area combustion source emission factors with a hexacopter unmanned aerial vehicle	Brian Gullett	5/12/2017

ord,nerl,ced	ORD-021264	The influence of ocean halogen and sulfur emissions in the air quality of a coastal megacity: The case of Los Angeles	Golam Sarwar	8/2/2017
ord,nrmrl,lrpcd,wmb	ORD-021266	Sequestration of U(VI) from Acidic, Alkaline, and High Ionic-Strength Aqueous Media by Functionalized Magnetic Mesoporous Silica Nanoparticles: Capacity and Binding Mechanisms	Kirk Scheckel	6/13/2017
ord,nheerl,wed,eeb	ORD-021337	Interactions of predominant insects and diseases with climate change in Douglas-fir forests of western Oregon and Washington, U.S.A.	EHenry Lee	4/26/2017

ord,nerl,emmd	ORD-021351	Calibration and performance of synchronous SIM/scan mode for simultaneous targeted and discovery (non-targeted) analysis of exhaled breath samples from firefighters	Ariel Wallace	7/26/2017
ord,nheerl,adh	ORD-021353	Fine Particulate Matter and Cardiovascular Disease: Comparison of Assessment Methods for Long-term Exposure	Robert Devlin	5/3/2017
ord,nerl,emmd	ORD-021359	Application of passive sorbent tube and canister samplers for volatile organic compounds at refinery fenceline locations in Whiting, Indiana	Shaibal Mukerjee	10/31/2017

ord,nheerl,ged	ORD-021379	Mode of Action (MOA) Assignment Classifications for Ecotoxicology: An Evaluation of approaches	Mace Barron	5/10/2017
ord,nerl,emmd	ORD-021472	Ozonolysis of α/β-farnesene mixture: Analysis of gas-phase and particulate reaction products	Mohammed Jaoui	9/5/2017
ord,nerl,emmd	ORD-021482	Effects of chlorpyrifos and trichloropyridinol on HEK 293 human embryonic kidney cells	Jeanette VanEmon	11/20/2017
ord,nheerl,ephd	ORD-021505	Dollars and Deadlines: Rule Reforms in Short Time Frames	Daniel Nelson	4/27/2017
ord,nerl,emmd	ORD-021579	Evidence of a sewer vapor transport pathway at the USEPA vapor intrusion research duplex	JohnH Zimmerman	6/13/2017

ord,nrmrl,lmmd,rteb	ORD-021605	Reactive gaseous mercury is generated from chloralkali factories resulting in extreme concentrations of mercury in hair of workers	Kirk Scheckel	11/13/2017
ord,nheerl,aed,mab	ORD-021614	Non-monetary valuation using Multi-Criteria Decision Analysis: Sensitivity of additive aggregation methods to scaling and compensation assumptions	DavidM Martin	5/22/2017
ord,ncea,nceartp,emag	ORD-021617	Research standardization tools: pregnancy measures in the PhenX Toolkit	Erin Hines	6/16/2017

ord,ncea,nceartp, emag	ORD-021619	The reduction of summer sulfate and switch from summertime to wintertime PM2.5 concentration maxima in the United States	Stephen McDow	9/28/2017
ord,nerl,emmd	ORD-021631	High‐resolution mass spectrometry of skin mucus for monitoring physiological impacts and contaminant biotransformation products in fathead minnows exposed to wastewater effluent	Jonathan Mosley	5/11/2017
ord,nerl,emmd,ieib	ORD-021633	Solar photo-Fenton treatment of microcystin-LR in aqueous environment: Transformation products and toxicity in different water matrices	Armah Delacruz	5/25/2017

ord,nheerl,adh,rcu	ORD-021652	AOP-DB: A database resource for the exploration of Adverse Outcome Pathways through integrated association networks.	Holly Mortensen	5/11/2017
ord,nerl,emmd	ORD-021688	The impact of the 2016 Fort McMurray Horse River Wildfire on ambient air pollution levels in the Athabasca Oil Sands Region, Alberta, Canada	Matthew Landis	10/4/2017
ord,nerl,sed	ORD-021690	Projecting state-level air pollutant emissions using an integrated assessment model: GCAM-USA.	Chris Nolte	11/6/2017
ord,nheerl,ged	ORD-021693	Toxicity of Cold Lake Blend and Western Canadian Select dilbits to standard aquatic test species	Mace Barron	5/15/2017

ord,nheerl,med,ttb	ORD-021749	The acute toxicity of major ion salts to Ceriodaphnia dubia: III. Mathematical models for mixture toxicity	Russell Erickson	6/21/2017
ord,ncea,nceartp	ORD-021764	Disparities in Distribution of Particulate Matter Emission Sources by Race and Poverty Status	Ihab Mikati	7/12/2017
ord,nheerl,aed,wdb	ORD-021768	An R Package for Open, Reproducible Analysis of Urban Water Systems, With Application to Chicago	Dan Campbell	6/1/2017
ord,nheerl,istd,sbb	ORD-021807	The PPARα-dependent rodent liver tumor response is not relevant to humans: Addressing misconceptions	Chris Corton	9/18/2017
ord,nrmrl,appcd,ecpb	ORD-021812	Influential factors affecting black carbon trends at four sites of differing distance from a major highway in Las Vegas	Sue Kimbrough	5/31/2017

ord,nrmrl,lmmd,lcdsb	ORD-021814	Exploring the relevance of spatial scale to life cycle inventory results using environmentally-extended input-output models of the United States	Wesley Ingwersen	6/28/2017
ord,nheerl,ephd,eb	ORD-021835	Asymptomatic norovirus infection associated with swimming at a tropical beach: A prospective cohort study	Tim Wade	6/16/2017
ord,nerl,sed,eib	ORD-021863	Green infrastructure and its catchment-scale effects: an emerging science	Heather Golden	6/12/2017
ord,nerl,emmd	ORD-021911	In vivo and in vitro methods for evaluating soil arsenic bioavailability: relevant to human health risk assessment	Karen Bradham	4/23/2018

ord,ncer,ased	ORD-021924	Impact of intercontinental pollution transport on North American ozone air pollution: an HTAP phase 2 multi-model study	Terry Keating	10/19/2017
ord,ncea,nceartp, emag	ORD-021942	Population-Based Case–Control Study of the Association between Weather-Related Extreme Heat Events and Neural Tube Defects	Tom Luben	5/25/2017
ord,ncea,nceartp	ORD-021991	Application of Epigenetic Data in Health Risk Assessment	John Vandenberg	6/8/2017
ord,nerl,ced,hed mb	ORD-021994	Investigating the state of physiologically based kinetic modelling practices and challenges associated with gaining regulatory acceptance of model applications	Cecilia Tan	9/7/2017

ord,nerl,emmd	ORD-021999	Differences in staining intensities affect reported occurrences and concentrations of Giardia spp. in surface drinking water sources	Eric Villegas	9/7/2017
ord,nrmrl,wswrd	ORD-022001	Quantitative CrAssphage PCR Assays for Human Fecal Pollution Measurement	Orin Shanks	8/11/2017
ord,ncea,nceartp, emag	ORD-022029	A cross-disciplinary evaluation of evidence for multipollutant effects on cardiovascular disease article	Tom Luben	7/19/2017
ord,nerl,ced	ORD-022061	An analysis of cumulative risks based on biomonitoring data for six phthalates using the Maximum Cumulative Ratio	PaulS Price	6/12/2017
ord,nheerl,med,esb	ORD-022064	Determining preferences for ecosystem benefits in Great Lakes Areas of Concern from photographs posted to social media	Theodore Angradi	10/24/2017

ord,nerl,emmd	ORD-022067	Impacts of a large boreal wildfire on ground level atmospheric concentrations of PAHs, VOCs and ozone	Matthew Landis	1/22/2018
ord,nheerl,ephd,crb	ORD-022089	In Vitro Exposure Systems and Dosimetry Assessment Tools for Inhaled Tobacco Products: Workshop Proceedings, Conclusions, and Paths Forward for In Vitro Model Use	Shaun McCullough	6/29/2017
ord,nerl,emmd	ORD-022096	Relating soil geochemical properties to arsenic bioaccessibility through hierarchical modeling.	Clay Nelson	1/23/2018
ord,nheerl,ephd,cib	ORD-022107	Zebrafish Locomotor Responses Reveal Irritant Effects of Fine Particulate Matter Extracts and a Role for TRPA1	Aimen Farraj	6/12/2017

ord,nheerl,istd	ORD-022111	Creating a Structured Adverse Outcome Pathway Knowledgebase via Ontology-Based Annotations	Stephen Edwards	6/8/2017
ord,nheerl,ephd,crb	ORD-022116	The Dynamics of Smoking-Related Disturbed Methylation: A Two Time-Point Study of Methylation Change in Smokers, Non-Smokers and Former Smokers	Cavin Ward-Caviness	2/28/2018
ord,nrmrl,aemd,ssb	ORD-022126	Light absorption of secondary organic aerosol: Composition and contribution of nitro-aromatic compounds	Amara Holder	6/15/2017
ord,nerl,emmd	ORD-022161	Suspect Screening and Non-Targeted Analysis of Drinking Water Using Point-Of-Use Filters	Seth Newton	12/8/2017
ord,nheerl,med,stb	ORD-022168	Metabolism of diazinon in rainbow trout liver slices	Mark Tapper	12/6/2017

ord,nrmrl,aemd	ORD-022184	Improving post-detonation energetics residues estimations for the Life Cycle Environmental Assessment process for munitions.	Brian Gullett	6/15/2017
ord,nerl,sed,ehcab	ORD-022221	Comparison of Five Modeling Approaches to Quantify and Estimate the Effect of Clouds on the Radiation Amplification Factor (RAF) for Solar Ultraviolet Radiation	EricS Hall	8/24/2017
ord,nerl,emmd	ORD-022236	Size-selective sampling performance of six low-volume “total” suspended particulate (TSP) inlets	Robert Vanderpool	9/11/2017
ord,nerl,emmd	ORD-022277	The Superstatistical Nature and Interoccurrence Time of Atmospheric Mercury Concentration Fluctuations	Matthew Landis	12/7/2017

ord,nerl,emmd,ieib	ORD-022280	Social hierarchy modulates responses of fish exposed to contaminants of emerging concern	Rong-Lin Wang	6/22/2017
ord,nerl,emmd	ORD-022287	The Role of Epigenomics in Aquatic Toxicology	Adam Biales	8/8/2017
ord,nerl,emmd	ORD-022355	Low-Cost Sensor POD Design Considerations	Ron Williams	8/10/2017
ord,nerl,sed,eib	ORD-022360	Estimating restorable wetland water storage at landscape scales	Charles Lane	8/15/2017
ord,nerl,sed,eib	ORD-022361	Empirically-based modeling and mapping to consider the co-occurrence of ecological receptors and stressors	Roy Martin	6/26/2017
ord,nheerl,aed,wdb	ORD-022424	Effect of nutrient pollution on dinoflagellate cyst assemblages across estuaries of the NW Atlantic	Jim Latimer	7/13/2017

ord,nrmrl,wsd,wmb	ORD-022432	Benefit transfer challenges: Perspectives from U.S. Practitioners	Matt Heberling	8/25/2017
ord,nheerl,ged,beprb	ORD-022436	3D-QSAR Study of Steroidal and Azaheterocyclic Human Aromatase Inhibitors using Quantitative Profile of Protein-Ligand Interactions	Mace Barron	7/13/2017
ord,nheerl,ged,beprb	ORD-022437	Mixed Phylogenetic Signal in Fish Toxicity Data across Chemical Classes	Mace Barron	9/29/2017
ord,ioaa,N/A	ORD-022438	EPA leadership on Science, Innovation, and Decision Support Tools for Addressing Current and Future Challenges	Alan Hecht	6/29/2017
ord,nerl,emmd,mieb	ORD-022449	Quantification of mold contamination in multi-level buildings using the Environmental Relative Moldiness Index	Stephen Vesper	11/20/2017

ord,nerl,ced	ORD-022473	Coupling of organic and inorganic aerosol systems and the effect on gas–particle partitioning in the southeastern US	Havala Pye	8/22/2017
ord,nheerl,ged,beprb	ORD-022477	A linked land-sea modeling framework to inform ridge-to-reef management in high oceanic islands	Susan Yee	7/7/2017
ord,nheerl,ephd,cib	ORD-022484	Differential exposure and acute health impacts of inhaled solid-fuel emissions from rudimentary and advanced cookstoves in female CD-1 mice.	Janice Dye	7/20/2017
ord,nheerl,wed,eeb	ORD-022513	HexSim: a modeling environment for ecology and conservation.	Nathan Schumaker	9/8/2017

ord,nrmrl,lmmd,eceb	ORD-022519	Dermal transfer and environmental release of CeO2 nanoparticles used as UV inhibitors on outdoor surfaces: Implications for human and environmental health	Todd Luxton	8/21/2017
ord,nheerl,wed,eeb	ORD-022541	Land use, climate, and water resources – global stages of interaction	Paul Mayer	9/25/2017
ord,nheerl,ged,edeb	ORD-022552	Water quality trends following anomalous phosphorus inputs to Grand Bay, Mississippi, USA	Marcus Beck	8/1/2017
ord,nerl,emmd	ORD-022569	Mutagenic atmospheres resulting from the photooxidation of aromatic hydrocarbon and NOx mixtures	Theran Riedel	1/29/2018

ord,nerl,emmd	ORD-022586	Assessment of mixed-layer height estimation from single-wavelength ceilometer profiles	Jim Szykman	9/14/2017
ord,nrmrl,gwerd	ORD-022588	Determination of Cr(III) solids formed by reduction of Cr(VI) in a contaminated fractured bedrock aquifer: evidence for natural attenuation of Cr(VI)	Rick Wilkin	8/3/2017
ord,nheerl,wed,feb	ORD-022589	Trends in Drinking Water Nitrate Violations Across the United States	Michael Pennino	8/8/2017
ord,nrmrl,wsd,wrrb	ORD-022598	Investigation clogging dynamic of permeable pavement systems using embedded sensors	Mike Borst	8/11/2017
ord,nheerl,ephd,crb	ORD-022602	Oxidative Stress from Environmental Exposures	James Samet	7/20/2017

ord,nrmrl,aemd,ssb	ORD-022628	Comparison of gaseous and particulate emissions from a pilot-scale combustor using three varieties of coal	Tiffany Yelverton	7/26/2017
ord,nerl,emmd,aqb	ORD-022629	Barrierless Reactions with Loose Transition States Govern the Yields and Lifetimes of Organic Nitrates Derived from Isoprene	Ivan Piletic	10/24/2017
ord,nerl,ced,amaab	ORD-022631	Impacts of different characterizations of large-scale background on simulated regional-scale ozone over the continental United States	Christian Hogrefe	4/10/2018
ord,nheerl,med	ORD-022639	Toxicokinetics of the neonicotinoid insecticide imidacloprid in rainbow trout (Oncorhynchus mykiss)	John Nichols	10/12/2017

ord,nrmrl,wsd,wrrb	ORD-022655	Factors contributing to the hydrologic effectiveness of a rain garden network (Cincinnati OH USA)	William Shuster	8/2/2017
ord,nheerl,aed,wdb	ORD-022659	Indicators of nutrient pollution in Long Island, New York, estuarine environments	Autumn Oczkowski	8/7/2017
ord,nheerl,aed,peb	ORD-022716	Detection and Quantification of Graphene-Family Nanomaterials in the Environment	Robert Burgess	9/15/2017
ord,nheerl,ged,beprb	ORD-022726	Photoenhanced toxicity of weathered crude oil in sediment and water to larval zebrafish	Mace Barron	9/18/2017
ord,nrmrl,wsd	ORD-022738	A Human Fecal Contamination Score for Ranking Recreational Sites using the HF183/BacR287 Quantitative Real-Time PCR Method	Orin Shanks	8/25/2017

ord,nheerl,ged,beprb	ORD-022823	A Framework for Linking Population Model Development with Ecological Risk Assessment Objectives.	Sandy Raimondo	9/7/2017
ord,nrmrl,wsd,wrrb	ORD-022834	Porous nitrogen-enriched carbonaceous material from marine waste: chitosan-derived layered CNX catalyst for aerial oxidation of 5-hydroxymethylfurfural (HMF) to 2,5-furandicarboxylic acid	Rajender Varma	8/25/2017
ord,nerl,sed	ORD-022844	Systematic Review: Land Cover, Meteorological, and Socioeconomic Determinants of Aedes Mosquito Habitat for Risk Mapping	Mohamed Sallam	11/17/2017

ord,nerl,emmd,mieb	ORD-022845	Comparison of indoor air sampling and dust collection methods for fungal exposure assessment using quantitative PCR	Stephen Vesper	9/1/2017
ord,nheerl,med	ORD-022861	Estimating intermittent individual spawning behavior via disaggregating group data	Gerald Ankley	8/9/2017
ord,nrmrl,lmmd,mmb	ORD-022866	Environmental aging and degradation of multiwalled carbon nanotube reinforced polypropylene	Endalkachew Sahle-Demessie	4/11/2018
ord,nheerl,ephd,cib	ORD-022894	Comparative cardiopulmonary effects of particulate matter- and ozone-enhanced smog atmospheres in mice	Mehdi Hazari	8/18/2017

ord,nerl,emmd	ORD-022913	Characterization of engineered nanoparticles in commercially available spray disinfectant products advertised to contain colloidal silver	Kim Rogers	12/7/2017
ord,nerl,sed,eib	ORD-022914	Comparing Pixel- and Object-Based Approaches in Effectively Classifying Wetland-Dominated Landscapes	Charles Lane	10/18/2017
ord,nheerl,aed,peb	ORD-022916	Multi-Century Record of Anthropogenic Impacts on an Urbanized Mesotidal Estuary: Salem Sound, MA	Mark Cantwell	8/17/2017
ord,nheerl,istd,gctb	ORD-022925	The Aggregate Exposure Pathway (AEP) and Adverse Outcome Pathway (AOP) frameworks facilitate the integration of human health and ecological endpoints for Cumulative Risk Assessment (CRA)	Stephen Edwards	9/14/2017

ord,nrmrl,gwerd,sppb	ORD-022935	Groundwater Co-Contaminant Behavior of Arsenic and Selenium at a Lead and Zinc Smelting Facility	Rick Wilkin	11/28/2017
ord,nheerl,med,stb	ORD-022967	A comparison of fish pesticide metabolic pathways with those of the rat and goat	Rick Kolanczyk	9/19/2017
ord,nheerl,istd,gctb	ORD-022988	Evaluation of an Air Quality Health Index for Predicting the Mutagenicity of Simulated Atmospheres	David DeMarini	9/11/2017
ord,nrmrl,aemd,dsbb	ORD-023013	On-road Emissions and Chemical Transformation of Nitrogen Oxides	Richard Baldauf	9/14/2017
ord,nerl,ced,hedmb	ORD-023019	Challenges Associated With Applying Physiologically Based Pharmacokinetic Modeling for Public Health Decision-Making	Cecilia Tan	11/6/2017

ord,nheerl,med	ORD-023043	Screening the ToxCast Phase 1 chemical library for inhibition of deiodinase type 1 activity	Michael Hornung	9/29/2017
ord,nheerl,aed,peb	ORD-023049	Bioaccumulation and Biological Effects of Dietary Exposure to the Alternative Brominated Flame Retardant, Bis(2-ethylhexyl) tetrabromophthalate (TBPH), in the Atlantic killifish, Fundulus heteroclitus.	Diane Nacci	8/30/2017
ord,nheerl,med,ttb	ORD-023060	Factors associated with bat mortality at wind energy facilities in the United States	Matthew Etterson	8/17/2017
ord,nerl,emmd	ORD-023073	Exhaled breath aerosol (EBA): the simplest non-invasive medium for public health and occupational exposure biomonitoring	Joachim Pleil	11/6/2017

ord,nheerl,tad	ORD-023081	Commentary: Should All Tests of Cognitive Function – Learning, Memory, Attention – be Eliminated From the Required Protocols for Developmental Neurotoxicity Testing?	David Herr	8/18/2017
ord,nerl,emmd	ORD-023096	Photochemical Conversion of Surrogate Emissions for Use in Toxicological Studies: Role of Particulate- and Gas-Phase Products	Jonathan Krug	8/24/2017
ord,nheerl,med,ttb	ORD-023119	Reproductive success and contaminant associations in tree swallows (Tachycineta bicolor) used to assess a beneficial use impairment in U.S. and Binational Great Lakes’ Areas of Concern	Matthew Etterson	8/31/2017

ord,nerl,ced	ORD-023139	Enhancements to AERMOD's building downwash algorithms based on wind-tunnel and Embedded-LES modeling	David Heist	3/9/2018
ord,nerl,sed,ehcab	ORD-023156	Distribution, Variability, and Predictors of Urinary Bisphenol-A Levels in 50 North Carolina Adults over a Six-Week Monitoring Period	Marsha Morgan	11/27/2017
ord,nerl,sed	ORD-023180	Demonstration of a consensus approach for the calculation of physicochemical properties required for environmental fate assessments	Caroline Stevens	9/19/2017
ord,nrmrl,aemd,ssb	ORD-023223	Evaluating the Performance of Household Liquefied Petroleum Gas Cookstoves	Jim Jetter	9/29/2017

ord,nerl,sed	ORD-023231	Monitoring wastewater for assessing community health: Sewage Chemical-Information Mining (SCIM)	Christian Daughton	11/15/2017
ord,nerl,emmd	ORD-023239	Geophysical Methods for Monitoring Soil Stabilization Processes	D Werkema	11/22/2017
ord,nrmrl,lmmd,eceb	ORD-023353	Toward Automated Inventory Modeling in Life Cycle Assessment: The Utility of Semantic Data Modeling to Predict Real-WorldChemical Production	Raymond Smith	9/20/2017
ord,nheerl,adh,rcu	ORD-023369	Leveraging human genetic and adverse outcome pathway (AOP) data to inform susceptibility in human health risk assessment	Holly Mortensen	9/22/2017

ord,nheerl,med	ORD-023375	A reduced transcriptome approach to assess environmental toxicants using zebrafish embryo tests	Dan Villeneuve	9/19/2017
ord,nheerl,med	ORD-023381	Effects of multiple life stage exposure to the fungicide prochloraz in Xenopus laevis: Manifestations of antiandrogenic and other modes of toxicity	Sigmund Degitz	12/18/2017
ord,nheerl,ged,beprb	ORD-023384	Simulated developmental and reproductive impacts on amphibian populations and implications for assessing long-term effects	Jill Awkerman	9/25/2017
ord,nerl,emmd	ORD-023388	Low-Cost Air Quality Monitoring Tools: From Research to Practice (A Workshop Summary)	Andrea Clements	10/16/2017

ord,nrmrl,lmmd,lcdsb	ORD-023451	Assessing cross-scale patterns and the composition of ecological communities of alternative lake regimes	Ahjond Garmestani	10/2/2017
ord,nheerl,ephd,crb	ORD-023462	Long-term air pollution exposure, genome-wide DNA methylation and lung function in the LifeLines cohort study.	Cavin Ward-Caviness	3/12/2018
ord,nerl,rpcs	ORD-023505	Characterizing Air Quality in a Rapidly Changing World	Gayle Hagler	11/14/2017
ord,nheerl,aed,peb	ORD-023551	Cross Validation of Two Partitioning-Based Sampling Approaches in Mesocosms Containing PCB Contaminated Field Sediment, Biota, and Activated Carbon Amendment	Robert Burgess	10/3/2017

ord,nheerl,med,esb	ORD-023613	Influence of dilution water ionic composition on acute major ion toxicity to the mayfly Neocloeon triangulifer	Dave Mount	3/2/2018
ord,nrmrl,lmmd,rteb	ORD-023628	Riparian spiders as sentinels of PCB contamination across heterogeneous aquatic ecosystems	Marc Mills	9/28/2017
ord,nerl,emmd	ORD-023642	Continuous flow hygroscopicity-resolved relaxed eddy accumulation (Hy-Res REA) method of measuring size-resolved sodium chloride particle fluxes	Jason Weinstein	4/12/2018
ord,ncct,N/A	ORD-023667	(Journal of Cheminformatics) The CompTox Chemistry Dashboard - A Community Data Resource for Environmental Chemistry	Antony Williams	3/19/2018

ord,ncea,nceartp,io	ORD-023674	Alternative Approaches for Acute Inhalation Toxicity Testing to Address Global Regulatory and Non-Regulatory Data Requirements: An International Workshop Report	Annie Jarabek	10/18/2017
ord,nerl,sed,efab	ORD-023764	Modeled De Facto Reuse and Contaminants of Emerging Concern in Drinking Water Source Waters	Susan Glassmeyer	1/9/2018
ord,nheerl,aed,wdb	ORD-023863	Carbon Stable Isotope Values in Plankton and Mussels Reflect Changes in Carbonate Chemistry Associated with Nutrient Enhanced Net Production	Autumn Oczkowski	10/16/2017

ord,nheerl,aed,mab	ORD-023917	Bamboo vs. crops: An integrated emergy and economic evaluation of using bamboo to replace crops in south Sichuan Province, China	Dan Campbell	11/20/2017
ord,nheerl,ephd,crb	ORD-023921	Transition and post-transition metals in exhaled breath condensate	Andy Ghio	11/2/2017
ord,nheerl,ged,beprb	ORD-023974	Response to Comment on “Mode of Action (MOA) Assignment Classifications for Ecotoxicology: An Evaluation of Approaches”	Mace Barron	10/31/2017
ord,nheerl,med,stb	ORD-024133	Year-round presence of neonicotinoid insecticides in tributaries to the Great Lakes, USA	Brett Blackwell	11/2/2017

ord,nerl,emmd,ieib	ORD-024201	Use of Selected Scavengers for the Determination of NF-TiO2 Reactive Oxygen Species During the Degradation of Microcystin-LR Under Visible Light Irradiation	Armah Delacruz	1/25/2018
ord,nerl,emmd	ORD-024302	Tenth anniversary special issue of the Journal of Breath Research: looking forward	Joachim Pleil	12/4/2017
ord,ioaa,N/A	ORD-024349	Accelerating the Pace of Chemical Risk Assessment	Maureen Gwinn	11/16/2017
ord,nrmrl,lmmd,rteb	ORD-024352	The Challenges of PFAS Remediation	John McKernan	11/17/2017
ord,nheerl,ephd,eb	ORD-024363	Exploring links between greenspace and sudden unexpected death: a spatial analysis	Laura Jackson	11/22/2017

ord,nerl,sed	ORD-024375	Estimating environmental co-benefits of U.S. low-carbon pathways using an integrated assessment model with state-level resolution	Yang Ou	12/4/2017
ord,nheerl,ephd,crb	ORD-024548	Review: Endogenously Produced Volatiles for In Vitro Toxicity Testing Using Cell Lines	Michael Madden	12/15/2017
ord,nheerl,med,esb	ORD-024549	A field observation of rotational feeding by Neogobius melanostomus	Theodore Angradi	12/14/2017
ord,nerl,emmd	ORD-024644	Towards a Satellite-Based Near Real-Time Monitoring System for Water Quality; September 27th 2017	Blake Schaeffer	3/5/2018
ord,nerl,ced,hedmb	ORD-024675	Refining the aggregate exposure pathway	Cecilia Tan	2/20/2018

ord,nhsrc,wipd	ORD-024682	Electrophoretic mobility of Legionella pneumophila serogroups 1 to 14	Helen Buse	1/24/2018
ord,nerl,emmd	ORD-024738	Environmental effects of ozone depletion, UV radiation and interactions with climate change: UNEP Environmental Effects Assessment Panel, update 2017	Richard Zepp	2/21/2018
ord,nheerl,med	ORD-025059	Updated polychlorinated biphenyl mass budget for Lake Michigan	Russell Kreis	3/2/2018
ord,nerl,emmd	ORD-025284	Performance metrics for the assessment of satellite data products: an ocean color case study	Blake Schaeffer	3/5/2018
ord,nerl,sed,eib	ORD-025494	Decision-Tree, Rule-Based, and Random Forest Classification of High-Resolution Multispectral Imagery for Wetland Mapping and Inventory	Charles Lane	3/6/2018

ord,nheerl,aed,peb	ORD-026144	Advancing the Use of Passive Sampling in Risk Assessment and Management of Sediments Contaminated with Hydrophobic Organic Chemicals: Results of an International Ex Situ Passive Sampling Interlaboratory Comparison	Robert Burgess	5/4/2018
ord,nheerl,aed,peb	ORD-026360	A Chemical Activity Approach to Exposure and Risk Assessment of Chemicals	Robert Burgess	5/4/2018

Published Date	Completed Date	EPA Data?/Justification	completed_review	published_data
1/1/2016	4/12/2016		TRUE	TRUE
6/1/2016	4/5/2017	Yes	FALSE	FALSE
11/15/2015	3/3/2016		TRUE	TRUE
5/11/2016	7/18/2016		TRUE	TRUE

4/28/2016	12/8/2016	Yes	FALSE	FALSE
3/1/2016	6/8/2016		TRUE	TRUE
2/1/2016	3/29/2016		FALSE	FALSE
10/16/2015	12/16/2015		TRUE	TRUE

12/1/2015	12/1/2015		FALSE	FALSE
12/1/2015	4/28/2016		FALSE	FALSE
1/5/2016	1/5/2016		FALSE	FALSE
3/1/2016	3/3/2016		FALSE	FALSE
3/3/2016	3/3/2016		TRUE	TRUE
5/16/2016	6/1/2016		FALSE	FALSE

4/15/2016	4/27/2016		FALSE	FALSE
7/1/2016	7/5/2016		TRUE	TRUE
8/2/2016	8/26/2016		FALSE	FALSE
3/3/2016	3/3/2016		FALSE	FALSE

11/1/2015	10/22/2015		TRUE	TRUE
7/3/2016	11/14/2016	No; Research data consisted of secondary data only	FALSE	FALSE
5/1/2016	7/13/2016		FALSE	FALSE
10/1/2015	5/24/2016		TRUE	TRUE

11/1/2016	4/20/2017	Yes	TRUE	TRUE
4/1/2016	5/17/2016		FALSE	FALSE
12/1/2015	6/22/2016		FALSE	FALSE
3/31/2016	4/12/2016		TRUE	TRUE
4/19/2016			FALSE	FALSE

4/1/2016	6/22/2016		FALSE	FALSE
12/1/2015	1/15/2016		TRUE	TRUE
1/5/2016	8/29/2016		TRUE	FALSE
12/16/2015	2/9/2016		TRUE	TRUE

4/1/2016	12/13/2016	No; data are from 2002-2006 spatially balanced probabilistic stream survey data from W VA Dept of EPA	FALSE	FALSE
10/30/2015	11/16/2015		FALSE	FALSE
10/7/2015	11/18/2015		TRUE	TRUE

10/1/2015	1/25/2016		FALSE	FALSE
10/28/2015	10/28/2015		FALSE	FALSE
11/25/2015	1/11/2016		FALSE	FALSE
9/1/2017	11/6/2017	Yes	TRUE	TRUE

12/15/2015	2/2/2016		FALSE	FALSE
12/15/2015	2/2/2016		FALSE	FALSE
12/15/2015	2/2/2016		FALSE	FALSE
12/15/2015	2/2/2016		FALSE	FALSE

12/15/2015	2/3/2016		FALSE	FALSE
2/15/2016	2/29/2016		TRUE	TRUE
1/4/2018	2/13/2018	Yes	TRUE	TRUE
11/7/2016	11/9/2016	Yes; n/a	FALSE	FALSE
10/1/2015	12/22/2016	Yes	FALSE	FALSE

12/5/2015	11/4/2015		FALSE	FALSE
12/15/2015	2/3/2016		FALSE	FALSE
12/15/2015	2/3/2016		FALSE	FALSE
12/15/2015	2/3/2016		FALSE	FALSE

9/29/2016	10/4/2016	Yes	FALSE	FALSE
8/1/2016	4/13/2017	Yes	FALSE	FALSE
6/14/2017	12/7/2017	Yes	TRUE	TRUE
4/19/2016	4/19/2016		FALSE	FALSE

9/16/2016	9/7/2016		FALSE	FALSE
10/1/2015	10/16/2015		FALSE	FALSE
3/20/2017	3/20/2017	Yes	TRUE	TRUE
10/1/2015	12/9/2015		TRUE	TRUE
9/23/2016	9/29/2016	Yes	FALSE	FALSE

3/15/2016	3/15/2016		FALSE	FALSE
2/11/2016	5/25/2016		TRUE	TRUE
1/5/2016	1/5/2016		FALSE	FALSE
2/1/2016	12/3/2015		FALSE	FALSE

1/1/2018	2/9/2018	No; Data used for this manuscript was generated and owned by Duke Univ Med. Center part of CATHGEN cohort	FALSE	FALSE
3/1/2016	5/5/2016		FALSE	FALSE
11/1/2015	12/1/2015		FALSE	FALSE
12/1/2015	5/27/2016		TRUE	TRUE
8/4/2017	4/23/2018	Yes	TRUE	TRUE

4/20/2016	3/22/2017	Yes	FALSE	FALSE
11/30/2015	1/6/2016		FALSE	FALSE
2/29/2016	5/25/2016		FALSE	FALSE
11/1/2016	1/31/2017	Yes	TRUE	TRUE

1/15/2016	11/4/2015		TRUE	TRUE
6/1/2016	5/31/2016		TRUE	TRUE
11/1/2015	6/1/2016		FALSE	FALSE

4/19/2016	4/20/2016		FALSE	FALSE
1/1/2016	1/5/2016		FALSE	FALSE
11/13/2015	11/18/2015		FALSE	FALSE
11/10/2015	3/8/2016		TRUE	TRUE

12/1/2015	10/20/2015		TRUE	TRUE
11/1/2015	1/11/2016		FALSE	FALSE
1/1/2016	2/8/2016		TRUE	TRUE
9/11/2016	6/21/2017	Yes	FALSE	FALSE

12/14/2015	12/14/2015		TRUE	TRUE
7/7/2016	7/7/2016		FALSE	FALSE
5/1/2016	5/31/2016		TRUE	TRUE
11/1/2015	10/21/2015		FALSE	FALSE
10/1/2015	10/14/2015		FALSE	FALSE

10/1/2015	6/30/2015		FALSE	FALSE
1/15/2016	1/5/2016		TRUE	TRUE
11/16/2015	11/16/2015		TRUE	TRUE
11/2/2015	10/26/2015		TRUE	TRUE
11/18/2015	1/13/2016		FALSE	FALSE

3/1/2017	2/27/2017	Yes	TRUE	FALSE
1/1/2016	11/12/2015		TRUE	TRUE
2/1/2017	2/6/2017	Yes	TRUE	TRUE
2/12/2016	2/18/2016		TRUE	TRUE

5/1/2016	5/26/2016		TRUE	TRUE
12/11/2015	1/22/2016		TRUE	TRUE
4/21/2016	4/21/2016		FALSE	FALSE

11/1/2016	2/23/2017	No; No EPA data used in this analysis/paper	FALSE	FALSE
9/1/2017	9/12/2017	Yes	FALSE	FALSE
10/1/2015	9/30/2015		TRUE	TRUE
2/1/2016	2/17/2016		TRUE	TRUE
12/1/2015	1/25/2016		FALSE	FALSE

6/1/2016	6/17/2016		TRUE	TRUE
1/1/2016	1/14/2016		FALSE	FALSE
6/30/2016	10/25/2016	Yes	FALSE	FALSE

2/1/2016	4/20/2016		TRUE	TRUE
4/15/2016	4/15/2016		FALSE	FALSE
10/1/2015	7/10/2015		FALSE	FALSE
7/1/2017	8/22/2017	No; Data from swfwmd and other published sources	FALSE	FALSE

11/1/2015	11/2/2015		TRUE	TRUE
10/1/2015	12/1/2015	No; Review article	FALSE	FALSE
10/1/2015	9/23/2015		FALSE	FALSE
11/15/2015	12/21/2015		TRUE	TRUE

2/5/2016	1/12/2016		TRUE	TRUE
1/20/2016	1/20/2016		FALSE	FALSE
2/29/2016	6/16/2017	Yes	FALSE	FALSE
1/6/2016	1/11/2016		TRUE	TRUE
1/26/2016	1/26/2016		FALSE	FALSE

2/22/2016	4/4/2016		FALSE	FALSE
6/30/2016	6/16/2016		FALSE	FALSE
11/24/2015	6/10/2016		TRUE	TRUE
2/19/2016	8/4/2016		FALSE	FALSE
10/23/2015	5/27/2016		FALSE	FALSE

3/30/2017	6/2/2017	Yes	FALSE	FALSE
10/30/2015	11/4/2015		TRUE	TRUE
11/1/2015	12/16/2015		TRUE	TRUE
8/16/2016	8/31/2016		TRUE	TRUE

6/17/2016	6/30/2016		TRUE	TRUE
11/1/2015	3/31/2016		FALSE	FALSE
3/1/2017	3/10/2017	No; This is a literature review.	FALSE	FALSE

2/18/2016	6/20/2017	No; Secondary data used	FALSE	FALSE
11/27/2015	2/9/2016		FALSE	FALSE
3/1/2017	12/6/2016	No; -	FALSE	FALSE
10/27/2015	11/30/2015		TRUE	TRUE

10/1/2015	12/21/2015		FALSE	FALSE
4/6/2016	5/26/2016		FALSE	FALSE
3/10/2017	6/23/2017	Yes	TRUE	TRUE

10/17/2016	2/28/2017	Yes	TRUE	TRUE
12/15/2015	2/5/2016		TRUE	TRUE
4/1/2016	3/2/2016		TRUE	TRUE
11/10/2015	5/27/2016		TRUE	TRUE

6/24/2017	5/23/2017	Yes	TRUE	TRUE
6/15/2016	6/28/2016		FALSE	FALSE
12/15/2015	2/3/2016		FALSE	FALSE
4/26/2016	6/16/2016		TRUE	TRUE

10/1/2015	9/15/2015		FALSE	FALSE
10/1/2015	9/24/2015	No; Data belongs to another entity	FALSE	FALSE
9/1/2016	7/28/2016		FALSE	FALSE
11/1/2015	11/23/2015		TRUE	TRUE

11/1/2015	11/25/2015		TRUE	TRUE
11/1/2015	11/25/2015		FALSE	FALSE
5/17/2016	5/17/2016		TRUE	TRUE
1/1/2016	1/4/2016		TRUE	TRUE
4/5/2016	4/26/2016		FALSE	FALSE

7/5/2016	7/13/2016		TRUE	TRUE
10/1/2015	7/15/2015		TRUE	TRUE
4/26/2016	4/26/2016		FALSE	FALSE
5/1/2017	4/4/2017	No; Research was the development of a management framework which was not data driven	FALSE	FALSE

1/1/2016	1/7/2016		FALSE	FALSE
2/15/2017	12/15/2016	Yes	TRUE	TRUE
3/29/2016	7/28/2016		TRUE	TRUE

10/1/2016	3/30/2017	Yes; n/a	FALSE	FALSE
5/6/2016	5/17/2016		FALSE	FALSE
1/16/2016	2/22/2016		TRUE	TRUE

12/31/2015	2/4/2016		FALSE	FALSE
12/1/2015	2/3/2016		FALSE	FALSE
4/12/2016	4/28/2016		TRUE	TRUE
9/1/2017	11/1/2017	Yes	TRUE	TRUE

2/1/2016	2/8/2016		TRUE	TRUE
12/15/2015	5/4/2017	Yes	FALSE	FALSE
2/1/2017	2/27/2017	Yes	TRUE	TRUE

4/26/2016			FALSE	FALSE
10/1/2015	11/13/2015		TRUE	FALSE
11/1/2015	10/22/2015		FALSE	FALSE
6/1/2016	6/3/2016		TRUE	TRUE
3/7/2016	9/1/2016		TRUE	TRUE

1/1/2016	12/23/2015		TRUE	TRUE
6/22/2016	6/27/2016		FALSE	FALSE
1/1/2017	12/19/2016	Yes; N/A	FALSE	FALSE
11/18/2015	1/11/2016		TRUE	TRUE
6/1/2016	5/23/2016		FALSE	FALSE
1/29/2016	5/25/2016		FALSE	FALSE

12/23/2015	3/10/2016		FALSE	FALSE
12/1/2015	11/16/2015		FALSE	FALSE
3/21/2016	3/21/2016		FALSE	FALSE
3/9/2016	3/31/2016		TRUE	TRUE
9/1/2016	2/15/2017	Yes	FALSE	FALSE

1/1/2016	6/8/2016		FALSE	FALSE
2/29/2016	5/3/2017	Yes	FALSE	FALSE
12/1/2015	12/1/2015		FALSE	FALSE
12/22/2015	12/22/2015		TRUE	TRUE

7/1/2017	9/27/2017	Yes	TRUE	TRUE
4/6/2016	4/7/2016		FALSE	FALSE
10/4/2015	10/1/2015		FALSE	FALSE
11/19/2015	12/31/2015		TRUE	TRUE
11/30/2015	12/1/2015		FALSE	FALSE

12/1/2016	11/18/2016	Yes	FALSE	FALSE
1/1/2017	7/19/2017	Yes	FALSE	FALSE
12/2/2015	12/2/2015		FALSE	FALSE

12/15/2015	11/16/2015		FALSE	FALSE
6/21/2016	10/13/2016	No; All data for this article was generated at the University of Texas.	TRUE	TRUE
2/28/2016	5/18/2016		TRUE	TRUE
3/7/2016	4/12/2016	No; Data belongs to another entity	FALSE	FALSE

4/1/2016	4/5/2016		TRUE	TRUE
10/13/2015	2/9/2016		TRUE	FALSE
10/1/2016	2/15/2017	Yes	FALSE	FALSE
9/1/2017	6/9/2017	No; EPA did not collect the data nor did EPA direclty fund the research effort described in the paper.	FALSE	FALSE
5/26/2016	8/25/2017	Yes	FALSE	FALSE

1/11/2016	1/14/2016		TRUE	TRUE
11/1/2016	1/5/2017	Yes; N/A	FALSE	FALSE
11/24/2015	3/2/2016		FALSE	FALSE
10/27/2015	10/27/2015		TRUE	TRUE

10/21/2015	3/16/2016		TRUE	TRUE
12/1/2015	12/15/2015		TRUE	FALSE
5/30/2017	8/4/2017	Yes	TRUE	TRUE
5/10/2016	10/12/2016	Yes	TRUE	TRUE

10/2/2015	4/4/2016		TRUE	TRUE
12/18/2015	3/2/2016		FALSE	FALSE
11/16/2015	11/20/2015		FALSE	FALSE
8/25/2016	10/21/2016	No; Research conducted was a literature review	FALSE	FALSE
8/10/2016	11/14/2016	No; The article is a review article outlining and discussing the conceptual basis for managing climate refugia	FALSE	FALSE

12/1/2015	1/25/2016		FALSE	FALSE
1/15/2016	12/14/2015		FALSE	FALSE
11/10/2015	4/13/2016	No; Review article with one figure from NOAA and NASA.	FALSE	FALSE
2/10/2016	5/27/2016		TRUE	TRUE

2/8/2016	4/5/2016		TRUE	TRUE
10/9/2015	5/9/2016		FALSE	FALSE
6/1/2016	6/10/2016		FALSE	FALSE

2/1/2016	4/22/2016		TRUE	TRUE
6/1/2016	6/22/2016		FALSE	FALSE
2/1/2016	8/2/2017	Yes	FALSE	FALSE
4/15/2016	6/7/2016		TRUE	FALSE
12/15/2015	8/20/2015		FALSE	FALSE

4/1/2016	4/28/2016		TRUE	TRUE
7/1/2017	6/20/2017	No; No data generated for this review paper discussing future research directions for ecological risk assessment	FALSE	FALSE
11/1/2016	11/7/2017	Yes	FALSE	FALSE

2/19/2016	6/20/2017	Yes	TRUE	TRUE
12/14/2015	12/14/2015		FALSE	FALSE
3/9/2016	3/31/2016		TRUE	TRUE
11/1/2015	10/13/2015		TRUE	TRUE
9/1/2016	5/8/2017	Yes	TRUE	TRUE

4/1/2016	4/20/2016		TRUE	TRUE
12/1/2015	12/15/2015		TRUE	TRUE
12/30/2015	11/17/2016	No; None of the papers has data that was generated by EPA. AG	FALSE	FALSE
5/15/2017	3/26/2018	Yes	FALSE	FALSE
1/20/2016	10/5/2016	No; Research data consisted of secondary data only	FALSE	FALSE

11/1/2015	6/2/2015		FALSE	FALSE
1/1/2018	4/23/2018	Yes	TRUE	TRUE
8/26/2016	1/11/2016		FALSE	FALSE
1/1/2016	4/20/2016		TRUE	TRUE

5/18/2016	5/18/2016		TRUE	TRUE
12/31/2015	4/1/2016		TRUE	TRUE
3/1/2016	6/1/2016		FALSE	FALSE
3/1/2016	3/3/2016		TRUE	TRUE
3/30/2016	5/27/2016		FALSE	FALSE

12/1/2015	11/18/2015		FALSE	FALSE
8/16/2016	7/24/2017	Yes	FALSE	FALSE
6/13/2016	6/13/2016	No; no data, software	FALSE	FALSE
3/25/2016	4/4/2016		FALSE	FALSE
5/5/2016	3/14/2017	Yes	TRUE	FALSE

2/12/2016	2/16/2016		FALSE	FALSE
10/6/2015	10/26/2015		FALSE	FALSE
3/1/2016	5/11/2016		TRUE	TRUE
8/22/2016	8/22/2016		TRUE	TRUE

11/1/2016	1/20/2017	Yes	TRUE	TRUE
3/1/2017	12/30/2016	No; Analysis is all based on secondary data (publicly available GIS files obtained from other agencies/lit review)	FALSE	FALSE
1/18/2017	2/13/2017	No; Reveiw of existing NMMAPS data	FALSE	FALSE
5/12/2016	5/12/2016		TRUE	TRUE

11/15/2015	9/3/2015		TRUE	TRUE
11/1/2016	2/27/2017	Yes	TRUE	TRUE
12/10/2015	12/18/2015		FALSE	FALSE
4/1/2016	2/4/2016		TRUE	TRUE

6/8/2017	8/25/2017	Yes	FALSE	FALSE
9/1/2016	2/27/2017	Yes	FALSE	FALSE
2/17/2016	3/1/2016		FALSE	FALSE
5/15/2017	7/6/2017	Yes	TRUE	TRUE

7/12/2016	10/20/2016	Yes	TRUE	TRUE
9/9/2016	12/30/2016	Yes	FALSE	FALSE
11/11/2015	12/21/2015		TRUE	TRUE
3/1/2016	3/1/2016		TRUE	TRUE

10/14/2015	10/27/2015		FALSE	FALSE
1/1/2016	5/26/2016		TRUE	TRUE
1/8/2016	7/7/2016		TRUE	TRUE
10/12/2015	12/2/2015		TRUE	TRUE

1/20/2016	1/20/2016		FALSE	FALSE
4/1/2017	6/9/2017	No; literature review	FALSE	FALSE
2/28/2017	3/20/2017	Yes	FALSE	FALSE
2/1/2016	3/9/2016		TRUE	TRUE

2/1/2017	2/27/2017	Yes	TRUE	TRUE
10/1/2015	7/15/2015		FALSE	FALSE
2/1/2016	4/27/2016		TRUE	TRUE
10/26/2015	1/26/2016		FALSE	FALSE
8/10/2016	8/26/2016		TRUE	TRUE

10/1/2016	7/22/2016		TRUE	TRUE
4/12/2016	5/28/2015		TRUE	TRUE
1/1/2016	2/5/2016		TRUE	TRUE
2/25/2016	4/12/2016	No; Review Articles	FALSE	FALSE

6/1/2016	10/21/2016	Yes	FALSE	FALSE
1/25/2016	1/27/2016		FALSE	FALSE
1/1/2016	1/29/2016	No; No EPA Data, this is a review article	FALSE	FALSE

1/4/2016	5/18/2016		FALSE	FALSE
10/30/2015	6/9/2016		TRUE	TRUE
2/8/2016	4/7/2016		TRUE	TRUE

4/1/2016	7/5/2016		FALSE	FALSE
11/19/2015	12/21/2015		TRUE	TRUE
6/16/2016	7/22/2016		TRUE	TRUE
9/1/2016	12/28/2016	Yes	TRUE	TRUE

4/1/2016	4/26/2016		TRUE	TRUE
3/1/2016	5/11/2016		TRUE	FALSE
10/7/2015	5/27/2016		FALSE	FALSE
10/15/2015	4/27/2016		FALSE	FALSE
7/12/2016	10/18/2016	Yes	FALSE	FALSE

1/1/2016	12/28/2015		FALSE	FALSE
1/18/2016	2/4/2016		FALSE	FALSE
10/30/2015	6/9/2016		TRUE	TRUE
8/1/2016	4/22/2016		TRUE	TRUE
8/19/2016	8/22/2016		FALSE	FALSE

12/5/2015	12/16/2015		TRUE	TRUE
9/16/2016	11/9/2016	No; The date was not generated by EPA, but had an EPA coauthor	FALSE	FALSE
6/1/2016	10/3/2016	Yes	TRUE	TRUE
12/1/2016	11/18/2016	Yes	FALSE	FALSE

11/15/2016	3/14/2017	Yes	TRUE	TRUE
3/1/2016	3/8/2016		TRUE	TRUE
12/1/2015	12/31/2015		TRUE	TRUE
10/1/2015	9/24/2015		FALSE	FALSE

12/9/2015	8/17/2016		TRUE	TRUE
1/1/2016	8/25/2015		FALSE	FALSE
2/28/2016	3/9/2016		TRUE	TRUE
2/29/2016	12/30/2016	Yes	FALSE	FALSE

12/30/2015	1/7/2016		TRUE	TRUE
10/31/2015	12/8/2016	Yes	FALSE	FALSE
12/11/2015	12/15/2015	No; Review Articles	FALSE	FALSE
4/21/2016	5/2/2016		TRUE	FALSE

1/27/2016	5/27/2016	No; Review Articles	FALSE	FALSE
11/1/2015	12/22/2015		TRUE	TRUE
7/1/2016	2/28/2017	Yes	FALSE	FALSE
10/31/2016	5/4/2017	Yes	FALSE	FALSE

10/1/2015	9/2/2015		TRUE	TRUE
3/1/2016	3/7/2016		FALSE	FALSE
8/1/2016	10/18/2016	No; Manuscript describes a software package developed to retrieve, organize, and analyze estuary monitoring data	FALSE	FALSE
10/23/2015	11/23/2015		FALSE	FALSE

9/1/2016	12/14/2016	No; *	FALSE	FALSE
10/1/2015	5/18/2016		FALSE	FALSE
12/1/2015	2/18/2016		TRUE	TRUE
12/1/2015	12/1/2015		FALSE	FALSE
12/1/2015	6/20/2017	Yes	FALSE	FALSE

2/10/2016	3/29/2016		TRUE	TRUE
7/26/2016	8/12/2016		FALSE	FALSE
1/1/2017	2/27/2017	No; SETAC lit review from workshop to set practical guidance for the application of the ecosystem services	FALSE	FALSE
1/1/2016	1/21/2016		FALSE	FALSE

12/17/2015	1/21/2016		FALSE	FALSE
12/16/2015	4/26/2016		TRUE	TRUE
11/1/2016	8/11/2016		TRUE	TRUE
2/1/2016	2/8/2016		TRUE	TRUE

9/30/2016	1/4/2016		FALSE	FALSE
11/25/2015	12/28/2016	No; We helped with design, supplies, and writing but did not generate data	FALSE	FALSE
2/23/2016	4/21/2016		FALSE	FALSE
10/1/2015	12/9/2015		TRUE	TRUE
11/2/2016	1/23/2017	No; A perspective article, utilizing publically available data for illustrating a point. No data generated.	FALSE	FALSE

11/1/2015	11/30/2015		FALSE	FALSE
4/25/2016	5/13/2016		FALSE	FALSE
7/1/2016	12/6/2016	No; Used literature data	FALSE	FALSE
6/6/2017	6/20/2017	No; the modeling was already published and the human data came directly from the published dissertation	FALSE	FALSE

11/3/2015	12/21/2015		TRUE	TRUE
1/1/2016	1/12/2016		TRUE	TRUE
6/15/2016	6/22/2016		FALSE	FALSE
12/15/2015	12/16/2015		FALSE	FALSE

11/2/2015	12/31/2015		TRUE	TRUE
11/2/2015	12/21/2015		TRUE	TRUE
2/1/2017	6/28/2017	Yes	TRUE	TRUE
10/20/2015	12/21/2015		TRUE	TRUE

12/21/2015	12/21/2015		TRUE	TRUE
3/30/2016	3/30/2016		FALSE	FALSE
4/1/2016	4/13/2016		TRUE	TRUE
3/1/2016	7/1/2016		FALSE	FALSE

9/1/2016	4/13/2016		FALSE	FALSE
12/1/2015	1/6/2016		FALSE	FALSE
4/21/2016	4/28/2016		FALSE	FALSE
1/26/2016	1/25/2016		FALSE	FALSE

11/1/2015	10/30/2015		FALSE	FALSE
11/1/2016	10/3/2016	No; Based on pre-esisting datasets collected by others. All data available publically, refs & links in the text.	FALSE	FALSE
5/1/2017	5/23/2017	Yes	FALSE	FALSE
1/1/2018	1/12/2018	No; This is a literature review and does not contain any analysis of data.	FALSE	FALSE

1/28/2016	2/17/2016		TRUE	TRUE
2/1/2016	4/21/2016		TRUE	TRUE
5/1/2016	3/24/2016		TRUE	TRUE
11/3/2015	12/21/2015		TRUE	TRUE

9/1/2016	1/30/2017	No; Based on summary of literature information and interviews, no lab or field gathering of data.	FALSE	FALSE
11/9/2015	12/21/2015		FALSE	FALSE
1/2/2017	5/5/2017	Yes	TRUE	TRUE

11/28/2017		No; NOAA generated data	FALSE	FALSE
12/15/2015	11/19/2015		TRUE	FALSE
11/17/2015	12/7/2015		TRUE	TRUE

6/2/2016	8/9/2016		FALSE	FALSE
12/30/2015	1/13/2016		TRUE	TRUE
5/5/2017	4/5/2017	Yes	FALSE	FALSE
12/1/2015	10/19/2015		TRUE	TRUE

6/1/2016	8/18/2016		FALSE	FALSE
11/30/2016	12/27/2016	Yes	FALSE	FALSE
9/14/2016	2/10/2017	Yes	TRUE	TRUE
1/1/2016	12/22/2015		FALSE	FALSE

6/1/2016	8/22/2016		TRUE	TRUE
5/13/2016	6/15/2016		TRUE	FALSE

3/17/2016	4/13/2016		TRUE	TRUE
11/10/2015	10/16/2015		FALSE	FALSE
6/30/2016	6/30/2016		TRUE	TRUE
12/17/2015	12/17/2015		TRUE	TRUE

9/2/2016	10/6/2016	Yes	FALSE	FALSE
11/1/2016	10/26/2016	No; Primary Review Article	FALSE	FALSE
3/11/2016	5/31/2016		FALSE	FALSE
6/7/2016	6/7/2016		TRUE	FALSE

1/31/2017	2/23/2017	Yes	FALSE	FALSE
12/15/2017	1/17/2018	Yes	FALSE	FALSE
2/13/2016	9/14/2016		TRUE	TRUE

10/27/2015	11/2/2015	No; Data belongs to another entity	FALSE	FALSE
11/1/2016	8/29/2017	No; Graduate students led research.	FALSE	FALSE
7/30/2016	6/21/2017	Yes	FALSE	FALSE
9/7/2016	12/22/2016	No; .	FALSE	FALSE

11/25/2015	12/14/2015		TRUE	TRUE
1/15/2016	4/13/2016		TRUE	TRUE
1/28/2016	2/18/2016		TRUE	FALSE
9/20/2016	9/26/2016	Yes; n/a	TRUE	TRUE
9/1/2016	9/6/2016		FALSE	FALSE
4/1/2016	4/1/2016		TRUE	TRUE

2/25/2016	6/7/2016		TRUE	TRUE
1/1/2016	2/29/2016		TRUE	TRUE
3/3/2016	12/28/2016	No; Used literature data only	FALSE	FALSE
10/27/2017	11/6/2017	Yes	TRUE	TRUE

11/2/2015	11/27/2015		FALSE	FALSE
11/4/2015	10/13/2015		TRUE	TRUE
10/14/2016	11/21/2016	Yes	FALSE	FALSE
11/1/2016	10/6/2016	No; Manuscript describes model-based analysis that used secondary data only.Original results are model output	FALSE	FALSE
4/22/2016	6/1/2016		TRUE	TRUE

5/11/2016	6/3/2016		TRUE	TRUE
7/24/2017	8/21/2017	Yes	FALSE	FALSE
12/10/2015	4/27/2016		TRUE	TRUE
10/7/2015	10/12/2016	Yes	FALSE	FALSE

5/31/2016	8/25/2017	Yes	FALSE	FALSE
1/13/2016	1/13/2016		FALSE	FALSE
12/16/2015	4/25/2016		TRUE	TRUE
11/24/2015	2/16/2016		TRUE	TRUE

10/5/2015	11/17/2015		FALSE	FALSE
11/17/2015	1/6/2016		FALSE	FALSE
3/19/2016	4/25/2016		FALSE	FALSE
3/29/2016	5/27/2016		TRUE	TRUE

4/1/2016	6/2/2016		TRUE	TRUE
1/23/2016	1/25/2016		TRUE	TRUE
4/6/2016	6/2/2016		TRUE	TRUE
1/1/2016	6/21/2017	No; Used publicly available data (non-EPA)	FALSE	FALSE

4/1/2017	9/19/2017	Yes	FALSE	FALSE
3/14/2016	3/14/2016		TRUE	TRUE
3/1/2016	4/27/2016		TRUE	TRUE
10/3/2016	10/27/2016	No; Secondary data	FALSE	FALSE

5/15/2016	6/3/2016		FALSE	FALSE
5/1/2016	2/29/2016		TRUE	TRUE
4/1/2016	2/26/2016		TRUE	TRUE

4/1/2016	2/26/2016		FALSE	FALSE
2/26/2016	4/26/2016		FALSE	FALSE
11/6/2015	12/21/2015		TRUE	TRUE
1/18/2016	4/7/2016		TRUE	TRUE
1/25/2016	2/18/2016		FALSE	FALSE

6/24/2016	8/29/2017	Yes	TRUE	TRUE
3/1/2017	9/29/2017	No; this research was not done at EPA and does not contain data generated by EPA. There is one EPA coauthor.	FALSE	FALSE
1/1/2017	3/20/2018	No; Oak Ridge Institute for Science and Education completed the research.	FALSE	FALSE
1/19/2016	8/31/2016		FALSE	FALSE

5/10/2016	1/20/2017	Yes	FALSE	FALSE
3/1/2016	2/29/2016		FALSE	FALSE
11/1/2017	12/14/2017	Yes; NAGE Exempt	FALSE	FALSE
1/5/2016	1/5/2016		TRUE	TRUE

10/3/2016	1/10/2017	Yes	TRUE	TRUE
11/23/2015	12/7/2015		TRUE	TRUE
5/15/2016	3/22/2016		FALSE	FALSE
3/31/2018	4/24/2018	Yes	TRUE	TRUE

10/13/2016	12/6/2016	Yes	TRUE	TRUE
4/1/2017	8/29/2017	Yes	FALSE	FALSE
10/19/2016	12/16/2016	Yes	TRUE	TRUE
3/1/2016	3/1/2016		FALSE	FALSE

10/3/2016	2/28/2017	Yes	TRUE	TRUE
5/1/2017	7/20/2017	Yes	TRUE	TRUE
1/1/2016	5/19/2016		TRUE	TRUE

6/28/2016	9/7/2016		TRUE	TRUE
1/1/2016	11/19/2015		FALSE	FALSE
1/10/2017	5/5/2017	Yes	FALSE	FALSE
5/20/2016	5/25/2016		TRUE	TRUE

11/1/2016	2/2/2017	Yes	FALSE	FALSE
12/8/2016	6/19/2017	Yes	TRUE	TRUE
3/1/2016	2/29/2016		TRUE	TRUE
10/1/2015	4/21/2016		TRUE	TRUE

10/25/2016	10/27/2016	Yes; n/a	FALSE	FALSE
7/8/2016	7/8/2016		FALSE	FALSE
10/1/2016	8/26/2016		TRUE	TRUE
2/9/2016	1/10/2018	Yes	FALSE	FALSE

4/1/2017	4/18/2017	Yes	FALSE	FALSE
4/16/2016	5/12/2016		TRUE	TRUE
2/3/2016	4/26/2016		FALSE	FALSE
1/1/2016	12/22/2015		TRUE	TRUE

12/1/2016	11/29/2016	Yes	TRUE	TRUE
11/1/2015	2/8/2016		TRUE	TRUE
12/20/2015	4/6/2016		FALSE	FALSE

4/19/2016	6/21/2017	No; Used publicly available data (non-EPA)	FALSE	FALSE
3/28/2016	6/21/2017	No; Used publicly available data (non-EPA)	FALSE	FALSE
9/6/2016	3/27/2017	Yes	FALSE	FALSE
11/1/2016	12/5/2017	Yes	FALSE	FALSE

6/1/2017	8/25/2017	Yes	FALSE	FALSE
7/11/2016	7/11/2016		TRUE	TRUE
8/5/2016	5/13/2016		TRUE	FALSE
3/14/2016	3/23/2016		TRUE	TRUE

2/11/2016	6/1/2016		FALSE	FALSE
3/3/2016	6/1/2016		FALSE	FALSE
4/19/2016	6/1/2016		FALSE	FALSE
10/6/2015	10/14/2015		TRUE	FALSE

2/3/2016	2/22/2016		TRUE	TRUE
10/12/2015	1/14/2016		TRUE	TRUE
12/1/2016	10/24/2016	No; No the paper doesn't have EPA data, and for that matter it doesn't have any data at all ahjond	FALSE	FALSE
5/12/2016	7/21/2016		TRUE	TRUE

9/1/2016	8/17/2016		FALSE	FALSE
11/15/2017	1/31/2018	No; Journal article is a review paper and no EPA data was generated for this manuscript.	FALSE	FALSE
1/15/2016	11/16/2015		TRUE	TRUE
12/8/2015	6/9/2017	Yes	FALSE	FALSE

4/8/2016	4/27/2016		FALSE	FALSE
1/15/2016	4/27/2016		TRUE	TRUE
2/2/2016	4/26/2016		TRUE	TRUE
11/25/2015	6/2/2016		FALSE	FALSE

2/1/2016	12/31/2015		TRUE	TRUE
11/3/2015	1/25/2016		FALSE	FALSE
4/19/2016	4/22/2016		TRUE	TRUE
4/3/2018	4/16/2018	Yes	TRUE	TRUE

10/1/2017	9/25/2017	Yes	TRUE	TRUE
9/1/2016	2/28/2017	Yes	FALSE	FALSE
4/21/2017		No	FALSE	FALSE
1/1/2016	2/29/2016	No; data belongs to Finnish Government	FALSE	FALSE
11/1/2016	8/11/2016		FALSE	FALSE

1/7/2016	5/11/2016		TRUE	TRUE
9/1/2016	9/14/2016		TRUE	TRUE
1/15/2016	1/26/2016		FALSE	FALSE
4/20/2016	1/31/2017	No; No EPA data, review only	FALSE	FALSE

10/25/2016	8/11/2017	No; All of the data were generated as part of the National Birth Defects Prevention Study (NBDPS) led by CDC.	FALSE	FALSE
9/1/2017	6/23/2017	No; No EPA data was used in this analysis, see SciHub entry for more info	TRUE	TRUE
4/15/2016	6/13/2016		FALSE	FALSE
9/28/2016	3/23/2018	Yes	FALSE	FALSE
10/15/2016	10/31/2016	Yes	TRUE	TRUE

3/7/2016	4/26/2016		FALSE	FALSE
4/3/2017	4/3/2017	Yes	TRUE	TRUE
1/21/2016	1/27/2016		TRUE	TRUE

10/25/2016	2/28/2017	Yes	FALSE	FALSE
11/29/2017	12/14/2017	Yes	TRUE	TRUE
2/4/2016	4/27/2016		TRUE	TRUE
4/1/2017	6/9/2017	Yes	FALSE	FALSE

9/1/2016	2/28/2017	Yes	TRUE	TRUE
12/1/2016	5/31/2017	Yes	TRUE	TRUE
9/28/2016	12/13/2016	Yes	FALSE	FALSE
4/1/2016	4/20/2016		TRUE	TRUE
10/20/2015	11/2/2015		TRUE	TRUE

7/19/2016	7/22/2016		TRUE	TRUE
10/15/2015	10/15/2015		TRUE	TRUE
12/29/2015	4/25/2016		TRUE	TRUE
5/1/2016	3/7/2016		FALSE	FALSE
3/3/2016	3/16/2016		TRUE	TRUE

6/1/2017	9/29/2017	No; no EPA data; all the data generated by external organizations; EPA coauthors	FALSE	FALSE
5/11/2016	6/17/2016		TRUE	TRUE
2/1/2017	2/28/2017	Yes	FALSE	FALSE

7/1/2016	6/14/2016		FALSE	FALSE
12/8/2016	8/23/2017	Yes	TRUE	TRUE
3/1/2016	3/1/2016		TRUE	TRUE

9/7/2017	11/2/2017	Yes	TRUE	FALSE
5/15/2016	6/20/2017	Yes	TRUE	TRUE
5/10/2016	10/18/2016	Yes	FALSE	FALSE

2/15/2016	4/7/2016		TRUE	TRUE
5/24/2016	8/9/2016		FALSE	FALSE
11/24/2016	2/27/2017	No; Data produced by UNC not EPA	FALSE	FALSE
2/26/2016	4/25/2016		TRUE	TRUE

1/1/2016	1/11/2016		TRUE	TRUE
1/1/2016	5/31/2016		TRUE	TRUE
6/10/2016	7/22/2016		TRUE	TRUE
7/21/2017	7/31/2017	Yes	TRUE	TRUE

8/31/2017	6/13/2017	Yes	TRUE	TRUE
4/13/2017	4/24/2017	No; The data was generated by researchers at the Univeristy of Michigan.	FALSE	FALSE
1/26/2018	1/31/2018	Yes	TRUE	TRUE
1/7/2016	9/20/2016	Yes	TRUE	TRUE
8/8/2016	8/8/2016		FALSE	FALSE

6/16/2016	6/16/2016		TRUE	TRUE
1/28/2016	4/25/2016		TRUE	TRUE
2/1/2017	5/10/2017	Yes	FALSE	FALSE
8/28/2016	8/1/2016		FALSE	FALSE

3/1/2016	3/3/2016		FALSE	FALSE
9/12/2016	2/27/2017	Yes	TRUE	TRUE
5/16/2017	4/13/2017	Yes	TRUE	TRUE
10/1/2016	6/13/2016		TRUE	TRUE
6/2/2016	12/28/2016	Yes	FALSE	FALSE

6/15/2016	6/16/2016		FALSE	FALSE
5/1/2016	4/4/2016		FALSE	FALSE
7/1/2017	8/8/2017	Yes; n/a	FALSE	FALSE
1/5/2017	5/25/2017	Yes	FALSE	FALSE

11/10/2015	10/22/2015		FALSE	FALSE
1/1/2018	1/29/2018	No; Data is generated by Generated using EPA methods	FALSE	FALSE
5/1/2017	4/20/2017	No; Data and analyses were generated and retained by the PI (Univ. S. Alabama)	FALSE	FALSE
5/2/2016	4/25/2016		TRUE	FALSE

1/13/2016	5/26/2016		FALSE	FALSE
10/1/2016	9/28/2016	No; The journal article builds upon a conceptual model developed in a 2000 Pellston Workshop.	FALSE	FALSE
10/1/2016	11/15/2016	No; Research done independently by Brazilian coauthors using EPA methods/designs but no EPA funding or agreement	FALSE	FALSE

3/17/2016	4/6/2016		TRUE	TRUE
10/23/2015	5/26/2016		FALSE	FALSE
5/10/2016	5/24/2016		TRUE	TRUE
10/21/2015	12/15/2015		FALSE	FALSE
2/1/2017	8/28/2017	No; used published EPA health values	TRUE	TRUE

2/25/2016	5/9/2016		FALSE	FALSE
9/10/2016	11/14/2016	Yes; Primary data collected was classified as CBI. All other data used was secondary data.	FALSE	FALSE
6/1/2016	5/23/2016		FALSE	FALSE
12/1/2016	2/22/2017	No; Papers do not have any data in them.	FALSE	FALSE
6/22/2016	4/28/2017	Yes	FALSE	FALSE

5/16/2016	5/2/2016		TRUE	TRUE
3/1/2017	3/3/2017	Yes	FALSE	FALSE
4/15/2016	4/26/2016		TRUE	TRUE
4/15/2016	9/30/2016	No; Research data consisted of secondary data only.	FALSE	FALSE

7/5/2016	6/20/2017	Yes	TRUE	TRUE
8/15/2016	1/31/2017	No; This manuscript utilized previously published data.	FALSE	FALSE
1/12/2016	2/25/2016		TRUE	TRUE
12/1/2016	1/6/2017	No; 2)No EPA data	FALSE	FALSE

5/3/2017	2/12/2018	Yes	TRUE	TRUE
12/1/2016	6/9/2017	No; State Health Department Data	FALSE	FALSE
9/8/2016	8/3/2016		TRUE	TRUE
9/1/2016	8/12/2016		FALSE	FALSE

4/1/2018	4/27/2018	No; Article focuses on problem formulation phase of enviro prot plan & does not include quantitative data analyses	FALSE	FALSE
2/27/2016	5/26/2016		TRUE	TRUE
2/11/2016	4/12/2016		TRUE	FALSE
3/21/2016	4/27/2016		FALSE	FALSE

7/18/2016	7/18/2016		TRUE	TRUE
7/28/2016	10/17/2016	Yes	FALSE	FALSE
11/11/2015	12/15/2015		FALSE	FALSE
1/11/2016	4/11/2016	No; No EPA Data, this is a review article	FALSE	FALSE

2/29/2016	4/27/2016		TRUE	TRUE
7/25/2016	1/25/2017	Yes	TRUE	TRUE
3/1/2017	2/7/2017	No; A discussion section - no data provided.	FALSE	FALSE
4/30/2016	5/25/2016		FALSE	FALSE

7/1/2016	4/12/2016		FALSE	FALSE
4/1/2016	2/19/2016		TRUE	TRUE
3/29/2016	3/30/2016		FALSE	FALSE
12/8/2016	12/13/2016	Yes	TRUE	TRUE

3/8/2016	2/10/2016		TRUE	TRUE
1/28/2016	5/3/2016		TRUE	TRUE
12/1/2016	11/15/2016	Yes	TRUE	TRUE
10/4/2016	11/22/2016	Yes	TRUE	TRUE

3/1/2017	6/9/2017	No; Review Article	FALSE	FALSE
10/4/2016	10/26/2016	Yes	FALSE	FALSE
4/1/2017	9/21/2017	No; Lead authorship from another federal agency.	FALSE	FALSE
2/1/2016	2/2/2017	Yes	FALSE	FALSE

6/1/2016	5/23/2016		FALSE	FALSE
4/18/2016	4/28/2016		FALSE	FALSE
10/21/2015	1/31/2017	Yes	FALSE	FALSE
11/29/2016	11/30/2016	Yes; n/a	FALSE	FALSE

4/1/2017	8/28/2017	No; all data is Oregon State University data.	FALSE	FALSE
7/1/2017	6/5/2017	No; Only data analyzed are from the Bureau of Water, South Carolina Department of Health and Environmental Control	FALSE	FALSE
2/1/2016	12/10/2015		FALSE	FALSE
1/27/2016	2/4/2016		FALSE	FALSE

1/6/2016	1/6/2016	No; Data belongs to another entity	FALSE	FALSE
3/8/2016	5/3/2016		TRUE	TRUE
3/31/2016	6/3/2016		TRUE	TRUE

11/15/2017	1/10/2018	Yes	TRUE	TRUE
6/6/2016	6/6/2016	No; Review Articles	FALSE	FALSE
8/1/2017	8/28/2017	Yes	FALSE	FALSE
4/27/2016	6/1/2016		FALSE	FALSE

4/4/2016	4/4/2016	No; Review Articles	FALSE	FALSE
7/15/2016	7/21/2016		FALSE	FALSE
6/27/2017	7/5/2017	No; This publication was a review article and did not generate new data	FALSE	FALSE

5/21/2016	6/2/2016		FALSE	FALSE
4/15/2016	4/15/2016		FALSE	FALSE
3/1/2016	3/3/2016		TRUE	TRUE
1/5/2016	1/8/2016		FALSE	FALSE
1/1/2017	12/14/2017	Yes	FALSE	FALSE

11/1/2017	11/3/2017	Yes	TRUE	TRUE
7/1/2016	5/22/2017	No; All data published in this manuscript were generated at the Medical College of Wisconsin	FALSE	FALSE
4/20/2016	2/29/2016		TRUE	TRUE
6/1/2016	7/7/2016		TRUE	TRUE

10/3/2016	8/26/2016		TRUE	TRUE
10/4/2016	12/9/2016	Yes	FALSE	FALSE
11/1/2016	11/1/2016	Yes; n/a	FALSE	FALSE
3/1/2017	5/31/2017	Yes	TRUE	TRUE

6/1/2016	7/20/2016		FALSE	FALSE
8/1/2016	8/17/2016		FALSE	FALSE
3/4/2016	4/8/2016		TRUE	TRUE
2/9/2016	4/13/2016		FALSE	FALSE
2/1/2017	2/28/2017	Yes	FALSE	FALSE

11/14/2016	11/14/2016	No; Review article, no data	FALSE	FALSE
7/5/2017	7/25/2017	No; Non EPA data - Data generated by Zhejiang University, China	FALSE	FALSE
10/1/2016	11/21/2016	Yes	FALSE	FALSE
10/19/2016	10/27/2016	No; this paper uses EPA public data to build new datasets and analysis by non-EPA authors	FALSE	FALSE

7/1/2017	8/10/2017	No; Data collected/interpreted by Brazilian universities using designs, field & analytical procedures adapted from	FALSE	FALSE
6/10/2016	11/9/2016	Yes	FALSE	FALSE
10/21/2016	10/27/2016	No; this paper uses EPA public data to build new datasets and analysis by non-EPA authors	FALSE	FALSE

11/1/2016	6/9/2017	Yes	TRUE	FALSE
6/2/2016	1/9/2017	No; 2)No EPA data	FALSE	FALSE
7/7/2017	12/14/2017	No; Assisted in the data interpretation and the writing of the manuscript.	FALSE	FALSE

6/29/2016	9/29/2016	Yes	TRUE	TRUE
2/1/2017	8/28/2017	No; review of existing data	FALSE	FALSE
11/1/2016	2/15/2017	No; No data, a review article	FALSE	FALSE

6/1/2016	7/8/2016		FALSE	FALSE
4/25/2016	7/8/2016		FALSE	FALSE
6/1/2017	8/30/2017	Yes	FALSE	FALSE
1/12/2016	1/28/2016		FALSE	FALSE

5/1/2017	2/12/2018	No; All work, including data analysis, was done outside of EPA	FALSE	FALSE
12/9/2016	6/21/2017	No; This paper is a review article.	FALSE	FALSE
12/14/2016	7/6/2017	Yes	TRUE	TRUE
2/15/2016	4/6/2016		FALSE	FALSE

11/15/2016	6/20/2017	Yes	FALSE	FALSE
2/1/2016	2/4/2016		FALSE	FALSE
8/1/2016	12/28/2016	No; This is a review article	FALSE	FALSE

1/1/2017	1/9/2017	No; No new data presented. Paper presents consensus views about advances that could improve risk assess. & mgmt.	FALSE	FALSE
1/1/2018	9/28/2017	No; no experimental data. authors analyze publication work from literature	FALSE	FALSE
3/8/2016	3/16/2016	No; Review Articles	FALSE	FALSE
5/7/2016	5/13/2016		TRUE	TRUE

7/7/2016	5/15/2017	Yes	FALSE	FALSE
2/1/2016	10/18/2016	Yes	FALSE	FALSE
2/1/2017	3/10/2017	Yes	FALSE	FALSE
7/19/2016	7/22/2016		TRUE	TRUE

1/1/2018	11/16/2017	Yes	TRUE	FALSE
1/6/2016	5/6/2016		TRUE	TRUE
11/1/2016	12/6/2016	Yes	TRUE	TRUE
5/8/2017	1/10/2018	Yes	FALSE	FALSE
6/21/2016	6/21/2016		FALSE	FALSE

4/1/2016	8/9/2016		FALSE	FALSE
4/15/2016	2/18/2016		FALSE	FALSE
3/1/2017	8/25/2017	Yes	FALSE	FALSE
1/31/2017	2/6/2017	Yes	FALSE	FALSE

3/17/2016	4/24/2018	Yes	FALSE	FALSE
12/1/2016	12/22/2016	Yes	FALSE	FALSE
2/15/2016	3/24/2016		FALSE	FALSE
1/1/2018	12/20/2017	Yes	TRUE	TRUE
5/27/2016	5/27/2016		FALSE	FALSE

2/13/2017	7/17/2017	No; Study relied on data collected by CDCÂ¿s NBDPS. All data variables were collected as part of the NBDPS' CATI.	FALSE	FALSE
12/1/2016	12/22/2016	Yes	FALSE	FALSE
12/29/2016	2/23/2017	Yes	TRUE	TRUE
9/19/2016	9/29/2016	Yes	TRUE	TRUE

4/19/2016	4/19/2016	No; No EPA Data, analysis of research methods	FALSE	FALSE
2/1/2016	5/4/2016		FALSE	FALSE
8/1/2016	2/9/2017	Yes	FALSE	FALSE
7/1/2017	6/14/2017	No; Using existing data.	FALSE	FALSE

9/5/2017	9/6/2017	Yes	FALSE	FALSE
1/1/2018	12/15/2017	No; Data came from graduate school work.	FALSE	FALSE
12/1/2016	2/23/2017	No; No, this is a literature review article with no EPA-generated or other data or analysis associated with it.	FALSE	FALSE
10/17/2016	10/17/2016	Yes	TRUE	TRUE

1/19/2017	6/30/2017	No; UNC hospital created data that were used in the publication but EPA did not.	FALSE	FALSE
8/9/2016	10/20/2016	Yes	FALSE	FALSE
6/1/2016	6/20/2017	Yes	FALSE	FALSE
7/1/2016	4/26/2016		TRUE	TRUE

4/21/2016	5/18/2016		TRUE	TRUE
10/13/2016	10/13/2016	Yes	TRUE	TRUE
9/11/2017	9/11/2017	No; EPA did not collect the data nor did EPA directly fund the research effort described in the paper.	FALSE	FALSE
3/1/2017	5/10/2017	Yes	FALSE	FALSE

2/11/2016	4/7/2016		FALSE	FALSE
11/1/2016	11/28/2016	Yes	TRUE	TRUE
9/22/2016	9/26/2016	Yes	TRUE	TRUE
5/5/2016	3/14/2016		FALSE	FALSE

5/13/2016	5/17/2016		FALSE	FALSE
1/24/2017	2/13/2017	Yes	FALSE	FALSE
3/28/2016	5/18/2016		FALSE	FALSE
12/1/2016	12/19/2016	No; *	FALSE	FALSE

3/16/2016	4/27/2016		TRUE	TRUE
3/1/2017	8/28/2017	Yes	FALSE	FALSE
12/1/2016	12/22/2016	Yes	FALSE	FALSE
8/29/2016	4/24/2017	Yes	FALSE	FALSE
1/16/2017	3/15/2017	Yes	TRUE	TRUE

12/15/2016	12/30/2016	No; contains literature data	FALSE	FALSE
4/1/2017	3/13/2017	Yes	FALSE	FALSE
4/28/2016	6/17/2016		FALSE	FALSE
9/1/2016	7/22/2016		TRUE	TRUE
2/22/2016	3/8/2016		FALSE	FALSE
9/10/2016	6/7/2016		FALSE	FALSE

12/28/2016	6/15/2017	Yes	TRUE	TRUE
3/1/2017	1/17/2017	Yes	TRUE	TRUE
4/1/2017	9/5/2017	Yes	FALSE	FALSE
4/1/2017	6/23/2017	Yes	TRUE	TRUE

3/1/2018		Yes	TRUE	FALSE
11/4/2016	11/4/2016	Yes	TRUE	TRUE
9/28/2016	10/6/2016	Yes	FALSE	FALSE
8/11/2016	12/22/2016	Yes	FALSE	FALSE

12/15/2016	1/6/2017	Yes	FALSE	FALSE
8/5/2016	7/20/2016		TRUE	TRUE
11/1/2016	8/25/2017	No; The manuscript describes a computational model.	FALSE	FALSE
9/28/2016	9/28/2016	Yes	FALSE	FALSE
11/1/2016	7/20/2016		TRUE	TRUE

9/1/2016	2/10/2017	Yes	TRUE	TRUE
1/30/2017	6/8/2017	Yes	FALSE	FALSE
11/1/2016	2/28/2017	Yes	TRUE	TRUE

9/30/2016	6/13/2017	Yes	FALSE	FALSE
5/10/2016	10/19/2016	Yes	FALSE	FALSE
9/1/2016	8/25/2017	Yes	TRUE	TRUE
4/3/2017	4/19/2017	Yes	TRUE	TRUE

12/1/2016	12/14/2017	Yes	FALSE	FALSE
7/15/2017	8/14/2017	No; no EPA generated data is associated with this article.	FALSE	FALSE
2/1/2016	2/28/2017	Yes	FALSE	FALSE
7/1/2016	7/7/2016		FALSE	FALSE

10/1/2016	6/16/2016		FALSE	FALSE
9/1/2016	7/22/2016		FALSE	FALSE
8/15/2017	5/24/2017	Yes	FALSE	FALSE
7/1/2016	5/12/2016		FALSE	FALSE

8/9/2016	9/7/2016		FALSE	FALSE
12/1/2016	9/22/2016	No; it is a review	FALSE	FALSE
9/20/2016	10/5/2016	Yes	FALSE	FALSE

2/1/2017	2/15/2017	Yes	FALSE	FALSE
2/1/2017	2/2/2017	No; No EPA-generated data was used; project is exempted from Science Hub because of personally identifiable info	FALSE	FALSE
3/3/2016	3/3/2016		FALSE	FALSE
5/19/2016	12/30/2016	Yes	FALSE	FALSE

11/15/2016	6/21/2017	Yes	TRUE	TRUE
3/14/2017	3/14/2017	Yes	TRUE	TRUE
5/1/2017	6/5/2017	No; Review article - no new data.	FALSE	FALSE
3/14/2017	3/14/2017	No; EPA did not collect the data nor did EPA directly fund the research effort described in the paper.	FALSE	FALSE

7/5/2016	10/17/2016	No; the lead author is not EPA and the data was not created by EPA, but is an analysis of publicly available data	FALSE	FALSE
4/13/2016	2/21/2018	No; Literature review	FALSE	FALSE
9/22/2016	12/14/2017	Yes	TRUE	TRUE
9/2/2016	9/6/2016	No; Review Articles	FALSE	FALSE

9/1/2016	2/16/2017	No; Review article	FALSE	FALSE
1/28/2016	5/27/2016	No; Review article	FALSE	FALSE
11/15/2016	11/15/2016	Yes	TRUE	TRUE
2/28/2017	3/27/2017	Yes	TRUE	TRUE

11/1/2017	9/27/2017	Yes; n/a	FALSE	FALSE
3/2/2016	3/29/2016		FALSE	FALSE
5/1/2017	5/8/2017	No; EPA author provided technical expertise and interpretation of existing data.	FALSE	FALSE
10/27/2016	11/9/2016	Yes; n/a	FALSE	FALSE
7/25/2016	9/8/2016		FALSE	FALSE
1/4/2017	1/10/2017	Yes	TRUE	TRUE

6/1/2016	7/20/2016		FALSE	FALSE
8/1/2016	5/17/2016		FALSE	FALSE
3/1/2017	4/3/2017	No; Papers do not have any data in them.	FALSE	FALSE
9/2/2016	8/9/2016		TRUE	TRUE
10/1/2016	8/9/2016		FALSE	FALSE
12/13/2016	12/13/2016	No; This is a review article.	FALSE	FALSE

11/1/2016	12/15/2016	Yes	TRUE	TRUE
12/6/2016	1/10/2018	Yes	FALSE	FALSE
1/1/2017	11/14/2016	Yes; n/a	FALSE	FALSE
11/1/2017	9/7/2017	Yes	TRUE	TRUE

7/11/2017	7/24/2017	No; This is a review article that is synthesizing the results of previously published analyses.	FALSE	FALSE
4/13/2017	5/5/2017	Yes	FALSE	FALSE
6/2/2016	6/2/2016	No; Review Articles	FALSE	FALSE
5/3/2017	7/19/2017	Yes	FALSE	FALSE

9/9/2016	10/26/2016	Yes	FALSE	FALSE
4/2/2018	4/10/2018	Yes	TRUE	TRUE
3/30/2017	4/14/2017	No; all work and anaylsis performed at UNC	FALSE	FALSE
5/1/2017	8/28/2017	Yes	FALSE	FALSE
6/1/2017	7/7/2017	No; There are not data associated with the paper	FALSE	FALSE

1/7/2017	1/11/2017	Yes	TRUE	TRUE
6/30/2017	6/26/2017	No; Papers do not have any data in them.	FALSE	FALSE
5/1/2017	5/5/2017	Yes	TRUE	TRUE
3/15/2016	4/6/2016		FALSE	FALSE

11/17/2016	2/8/2017	Yes	FALSE	FALSE
2/1/2017	1/31/2017	Yes	TRUE	TRUE
2/1/2017	1/30/2017	Yes	FALSE	FALSE
7/1/2016	2/14/2017	Yes	FALSE	FALSE

2/1/2017	2/10/2017	No; Study evaluated 2 methods for analysis of water quality trends. We used monitoring data from existing programs	FALSE	FALSE
10/1/2016	2/9/2017	Yes	TRUE	TRUE
1/12/2017	1/12/2017	No; Review Article	FALSE	FALSE

5/1/2017	6/6/2017	Yes	TRUE	TRUE
2/1/2017	7/7/2017	No; All experiments and data generation were conducted by collaborators at Nanjing University.	FALSE	FALSE
5/1/2017	3/31/2017	No; This is a review article.	FALSE	FALSE
8/26/2017	9/8/2017	No; The article does not contain any new U.S. EPA data, only data is cited from the literature.	FALSE	FALSE

12/19/2016	2/1/2017	Yes	TRUE	TRUE
7/5/2016	7/13/2016	No; No EPA Data, this is a review article	FALSE	FALSE
12/1/2016	9/30/2017	No; this is a review of already published data	FALSE	FALSE
2/7/2017	2/10/2017	Yes	FALSE	FALSE
11/1/2016	10/25/2017	No; .	FALSE	FALSE
12/13/2016	12/13/2016	No; Concept only, no EPA dataset created	FALSE	FALSE

9/9/2016	9/14/2016		FALSE	FALSE
5/18/2016	5/18/2016		FALSE	FALSE
11/1/2016		No	FALSE	FALSE
4/28/2016	7/29/2016		FALSE	FALSE

5/10/2017	5/3/2017	Yes	TRUE	TRUE
4/1/2016	12/12/2016	No; *	FALSE	FALSE
10/1/2016	12/22/2016	Yes	FALSE	FALSE
7/22/2016	7/22/2016		TRUE	TRUE
12/1/2016	12/28/2016	Yes	FALSE	FALSE

2/7/2017	2/7/2017	No; Data belongs to UNC	FALSE	FALSE
6/6/2016	6/16/2016		TRUE	TRUE
1/12/2017	1/12/2017	Yes	TRUE	TRUE

5/10/2017	5/3/2017	Yes	TRUE	TRUE
10/1/2017	2/2/2018	Yes	FALSE	FALSE
3/21/2017	5/2/2017	Yes	TRUE	TRUE
1/14/2017	5/23/2017	Yes	TRUE	TRUE

12/31/2016	2/8/2017	No; all analysis was based on USGS data	FALSE	FALSE
5/12/2016	5/12/2016		TRUE	TRUE
10/1/2016	11/8/2016	No; This paper resulted from some university collaboration and advisement. The university scientist generated all of the data associated with this paper. My role was to offer advice and review the results.	FALSE	FALSE
11/1/2017	11/6/2017	No; commentary article	FALSE	FALSE

6/16/2017	9/27/2017	Yes	TRUE	TRUE
5/17/2017	1/17/2018	Yes	FALSE	FALSE
10/1/2016	1/4/2017	Yes	FALSE	FALSE

2/1/2017	3/21/2017	No; this is a non-EPA workshop summary and review paper. There is no EPA data associated with the paper.	FALSE	FALSE
8/27/2016	2/14/2017	Yes	FALSE	FALSE
1/1/2018	1/12/2018	Yes	TRUE	TRUE
5/10/2017	5/2/2017	Yes	TRUE	TRUE

12/28/2016	1/3/2017	No; EPA did not collect the data nor did EPA direclty fund the research effort described in the paper.	FALSE	FALSE
6/1/2016	8/16/2016		FALSE	FALSE
2/1/2017	7/13/2017	Yes	TRUE	TRUE
5/23/2016	7/27/2016		FALSE	FALSE

12/1/2016	11/21/2016	No; The article is a review paper which has no data associated with it.	FALSE	FALSE
9/15/2017	4/2/2018	No; Data generated by DISL	FALSE	FALSE
11/1/2016	12/30/2016	Yes	FALSE	FALSE
6/24/2016	7/11/2016	No; Review Articles	FALSE	FALSE

7/1/2016	11/17/2017	Yes	FALSE	FALSE
11/2/2016	11/14/2016	Yes	FALSE	FALSE
10/24/2016	11/21/2016	Yes	FALSE	FALSE

5/1/2017	4/12/2017	No; Rsrch led by Rep of Tajikistan scientists, w/ EPA tech overview. All data generated/owned by Tajik scientists	FALSE	FALSE
2/7/2018	2/7/2018	No; This is a review article	FALSE	FALSE
5/1/2017	8/28/2017	No; The research which produced this data was not funded by EPA. The EPA coauthor helped write the manuscript.	FALSE	FALSE
10/2/2017		No	FALSE	FALSE

12/1/2016	2/27/2017	Yes	TRUE	TRUE
11/14/2016	11/16/2016	Yes	TRUE	TRUE
4/11/2017	8/29/2017	No; Graduate student was lead for this article.	FALSE	FALSE
2/27/2017	11/17/2017	No; SETAC Workshop summary	FALSE	FALSE

10/14/2016	6/15/2017	No; No EPA Data, review article.	FALSE	FALSE
5/22/2017	5/22/2017	Yes	TRUE	TRUE
8/5/2016	8/9/2016	No; Review Articles	FALSE	FALSE
1/2/2017	5/8/2017	Yes	FALSE	FALSE

1/1/2018		No	FALSE	FALSE
6/23/2016	7/15/2016		TRUE	TRUE
12/1/2017	1/31/2018	Yes	TRUE	TRUE

3/1/2017	6/23/2017	No; Papers do not have any data in them.	FALSE	FALSE
3/17/2017	4/3/2017	No; Papers do not have any data in them.	FALSE	FALSE
11/1/2016	11/6/2017	No; published before requirement	FALSE	FALSE
9/21/2017	8/29/2017	Yes	TRUE	TRUE
10/26/2016	11/9/2016	Yes	FALSE	FALSE

6/15/2016	6/16/2016		FALSE	FALSE
2/1/2017	1/11/2017	No; A review of published literature	FALSE	FALSE
9/1/2016	8/12/2016		TRUE	TRUE
11/28/2016	2/27/2017	Yes	TRUE	TRUE

11/1/2016	8/15/2016		FALSE	FALSE
4/11/2016	6/3/2016		TRUE	TRUE
8/1/2016	7/11/2016		FALSE	FALSE

11/15/2016	8/12/2016		TRUE	TRUE
2/1/2017	11/23/2016	No; No data was collected; all data are from analysis of textual statements in published reports and articles	FALSE	FALSE
10/27/2016		Yes	TRUE	FALSE
5/18/2017	5/18/2017	Yes	TRUE	TRUE

10/4/2016	10/26/2016	No; The papers contribute to research being conducted through an agreement between the Chinese Ministry of Science and Technology and EPA. Lead authors not from EPA.	FALSE	FALSE
11/7/2016	5/5/2017	No; The papers contribute to research being conducted through an agreement between the Chinese Ministry of Science and Technology and EPA. Lead authors not from EPA.	FALSE	FALSE
10/10/2016	12/28/2016	Yes	TRUE	TRUE

6/15/2017	9/29/2017	No; The paper has data generated by NIH and the EPA coauthors provided input into the prepartion of the manuscript	FALSE	FALSE
3/1/2018	2/12/2018	No; Article is based on secondary data from sources like satellite remote sensing and state environmntl agencies	FALSE	FALSE
11/1/2016	1/10/2017	Yes	TRUE	TRUE
12/1/2016	9/22/2016	No; review only	FALSE	FALSE

1/24/2017	5/1/2017	Yes	TRUE	TRUE
8/1/2016	11/17/2017	No; Authorship granted only due to samples provided	FALSE	FALSE
7/1/2017	6/6/2017	Yes	TRUE	TRUE
11/1/2017	1/12/2018	Yes	TRUE	TRUE

12/28/2016	2/8/2017	Yes	TRUE	TRUE
5/1/2016	3/29/2018	No; introduction to special issue - no data	FALSE	FALSE
2/14/2017	2/14/2017	Yes	TRUE	TRUE
5/1/2016	6/3/2016		FALSE	FALSE

9/1/2017	8/24/2017	No; All data generated by Oregon State University	FALSE	FALSE
11/15/2016	10/19/2016	Yes	FALSE	FALSE
3/27/2017	4/11/2018	Yes	FALSE	FALSE

8/1/2017	8/4/2017	No; No. This is a methods paper. There is no data - it is all secondary data.	FALSE	FALSE
3/28/2017	6/29/2017	Yes	TRUE	TRUE
4/30/2017	2/13/2017	Yes	TRUE	TRUE

11/1/2016	7/24/2017	Yes	TRUE	TRUE
3/7/2017	6/15/2017	Yes	TRUE	TRUE
12/9/2015	1/11/2018	No; Information gathered by NIH, Univ. of Calif, and Harvard University.	FALSE	FALSE
3/1/2017	3/2/2017	No; This manuscript is a commentary, and it does not use EPA generated data.	FALSE	FALSE

4/15/2017	5/5/2017	Yes	TRUE	TRUE
9/16/2016	2/23/2017	Yes	FALSE	FALSE
2/1/2018	3/5/2018	Yes	TRUE	TRUE
3/1/2017	11/17/2017	Yes	TRUE	TRUE

3/1/2017	3/14/2017	No; Workshop that did not employ any EPA data.	FALSE	FALSE
3/1/2017	3/14/2017	No; Workshop that did not employ any EPA data.	FALSE	FALSE
11/1/2017	2/8/2018	No; Data analysis of human subjects with individual-level data that is potentially sensitive and not shareable.	FALSE	FALSE

2/1/2017	2/16/2017	Yes	TRUE	TRUE
9/1/2017	8/28/2017	Yes	FALSE	FALSE
3/1/2017	5/10/2017	No; opinion of outcomes of NIH-Bethesda, MD workshop	FALSE	FALSE
6/14/2017	6/16/2017	Yes	TRUE	TRUE

5/1/2018		No	FALSE	FALSE
12/20/2016	12/20/2016	Yes	TRUE	TRUE
11/1/2017	11/2/2017	Yes	TRUE	TRUE
1/1/2017	12/28/2016	Yes	TRUE	TRUE

11/1/2016	11/22/2016	Yes	TRUE	TRUE
12/20/2016	8/23/2017	Yes	FALSE	FALSE
8/1/2017	8/29/2017	No; Data is from drinking water pland and the Baltimore long term ecological research site	TRUE	TRUE
2/16/2017	2/23/2017	Yes	TRUE	TRUE
10/26/2016	10/26/2016	No; Review Article	FALSE	FALSE

8/26/2016	12/22/2016	Yes	FALSE	FALSE
8/1/2016	3/24/2017	Yes	FALSE	FALSE
10/18/2016	4/27/2017	Yes	TRUE	TRUE
3/14/2017	3/14/2017	Yes	TRUE	TRUE

1/1/2017	1/26/2017	No; Book Review in a Journal	FALSE	FALSE
11/1/2016	11/28/2016	Yes	TRUE	TRUE
6/20/2016	7/15/2016		TRUE	TRUE
11/24/2016	1/4/2017	No; Published ocean data (Hemsley et al. 2015) is used in the journal article.	FALSE	FALSE

3/30/2017	5/8/2017	Yes	TRUE	TRUE
11/10/2016		No	FALSE	FALSE
7/28/2017	8/25/2017	Yes	TRUE	FALSE
10/1/2016	9/29/2016	Yes	FALSE	FALSE

1/11/2018	2/9/2018	Yes	TRUE	TRUE
10/25/2016	10/27/2016	No; workshop summary manuscript presented as journal Forum article with no EPA generaged data	FALSE	FALSE
9/1/2016	8/29/2016		TRUE	TRUE
11/9/2016	4/5/2017	Yes	TRUE	TRUE
1/1/2017	4/5/2017	Yes	TRUE	TRUE

10/13/2016	2/5/2018	No; Data was generated by Stanford University, Stanford, California.	FALSE	FALSE
9/1/2016	9/12/2016		TRUE	TRUE
1/31/2017	12/14/2016	Yes	TRUE	TRUE
7/1/2017	7/28/2017	Yes	FALSE	FALSE

11/1/2016	10/6/2016	Yes	FALSE	FALSE
4/3/2017	5/25/2017	Yes	TRUE	TRUE
2/1/2017	2/23/2017	Yes	TRUE	TRUE
6/1/2017	5/31/2017	Yes	TRUE	TRUE

11/1/2016	11/4/2016	Yes	FALSE	FALSE
9/1/2016	6/6/2017	Yes	FALSE	FALSE
1/1/2017	9/19/2016	No; Data collected by Brazilian coauthors in Brazil using published guidance cited in text and references	FALSE	FALSE
3/15/2017	2/16/2017	Yes	TRUE	TRUE

11/7/2016	12/14/2016	No; .	FALSE	FALSE
3/3/2017	7/26/2017	Yes	TRUE	TRUE
10/29/2016	11/7/2016	No; This paper is a workshop review and contains no EPA data and therefore needs no SDM plan or associated QAPP.	FALSE	FALSE
4/21/2017	6/26/2017	Yes	FALSE	FALSE

7/30/2016	8/1/2016		TRUE	TRUE
6/15/2017	9/14/2017	Yes	TRUE	FALSE
7/31/2016	6/6/2017	No; highlights from a conference	TRUE	TRUE
9/1/2017	5/31/2017	Yes	TRUE	TRUE

4/6/2017	3/14/2017	Yes	TRUE	FALSE
11/22/2016	11/28/2016	No; Math Tutorial	FALSE	FALSE
8/10/2016	2/14/2017	Yes	FALSE	FALSE
3/29/2017	4/14/2017	Yes	FALSE	FALSE

2/7/2017	6/6/2017	Yes	TRUE	TRUE
9/15/2016	7/22/2016		TRUE	TRUE
10/15/2017	9/12/2017	No; The data were collected or compiled by non-EPA co-authors.	FALSE	FALSE
8/1/2017	6/6/2017	Yes	TRUE	TRUE

8/14/2016	4/18/2017	No; I was intellectual contributor - not data contributor. I helpied primary author interpret data & gave advice.	FALSE	FALSE
2/16/2017	5/3/2017	No; Secondary data only	FALSE	FALSE
3/1/2017	2/16/2017	Yes	TRUE	TRUE
3/6/2018		No	TRUE	FALSE

3/31/2017	2/8/2017	Yes	FALSE	FALSE
1/1/2017	12/2/2016	Yes	TRUE	TRUE
8/1/2016	4/18/2017	Yes	FALSE	FALSE
4/2/2018	1/11/2018	Yes	TRUE	TRUE

10/28/2016	8/23/2017	Yes	TRUE	TRUE
6/23/2017	8/23/2017	Yes	TRUE	TRUE
2/28/2017	6/6/2017	Yes	TRUE	TRUE
11/7/2016	12/19/2016	No; -	FALSE	FALSE

12/27/2017	1/3/2018	No; The article is an overview of the findings of qualitative interviews with coastal managers.	FALSE	FALSE
3/1/2017	11/17/2017	No; Review article	FALSE	FALSE
1/6/2017	2/10/2017	Yes	TRUE	TRUE
7/1/2017	5/10/2017	Yes	TRUE	TRUE

4/1/2017	6/6/2017	Yes	TRUE	TRUE
1/2/2017	2/23/2017	No; Review paper on integrated modeling systems.	FALSE	FALSE
1/27/2017	3/6/2017	Yes	FALSE	FALSE
1/1/2017	2/8/2017	Yes	FALSE	FALSE

8/1/2017	5/31/2017	Yes	TRUE	TRUE
12/1/2017	11/14/2017	No; This publication contains EPA generated data, however it was finalized and cleared for publication before the Science Hub workflow process was developed for studies that contain personally identifiable information and sensitive medical data. Per Dr. T	FALSE	FALSE
9/1/2017	9/8/2017	Yes	FALSE	FALSE

12/15/2016	11/2/2016	Yes	TRUE	TRUE
6/13/2017	3/14/2018	No; Data was generated by Lead Author at the University of Maryland. The EPA provided advice and data interpretat	FALSE	FALSE
2/1/2017	2/24/2017	No; A review/Database/analysis	FALSE	FALSE
7/1/2017	8/29/2017	Yes	FALSE	FALSE

9/21/2017	11/1/2017	Yes	TRUE	TRUE
3/1/2017	11/17/2017	Yes	TRUE	TRUE
2/15/2017	2/23/2017	Yes	TRUE	TRUE
12/8/2016	2/15/2017	No; All the data in this manuscript is generated by the Romanian couthors.	TRUE	TRUE
2/6/2018		No; publicaton cleared prior to Science Hub workflow process was developed for personally identifiable information	FALSE	FALSE

11/1/2017	1/3/2018	Yes	TRUE	TRUE
4/3/2017	5/9/2017	No; All data represented in this article is contained in the manuscript and/or its associated Supplemental Material.	FALSE	FALSE
6/12/2017	1/22/2018	No; No data associated with this article. This paper introduced GIFMod and provided some example applications.	FALSE	FALSE
3/1/2017	11/17/2017	Yes	TRUE	TRUE

9/1/2016	3/1/2017	No; All data is from University of Georgia	FALSE	FALSE
5/9/2017	5/10/2017	No; Data was gathered during a US Park Service led workshop	FALSE	FALSE
5/2/2017	5/10/2017	No; No data collected - paper is an intellectual application of FEGS to a problem	FALSE	FALSE
5/16/2017	9/29/2017	Yes	TRUE	TRUE
11/23/2016	2/23/2017	Yes	TRUE	TRUE

3/3/2017	6/15/2017	Yes	TRUE	TRUE
11/1/2017	11/6/2017	Yes	TRUE	TRUE
8/8/2017	8/9/2017	No; Data were collected as part of the National Birth Defects Prevention Study (NBDPS) through the CDC.	FALSE	FALSE
8/1/2017	8/1/2017	No; Review article, no data	FALSE	FALSE

3/1/2017	2/23/2017	No; This product is a literature review.	TRUE	TRUE
12/26/2017	2/9/2018	Yes	TRUE	TRUE
1/6/2017	8/23/2017	Yes	FALSE	FALSE
12/9/2016	12/12/2016	Yes	FALSE	FALSE

7/7/2017	8/16/2017	Yes	TRUE	TRUE
2/1/2018	2/26/2018	Yes	FALSE	FALSE
5/17/2017	6/8/2017	No; Journal article is a review of EPA documents and assessment processes and did not use EPA-generated data.	FALSE	FALSE
8/16/2017	9/6/2017	No; The paper focuses on an already existing model called EXP-HYDRO from Patil and Stieglitz (2014)	FALSE	FALSE

12/1/2017	12/1/2017	Yes	FALSE	FALSE
9/1/2017	12/19/2017	No; No data in article	FALSE	FALSE
2/10/2017	2/10/2017	Yes	FALSE	FALSE
12/22/2017	1/30/2018	No; Lead author developed and ran the model using published literature values and NOAA data.	FALSE	FALSE
9/5/2017	9/7/2017	Yes	TRUE	TRUE
6/15/2017	6/28/2017	Yes	FALSE	FALSE

12/1/2016	2/10/2017	Yes	FALSE	FALSE
3/1/2017	2/8/2018	No; Data were generated by USGS and are publically available through their process	FALSE	FALSE
2/1/2017	3/14/2017	Yes	TRUE	TRUE
9/5/2016	2/14/2017	Yes	FALSE	FALSE

6/20/2017	8/28/2017	Yes	FALSE	FALSE
1/10/2017	12/14/2017	No; Helped with writing, provided expertise in tree physiology that helped data be interpreted by Univ of Idaho	FALSE	FALSE
5/18/2017	5/18/2017	Yes	TRUE	TRUE
5/15/2017	5/9/2017	Yes	TRUE	TRUE
5/1/2017	12/18/2017	No; There was no EPA generated data for this article (data was taken from literature)	FALSE	FALSE

5/16/2017	5/16/2017	Yes	TRUE	TRUE
7/1/2017	7/7/2017	No; ORD-018108 was led by a graduate student and the data are hers as part of her dissertation.	FALSE	FALSE
5/2/2017	6/6/2017	Yes	TRUE	TRUE
11/17/2016	2/14/2017	Yes	FALSE	FALSE

12/1/2017	2/2/2018	Yes	FALSE	FALSE
5/26/2017	4/16/2018	No; revisiting for 2002 publication by same author	FALSE	FALSE
2/23/2017	5/31/2017	Yes	TRUE	TRUE
9/1/2016	3/12/2018	No; Data consisit of secondary data only	FALSE	FALSE
2/1/2017	6/23/2017	Yes	TRUE	TRUE

4/21/2017	5/8/2017	Yes	TRUE	TRUE
3/20/2017	5/5/2017	Yes	FALSE	FALSE
11/1/2017	9/21/2017	Yes	TRUE	TRUE
1/1/2017	11/17/2017	Yes	TRUE	TRUE

5/4/2017	4/24/2018	No; Review of previously published article results only	FALSE	FALSE
12/9/2016	12/12/2016	Yes	FALSE	FALSE
11/25/2016	9/27/2017	Yes	TRUE	TRUE
2/21/2017	2/24/2017	Yes	TRUE	TRUE

8/24/2017	9/27/2017	Yes	TRUE	TRUE
3/18/2018	4/16/2018	No; This is a literature review article. It contains no new data or analyses, either EPA-generated or otherwise	FALSE	FALSE
9/7/2016	4/14/2017	No; This journal article is observational based on analysis of existing population data.	FALSE	FALSE
4/17/2017	9/7/2017	Yes	FALSE	FALSE
10/1/2016	10/6/2016	No; Product is being cleared for completion-work prior to EPA	FALSE	FALSE

5/1/2017	4/23/2018	Yes	TRUE	TRUE
10/2/2017	11/28/2017	No; This is literature review.. No original data was generated. It used data from outside sources	FALSE	FALSE
12/16/2016	12/21/2016	Yes	TRUE	TRUE
4/1/2017	12/30/2016	Yes	TRUE	TRUE

4/17/2017	9/7/2017	Yes	TRUE	TRUE
11/1/2016	5/5/2017	No; All calculations were performed using published data on chemical manufacturing processes from the scientific literature.	FALSE	FALSE
1/15/2018	4/10/2018	No; Research data consisted of secondary data only.	FALSE	FALSE
5/25/2017	5/25/2017	No; The data was generated by researchers in Australia	FALSE	FALSE
12/1/2017	9/25/2017	Yes	TRUE	TRUE
12/22/2016	1/4/2017	No; Secondary data only	FALSE	FALSE

4/1/2017	7/7/2017	Yes	TRUE	TRUE
8/1/2017	5/10/2017	No; Paper describes the modeling enviornment.	FALSE	FALSE
6/1/2017	8/23/2017	No; The manuscript reviews existing available models, indicators, and metrics for climate event resilience.	FALSE	FALSE
5/15/2017	3/1/2017	Yes	TRUE	TRUE

6/29/2017	11/17/2017	No; Review paper, no data to report	TRUE	FALSE
4/1/2017	3/17/2017	Yes	FALSE	FALSE
6/1/2017	7/7/2017	Yes	TRUE	TRUE
2/1/2018	1/11/2018	Yes	TRUE	TRUE

4/2/2018	3/5/2018	Yes	FALSE	FALSE
2/6/2017	4/13/2017	Yes	TRUE	TRUE
2/23/2017	3/9/2018	Yes	TRUE	TRUE

7/12/2017	7/26/2017	No; Research data consisted of secondary data only	FALSE	FALSE
5/1/2017	7/28/2017	No; Publicly available datasets were reanalyzed They are identified and described appropriately within the article	FALSE	FALSE
2/13/2017	6/6/2017	Yes	TRUE	TRUE

4/1/2017	6/9/2017	No; This article proposes a new conceptual approach to modeling of ecotoxicological effects.	FALSE	FALSE
3/1/2017	6/9/2017	No; It does not have any data because it describes an outreach activity conducted in the Western Balkans	FALSE	FALSE
7/1/2017	2/8/2018	No; This is a review paper - no data, just summary and interpretation	TRUE	TRUE
11/8/2016	11/8/2016	No; Data does not belong to the EPA. Started prior to joining EPA	FALSE	FALSE
4/1/2018	4/16/2018	No; Data belongs to USDA-ARS	FALSE	FALSE

6/1/2017	9/25/2017	Yes	TRUE	TRUE
6/1/2017	6/9/2017	Yes	TRUE	TRUE
11/9/2017		Yes	TRUE	FALSE
8/24/2017	9/21/2017	Yes	TRUE	TRUE

2/2/2017	2/16/2017	Yes	TRUE	TRUE
11/1/2016	6/15/2017	No; Research data consisted of secondary data only	FALSE	FALSE
4/1/2017	6/12/2017	Yes	TRUE	TRUE
1/4/2017	3/15/2017	Yes	TRUE	TRUE

11/1/2017	9/7/2017	Yes	TRUE	TRUE
4/5/2017	5/31/2017	Yes	TRUE	TRUE
12/13/2016	2/6/2017	Yes	TRUE	TRUE
11/1/2017	8/22/2017	No; Article is a review/synthesis, presenting no EPA data or outside data whatsoever.	FALSE	FALSE

6/12/2017	6/12/2017	Yes	TRUE	TRUE
1/1/2017	5/10/2017	No; This is a news column of recent technology reports.	FALSE	FALSE
5/15/2017	5/9/2017	Yes	FALSE	FALSE
6/1/2017	9/11/2017	Yes	TRUE	TRUE

11/20/2017		Yes	TRUE	FALSE
8/1/2017	8/29/2017	No; Article is a review of published literature	FALSE	FALSE
3/1/2017	2/9/2017	No; Review article, utilizes secondary data from the literature	FALSE	FALSE
1/24/2018	12/13/2017	No; Research data consisted of secondary data only	FALSE	FALSE

10/1/2017	4/30/2018	Yes	TRUE	TRUE
12/16/2016	4/19/2017	Yes	TRUE	TRUE
4/1/2017	3/6/2017	No; Data was generated at Oregon State University. EPA was a collaborator.	FALSE	FALSE

7/31/2017	8/1/2017	Yes	TRUE	TRUE
2/1/2017	1/25/2017	No; Study by a laboratory in China	FALSE	FALSE
5/22/2017		Yes	TRUE	FALSE

11/9/2017	12/7/2017	Yes	TRUE	TRUE
8/16/2017	8/16/2017	No; USGS owns the datasets that were used to build the software.	FALSE	FALSE
5/2/2017	5/8/2017	No; This manuscript contains a small amount of methodological data that were only used to optimize** see comments	FALSE	FALSE

1/31/2017	2/8/2018	No; EPA did not generate any of the model inputs described in the journal article.	FALSE	FALSE
9/1/2017	6/6/2017	Yes	TRUE	TRUE
9/20/2017	8/28/2017	No; Research Consisted of secondary data only	FALSE	FALSE

5/27/2017	10/4/2017	Yes	TRUE	TRUE
6/7/2017	9/28/2017	Yes	TRUE	TRUE
12/1/2017	9/28/2017	Yes	TRUE	TRUE
6/12/2017	9/14/2017	Yes	TRUE	TRUE

7/1/2017	6/15/2017	Yes	TRUE	TRUE
1/15/2016	3/21/2017	No; This is a review article primarily by external non-EPA authors, and has no associated data.	FALSE	FALSE
10/20/2017	4/30/2018	No; Uses secondary data only, including some from EPA National Wetland Condition Assessment	FALSE	FALSE
12/1/2016	2/8/2017	Yes	FALSE	FALSE
11/28/2016	11/28/2016	No; Scientific meeting report	FALSE	FALSE

1/9/2017	1/12/2017	No; Scientific perspective	FALSE	FALSE
7/20/2017	12/7/2017	Yes	TRUE	TRUE
9/28/2017	9/28/2017	Yes	TRUE	TRUE
3/17/2017	4/19/2017	No; No EPA data	FALSE	FALSE

5/20/2017	8/29/2017	No; Data in this paper were generated by an Oregon State University student and not by EPA.	FALSE	FALSE
7/1/2017	11/21/2017	No; No primary data was generated. Secondary data from non-EPA LCA databases was used for this analysis.	TRUE	TRUE
2/1/2018	3/14/2018	No; DBP and health data came from state agencies in Massachusetts, and from individual public water utilities	FALSE	FALSE
4/2/2018	4/5/2018	No; This paper reviews the published literature; it contains no EPA-generated data.	FALSE	FALSE

5/1/2017	6/9/2017	No; Editorial only	FALSE	FALSE
10/24/2016	3/15/2017	No; All the data presented in the STICS entry ORD-019266 was generated by our European collaborators. EPA's contribution (me and Kellie Fay) was limited to generation of the biological material used to collect the data, technical guidance on performing th	FALSE	FALSE
4/13/2017	5/8/2017	Yes	FALSE	FALSE

4/13/2017	5/8/2017	No; The work was supported by a Cooperative Agreement; data was collected by participating instituions.	FALSE	FALSE
11/15/2017	11/3/2017	No; This work was conducted prior to my employment at the EPA, and it is composed of qualitative interviews.	FALSE	FALSE
12/1/2016	12/22/2016	No; Data was generated by Duke and analyzed at HMGU. EPA authors are part of Cathgen team and guide/provide advice	FALSE	FALSE
7/1/2017	6/21/2017	No; Review article	FALSE	FALSE
11/28/2016	11/28/2016	No; Review Article	FALSE	FALSE

10/20/2016	11/27/2017	No; This is a small abstract contained within a workshop report for SETAC.	FALSE	FALSE
9/10/2017	6/14/2017	No; Data was generatred by scientists in Chile.	FALSE	FALSE
2/2/2017	5/5/2017	No; Data was generated by the author(s); EPA provided financial support for data analysis and publication only.	FALSE	FALSE

11/2/2017	11/2/2017	Yes	TRUE	TRUE
4/1/2017	5/8/2017	No; The data was collected by universities as part of a cooperative agreement 83563201 to Univ. of Virginia.	FALSE	FALSE
3/1/2017	1/3/2018	No; No data used in article	FALSE	FALSE
9/24/2017	12/14/2017	No; Article includes insights from an investigation of the primary literature. No data was generated or analyzed.	FALSE	FALSE

7/14/2017	9/7/2017	Yes	TRUE	TRUE
2/23/2017	5/8/2017	Yes	TRUE	TRUE
9/1/2017	9/7/2017	No; Used data from the Korean National Environmental Health Survey and from published articles	FALSE	FALSE
10/1/2017	9/30/2017	No; PM samples collected by the EPA were sent to outside collaborators who used them to generate data	FALSE	FALSE

11/1/2017	11/13/2017	No; The data in this manuscript was gathered as part of my dissertation research at The Ohio State University.	FALSE	FALSE
5/2/2017	6/6/2017	Yes	TRUE	TRUE
7/1/2017	8/29/2017	No; Literature review article	FALSE	FALSE
4/1/2017	5/5/2017	No; This journal article was a review product of a workshop on ionizable organic chemicals, involving no new data generation.	FALSE	FALSE

2/22/2018	2/28/2018	Yes	TRUE	TRUE
8/1/2017	5/25/2017	No; Data gathering and analysis took place in China.	FALSE	FALSE
8/1/2017	10/30/2017	No; This is a workshop analysis/report that involved no generation of new data.	FALSE	FALSE
12/15/2017	11/6/2017	No; This is a review article.	FALSE	FALSE

9/1/2017	9/13/2017	No; Research data consisted of secondary data only	FALSE	FALSE
6/1/2017	8/18/2017	No; We provided samples (dosed rat urine) that contained the analytes to researchers	FALSE	FALSE
1/1/2018	11/7/2017	Yes	TRUE	TRUE
8/15/2017	9/11/2017	No; This was a collaborative study. I have provided selection of chemicals with doses & provided guidance	FALSE	FALSE

7/1/2017	6/6/2017	Yes	TRUE	TRUE
10/25/2017	10/25/2017	No; no EPA data was generated for this article	FALSE	FALSE
4/13/2017	4/19/2017	Yes	TRUE	TRUE
5/2/2017	11/17/2017	Yes	TRUE	TRUE

11/10/2017	11/21/2017	Yes; NAGE Exempt	FALSE	FALSE
5/24/2017	7/31/2017	Yes	TRUE	TRUE
4/7/2017	4/24/2017	No; It is a literature review and reflects peer reviewed literature external to EPA	FALSE	FALSE
3/14/2017	6/9/2017	Yes	TRUE	TRUE

3/8/2017	11/7/2017	No; This is a state-of-the-science literature review article.	FALSE	FALSE
1/15/2017	12/19/2016	No; This is a review article.	FALSE	FALSE
11/1/2017	11/16/2017	Yes	TRUE	TRUE
12/20/2016	1/11/2018	Yes	TRUE	TRUE

1/2/2018	1/10/2018	No; This work was done by NOAA led researchers as part of a REServ Program that started in 2011.	FALSE	FALSE
5/1/2017	6/29/2017	Yes	TRUE	TRUE
8/1/2017	5/16/2017	Yes	TRUE	TRUE
5/8/2017	3/12/2018	Yes	TRUE	TRUE

10/10/2017	1/11/2018	Yes	TRUE	TRUE
6/1/2017	9/29/2017	No; no EPA data; all the data generated by external organizations; EPA coauthors	FALSE	FALSE
2/10/2017	2/16/2017	No; This article from participation in an expert panel (no data collection or analysis)	TRUE	TRUE
2/26/2016	1/30/2017	Yes	TRUE	TRUE

12/1/2016	4/20/2018	No; review article	TRUE	TRUE
2/10/2017	2/15/2017	Yes	TRUE	TRUE
12/15/2017	5/4/2018	No; This is a literature review and includes officially available data from EPA.	FALSE	FALSE
1/12/2017	2/9/2017	Yes	TRUE	TRUE

5/10/2017	6/9/2017	Yes	TRUE	TRUE
9/10/2017		Yes	TRUE	FALSE
11/15/2017	6/9/2017	Yes	TRUE	TRUE
4/19/2017	5/17/2017	Yes	TRUE	TRUE

9/30/2017	11/6/2017	Yes	FALSE	FALSE
12/13/2016	12/21/2016	Yes	TRUE	TRUE
11/6/2017	11/14/2017	Yes	TRUE	TRUE
4/18/2017	4/19/2017	Yes	TRUE	TRUE
10/1/2017	7/31/2017	Yes	TRUE	TRUE

7/1/2017	8/9/2017	Yes	FALSE	FALSE
3/1/2017	12/15/2017	No; review article	FALSE	FALSE
6/15/2017	6/15/2017	Yes	TRUE	TRUE
10/24/2017	2/15/2018	Yes	TRUE	TRUE
1/25/2018	3/9/2018	No; I am editing a special edition of a journal	FALSE	FALSE

2/1/2018	4/10/2018	Yes	TRUE	TRUE
6/1/2017	6/22/2017	No; Data generated at Stanford, used as part of a new analysis here.	FALSE	FALSE
1/29/2018		Yes; NAGE Exempt	FALSE	FALSE
4/7/2017	4/12/2017	Yes	TRUE	TRUE

9/1/2017	9/7/2017	Yes	TRUE	FALSE
3/1/2018	2/27/2018	Yes	TRUE	TRUE
4/2/2018	4/20/2018	No; review	FALSE	FALSE
8/1/2017	11/6/2017	No; Review paper	FALSE	FALSE

5/2/2017	10/27/2017	No; All sampling and chemical analyses published in the current paper were conducted by USGS personnel.	FALSE	FALSE
3/1/2017	4/2/2018	No; Data were generated by the USGS	FALSE	FALSE
4/1/2017	6/12/2017	No; This is a review article that contains no new EPA generated data.	FALSE	FALSE
1/1/2018	1/25/2018	Yes	TRUE	TRUE

6/1/2017	8/22/2017	No; Paper based on workshop discussions. No original data included.	FALSE	FALSE
11/1/2017	1/26/2018	No; Data were generated by Lead Author from Central Washington University.	FALSE	FALSE
5/1/2018	4/2/2018	Yes; GED exempt - paper cleared before 6/30/2017	FALSE	FALSE
8/31/2017	5/11/2017	Yes	TRUE	TRUE

3/30/2018	4/23/2018	Yes	TRUE	TRUE
4/1/2017	4/18/2017	Yes	TRUE	TRUE
5/2/2017	5/30/2017	Yes	TRUE	TRUE
8/30/2017	9/28/2017	Yes	TRUE	TRUE
3/1/2018	2/27/2018	Yes	TRUE	TRUE
11/1/2017	11/3/2017	Yes	TRUE	TRUE

8/4/2017		Yes	TRUE	FALSE
7/10/2017	8/2/2017	No; Data were from existing external published papers.	FALSE	FALSE
4/20/2017	9/27/2017	Yes	TRUE	TRUE
11/1/2016	10/16/2017	Yes	TRUE	TRUE

6/30/2017	2/22/2018	Yes	TRUE	TRUE
3/2/2018	4/23/2018	Yes	TRUE	TRUE
11/21/2017	11/22/2017	Yes	TRUE	TRUE
10/17/2017	3/21/2018	No; Human health data	FALSE	FALSE

2/1/2018	3/19/2018	Yes	TRUE	TRUE
9/1/2017	11/17/2017	Yes	TRUE	TRUE
3/28/2017	3/30/2017	No; It is a Letter to the Editor with no data presented.	FALSE	FALSE
7/14/2017	7/19/2017	No; Data analyses conducted by collaborator at SUNY-Binghamton. EPA contribution on interpretation and reporting.	FALSE	FALSE

1/18/2018	1/22/2018	Yes	TRUE	TRUE
9/10/2017	4/10/2018	No; This is a framework article	FALSE	FALSE
10/11/2017	3/19/2018	Yes	TRUE	TRUE
11/7/2017	1/3/2018	Yes	TRUE	FALSE
12/1/2017	12/8/2017	No; Research was a graduate research project conducted by the Univ of MN-Duluth with funding from MN Sea Grant.	FALSE	FALSE

11/27/2017	11/28/2017	No; The data was generated by Oregon State University	FALSE	FALSE
10/1/2017	7/19/2017	Yes	TRUE	TRUE
4/1/2018	3/22/2018	No; The article proposed a methodological approach and did not require data creation.	FALSE	FALSE
1/9/2017	9/27/2017	No; no EPA data; all the data generated by external organizations; EPA coauthors	FALSE	FALSE

9/7/2017	9/7/2017	No; Commentary	FALSE	FALSE
11/1/2017	11/20/2017	Yes	TRUE	TRUE
8/15/2017	6/28/2017	Yes	TRUE	TRUE
11/21/2017	1/22/2018	Yes	FALSE	FALSE

12/1/2017	12/5/2017	Yes	TRUE	TRUE
9/15/2017	1/10/2018	No; Work was conducted at University of Wisconsin.	TRUE	TRUE
9/15/2017	2/8/2018	No; ItÂ¿s a review and synthesis paper (only public domain data used)	FALSE	FALSE

7/12/2017	9/28/2017	Yes	TRUE	TRUE
2/21/2017	2/21/2017	Yes	TRUE	TRUE
1/1/2018	4/16/2018	Yes	TRUE	TRUE
7/1/2017	8/28/2017	No; EPA role was providing tecnical and scientific advice. All work performed in U. Georgia	FALSE	FALSE
1/31/2018	2/1/2018	Yes	TRUE	TRUE

4/17/2017	4/13/2017	Yes	TRUE	TRUE
8/16/2017		Yes	TRUE	TRUE
1/1/2017	3/1/2017	Yes	TRUE	TRUE
1/3/2018	11/28/2017	Yes	TRUE	TRUE

9/1/2017	12/13/2017	No; Article is an opinion piece containing no data.	FALSE	FALSE
9/1/2017	6/8/2017	Yes	TRUE	TRUE
11/7/2017	4/20/2018	No; main PIs at NKU	FALSE	FALSE
10/1/2017	8/25/2017	No; The research involved mining and synthesizing existing health, landcover, and census data.	TRUE	TRUE
12/1/2017	1/11/2018	Yes; GED exempt - paper cleared before June 30 2017	FALSE	FALSE

3/21/2017	5/9/2017	Yes	TRUE	TRUE
7/21/2017	11/8/2017	No; A Framework not research results	FALSE	FALSE
7/21/2017	11/8/2017	No; A Framework not research results	FALSE	FALSE
7/13/2017	12/19/2017	No; It uses some 2013 EPA data but they werent generated by us for the paper- we just used them	FALSE	FALSE
6/1/2017	5/30/2017	Yes	TRUE	TRUE

1/13/2018	2/8/2018	Yes	FALSE	FALSE
12/1/2017	12/7/2017	Yes	TRUE	TRUE
9/5/2017	9/19/2017	Yes	TRUE	TRUE
10/21/2017	10/31/2017	Yes	FALSE	FALSE
5/24/2017	6/6/2017	Yes	TRUE	TRUE

8/1/2017	8/1/2017	Yes	TRUE	TRUE
5/29/2017	9/27/2017	No; This is a review type of article.	FALSE	FALSE
2/1/2018	12/4/2017	Yes	TRUE	TRUE

4/17/2017	5/3/2017	No; Data were generated by the University of Idaho. I contributed to the project prior to joining EPA.	FALSE	FALSE
5/9/2017	4/4/2018	Yes	FALSE	FALSE
1/1/2018	9/25/2017	Yes; NAGE Exempt	FALSE	FALSE
6/27/2017	12/20/2017	No; all coauthor data	FALSE	FALSE

9/7/2016	4/24/2018	No; Literature review only	FALSE	FALSE
8/18/2017	11/17/2017	Yes	TRUE	TRUE
10/2/2017		No; Research data consisted of secondary data only, e.g., Nat'l Hydrogr. Dataset, AK Anadromous Waters Catalog	FALSE	FALSE

10/12/2017	11/30/2017	Yes	TRUE	TRUE
8/22/2017	8/25/2017	Yes	TRUE	TRUE
11/9/2017	11/28/2017	Yes	TRUE	TRUE

12/15/2017	7/19/2017	Yes	TRUE	TRUE
10/1/2017	9/7/2017	Yes	TRUE	TRUE
3/2/2018	4/12/2018	No; Commentary/Review-type paper	FALSE	FALSE
12/1/2017	3/12/2018	No; review type-article no data	FALSE	FALSE

8/1/2017	8/22/2017	Yes	TRUE	TRUE
1/26/2017	6/6/2017	No; Author's section is a review of current research as it relates to climate change	FALSE	FALSE
8/1/2017	2/8/2018	No; Editorial article - no data involved	FALSE	FALSE
11/14/2017	1/11/2018	Yes	TRUE	TRUE
5/1/2017	12/4/2017	No; no new data collected	FALSE	FALSE

12/1/2017	1/12/2018	No; Data belongs to Zhejiang University	FALSE	FALSE
4/1/2018	11/3/2017	No; This was work done at URI before my hire at EPA	FALSE	FALSE
12/1/2017	11/3/2017	Yes	TRUE	TRUE

3/1/2017	4/2/2018	No; Article presents conceptual framework resulting from multi-collaborative workshop	FALSE	FALSE
5/6/2017	5/9/2017	Yes	FALSE	FALSE
9/20/2017	11/6/2017	Yes	FALSE	FALSE
9/15/2017	11/6/2017	Yes	TRUE	TRUE

7/18/2017	2/8/2018	No; Research led and data archiving done by senior university author. ICE data is public domain	FALSE	FALSE
9/7/2017	10/30/2017	Yes	TRUE	TRUE
1/1/2018	1/22/2018	No; Johnston provided modeling training, guidance and oversight to MRC staff, while did modeling & GIS analyses	FALSE	FALSE

11/1/2017	11/20/2017	Yes	TRUE	TRUE
4/2/2018	4/20/2018	Yes	TRUE	TRUE
9/22/2017	9/26/2017	Yes	TRUE	TRUE
5/1/2018	4/10/2018	No; No data	FALSE	FALSE
9/24/2017	9/22/2017	Yes	TRUE	TRUE

6/1/2017	1/3/2018	No; These data were generated by a student at the University of Delaware and have been subject to QA/QC and will b	FALSE	FALSE
10/2/2017	9/18/2017	Yes	TRUE	TRUE
10/3/2017	10/31/2017	Yes	TRUE	TRUE
1/12/2018	1/17/2018	Yes	TRUE	TRUE

3/1/2018	1/12/2018	Yes	TRUE	TRUE
11/1/2017	1/25/2018	Yes	TRUE	TRUE
1/15/2018	9/6/2017	Yes	TRUE	TRUE
4/15/2018	5/4/2018	No; Research data consisted of secondary data only	FALSE	FALSE
10/1/2017	9/11/2017	Yes	TRUE	TRUE

11/1/2017	11/6/2017	No; This was a review article.	TRUE	FALSE
10/26/2017	10/26/2017	Yes	TRUE	TRUE
3/1/2018	3/1/2018	No; no EPA data is involved with this article	FALSE	FALSE
1/1/2018	3/16/2018	No; data from Kansas State when author was a grad student there	TRUE	TRUE

8/2/2017		Yes	TRUE	FALSE
11/10/2017	9/6/2017	Yes	TRUE	TRUE
4/1/2018	4/16/2018	Yes	TRUE	TRUE
1/1/2018	8/25/2017	No; Review of existing epidemiologic data.	FALSE	FALSE

10/25/2017	12/11/2017	No; EPA coauthor, no data generated here	FALSE	FALSE
4/2/2018	4/5/2018	No; This is a review article	FALSE	FALSE
12/27/2017	4/16/2018	Yes	TRUE	TRUE
4/4/2017	4/19/2017	Yes	TRUE	TRUE

9/11/2017	4/24/2018	Yes	TRUE	TRUE
12/1/2017	1/22/2018	Yes	TRUE	TRUE
2/27/2018	4/16/2018	No; no EPA data	FALSE	FALSE
9/12/2017	11/20/2017	Yes	TRUE	TRUE
12/1/2017	11/3/2017	No; no data used	FALSE	FALSE

10/19/2017	11/6/2017	Yes	TRUE	TRUE
8/2/2017		Yes	TRUE	FALSE
12/1/2017	12/20/2017	No; no EPA data	FALSE	FALSE
8/4/2017	8/10/2017	No; Scientific meeting report	FALSE	FALSE

1/1/2018	1/30/2018	No; Lead author (NOAA) and other co-authors (USGS and UW) provided data.	FALSE	FALSE
3/20/2018	3/20/2018	Yes; N/A	TRUE	TRUE
3/9/2018	3/29/2018	Yes	TRUE	TRUE
10/20/2017	2/21/2018	Yes	TRUE	TRUE

1/1/2018	11/6/2017	Yes	TRUE	TRUE
12/19/2017	3/14/2018	Yes	TRUE	TRUE
2/1/2018	11/28/2017	No; This is a synthesis paper that reviews the literature.	FALSE	FALSE

9/22/2017	9/6/2017	Yes	TRUE	TRUE
11/1/2017	8/11/2017	Yes	TRUE	TRUE
2/2/2018	2/1/2018	Yes	TRUE	TRUE

9/5/2017	2/9/2018	No; Research led and records maintained by non-EPA authors; data obtained from public sources and modeling tools	FALSE	FALSE
11/1/2017	9/25/2017	Yes	TRUE	TRUE
1/1/2018	11/30/2017	Yes	TRUE	TRUE
7/1/2017	9/30/2017	No; No data-Peer commentary on target article that is being published. Our article will be in the same issue.	FALSE	FALSE
11/15/2017	6/27/2017	No; All data was generated by the lead author with no funding from EPA.	FALSE	FALSE

5/4/2018	5/4/2018	No; Data collected collaboratively while on sabbatical in Australia (2011) at the University of South Australia	FALSE	FALSE
2/1/2018	12/18/2017	No; Used published data set	FALSE	FALSE
5/31/2017		No; This manuscript is about pre-existing publicly available protocols. No data collected, used, or analyzed.	FALSE	FALSE

12/2/2017	2/28/2018	Yes	TRUE	TRUE
2/26/2018	4/16/2018	Yes	TRUE	TRUE
5/5/2018	4/16/2018	No; Data created by primary author - UC postdoc & personnel generated the data	FALSE	FALSE

3/15/2018	4/10/2018	No; This article contains only previously published EPA data and publicly available information	FALSE	FALSE
3/1/2018	1/17/2018	No; N/A	FALSE	FALSE
12/15/2017	11/6/2017	Yes	TRUE	TRUE
1/1/2018	2/8/2018	Yes; GED exempt - paper cleared before June 30 2017	FALSE	FALSE

11/30/2017	12/7/2017	Yes	TRUE	TRUE
3/7/2018	3/29/2018	Yes	FALSE	FALSE
2/1/2018	2/2/2018	No; All pre-exisiting data from federal, state and local agencies	FALSE	FALSE
1/21/2018	1/22/2018	No; This is a review article, not a research article.	FALSE	FALSE
3/5/2018		Yes	TRUE	FALSE

1/1/2018	12/19/2017	Yes	TRUE	TRUE
3/28/2018	5/1/2018	Yes	TRUE	TRUE
1/1/2018	1/5/2018	No; This is an overview article without data	TRUE	TRUE
3/19/2018	4/23/2018	No; Review Article	FALSE	FALSE

5/8/2017	2/6/2018	No; Work involves modeling done at other organizations. Terry's role is overall interpretation.	FALSE	FALSE
8/2/2017	8/7/2017	No; CDC-generated data, SDP in ScienceHub outlines protocol for public access	FALSE	FALSE
11/6/2017	12/14/2017	No; This is an invited opinion paper with no associated data.	FALSE	FALSE
11/1/2017	9/7/2017	No; The survey and analysis of survey results were conducted by the lead author at JRC	FALSE	FALSE

11/15/2017	4/16/2018	Yes	TRUE	TRUE
7/12/2017	8/29/2017	Yes	TRUE	TRUE
11/3/2017	12/14/2017	No; Review article - EPA did not generate data	FALSE	FALSE
3/1/2018	1/22/2018	Yes	TRUE	TRUE
4/1/2018	5/3/2018	Yes	TRUE	TRUE

4/2/2018	1/29/2018	No; Publicly available data collected and QAÂ¿d by the Canadian Wood Buffalo Environmental Association	FALSE	FALSE
7/1/2017	9/1/2017	No; Conference proceeding	FALSE	FALSE
1/16/2018	2/20/2018	Yes	TRUE	TRUE
2/1/2018	5/1/2018	Yes	TRUE	TRUE

12/1/2017	12/28/2017	Yes	FALSE	FALSE
10/18/2017	5/3/2018	No; Data was generated and analyzed at the Helmholtz Institute. I have provided technial assistance and direction	FALSE	FALSE
10/17/2017		Yes	TRUE	FALSE
3/1/2018	12/11/2017	Yes	TRUE	TRUE
3/1/2018	5/2/2018	Yes	TRUE	TRUE

3/6/2018	2/13/2018	Yes	TRUE	TRUE
8/18/2017	8/25/2017	Yes	TRUE	TRUE
1/1/2018	1/17/2018	Yes	TRUE	TRUE
1/27/2018	2/28/2018	Yes	TRUE	TRUE

10/19/2017	11/6/2017	No; The data were generated by researchers from St Cloud State Univ	FALSE	FALSE
10/1/2017	11/6/2017	No; perspectives article	FALSE	FALSE
11/1/2017	11/6/2017	No; No data from EPA or anyone else.	FALSE	FALSE
1/18/2018	1/22/2018	No; EPA scientists provided their technical expertise in interpreting data collected and analyzed by co-authors	FALSE	FALSE
2/1/2018	11/6/2017	Yes	TRUE	TRUE
8/15/2017	7/26/2017	No; this research was done at an acedemic institution with no EPA support	FALSE	FALSE

3/19/2018	3/13/2018	No; This is an essay of EPA's perspective on benefit transfer challenges.	FALSE	FALSE
1/18/2018	2/6/2018	Yes	TRUE	TRUE
4/20/2018	4/27/2018	No; research lead and data owned by external authors	FALSE	FALSE
10/16/2017	11/30/2017	Yes	FALSE	FALSE
1/1/2018	1/3/2018	No; Data were generated by commercial lab.	FALSE	FALSE

1/12/2018	1/22/2018	Yes	TRUE	TRUE
3/14/2018	3/26/2018	No; This is work done by the University of Hawaii. EPA is only a co-author and did not generate any data.	FALSE	FALSE
2/1/2018		Yes	TRUE	FALSE
2/1/2018	2/15/2018	No; The article has no data.	FALSE	FALSE

2/1/2018	4/13/2018	Yes	TRUE	TRUE
10/24/2017	11/3/2017	No; Manuscript represents an introduction to special issue of journal WATER; only conceptual ideas and synthesis	FALSE	FALSE
2/12/2018	2/13/2018	No; All data were provided by the System Wide Monitoring Program of the Grand Bay National Estuarine Research Rese	FALSE	FALSE
4/2/2018	2/6/2018	Yes	TRUE	TRUE

10/25/2017	10/31/2017	Yes	TRUE	TRUE
10/11/2017	3/22/2018	No; Reg 2 RARE project QA/QC plan was prepared by Univ of Ottawa & reviewed by EPA. EPA did not provide any data.	TRUE	TRUE
11/21/2017	12/14/2017	Yes	FALSE	FALSE
2/1/2018	1/17/2018	Yes	TRUE	TRUE
2/20/2018	11/17/2017	No; This is a review only, no data are presented.	FALSE	FALSE

3/1/2018	4/24/2018	Yes	TRUE	TRUE
11/2/2017	11/3/2017	Yes; N/A	TRUE	TRUE
3/16/2018	4/11/2018	Yes	TRUE	TRUE
2/1/2018	2/9/2018	No; All measured values presented in article, were generated at the Univ. of WA. John Frew was a graduate student.	FALSE	FALSE

9/6/2017	1/22/2018	Yes	TRUE	TRUE
3/1/2018	2/5/2018	No; These data were generated by colleagues at Drexel University and the Nature Conservancy.	FALSE	FALSE
4/17/2018	4/17/2018	No; This article is a critical review of existing data.	FALSE	FALSE
1/1/2018	1/23/2018	Yes	TRUE	TRUE
1/1/2018	1/22/2018	Yes	TRUE	TRUE

5/1/2018	4/16/2018	No; This paper describes a methodological framework and does not use data	FALSE	FALSE
10/19/2017	11/28/2017	Yes	TRUE	TRUE
10/16/2017	11/30/2017	No; Review Article	FALSE	FALSE

10/1/2017	10/31/2017	No; This is the result of a study conducted by the University of Cincinnati.	FALSE	FALSE
3/1/2018	2/22/2018	Yes	TRUE	TRUE
4/1/2018	4/11/2018	Yes	TRUE	TRUE
3/6/2018	5/7/2018	Yes	TRUE	FALSE

4/1/2018	12/11/2017	Yes	TRUE	TRUE
1/1/2018	1/17/2018	Yes	FALSE	FALSE
3/1/2018	5/7/2018	Yes; NAGE EXEMPT	FALSE	FALSE
1/16/2018	1/22/2018	No; We assembled a multi-species dataset based on previously published studies.	TRUE	TRUE

12/14/2017	5/3/2018	Yes	TRUE	TRUE
2/1/2018	2/6/2018	Yes	TRUE	TRUE
2/6/2018	3/9/2018	Yes	TRUE	TRUE
8/14/2017	9/27/2017	Yes	FALSE	FALSE
4/1/2018	4/20/2018	No; This is a review article that discusses some challenges in applying a tool in risk assessment	FALSE	FALSE

4/1/2018	3/30/2018	Yes	TRUE	TRUE
9/7/2017	9/7/2017	No	FALSE	FALSE
11/1/2017	9/25/2017	No; The data were all supplied by USGS.	FALSE	FALSE
2/6/2018	2/6/2018	No; journal article is a commentary based on the authors' collective opinions. There are no data.	FALSE	FALSE

1/2/2017	11/20/2017	No; Commentary, no new data included	FALSE	FALSE
3/6/2018	4/16/2018	Yes	TRUE	TRUE
5/1/2018	5/3/2018	No; The data were all supplied by USGS.	FALSE	FALSE

4/2/2018	4/20/2018	Yes	TRUE	TRUE
3/1/2018	1/4/2018	Yes	TRUE	TRUE
3/1/2018	1/11/2018	Yes	TRUE	TRUE
12/15/2017	4/3/2018	Yes	FALSE	FALSE

4/1/2018	12/15/2017	No; Presenting a new concept-no data generated	FALSE	FALSE
1/1/2018	12/15/2017	No; No EPA-generated data are associated with this product.	FALSE	FALSE
12/6/2017	4/10/2018	No; All of the data presented in this journal article comes from outside references.	FALSE	FALSE
2/1/2018	4/10/2018	No; all data presented is publically available, and has already been published	FALSE	FALSE

1/18/2018	2/9/2018	No; All experimental work was done at Nanjing Univ. China group conducted the experiments/data collections.	FALSE	FALSE
4/3/2018	4/20/2018	Yes	TRUE	TRUE
3/1/2018	11/28/2017	No; Models were based on simulations using published values in literature.	FALSE	FALSE
11/1/2017	10/30/2017	No; This paper is a review and therefore summarizes only the major lessons and conclusions of other work.	FALSE	FALSE

4/10/2018	4/10/2018	No; Secondary data	TRUE	TRUE
2/6/2018	3/20/2018	No; Article uses data generated during my postdoctoral research to associate exposure to NO2 with DNA methylation	FALSE	FALSE
11/1/2017	12/15/2017	No; This is an opinion article, does not contain data.	FALSE	FALSE
9/5/2017	11/3/2017	No; The U.S. EPA author collaborated in the experimental design and analysis data generated by the study.	FALSE	FALSE

4/1/2018		No; experiments performed by IL Natural History Survey; EPA only provided input on expermntl design, data,ms prep	FALSE	FALSE
5/1/2017	3/21/2018	No; Data was generated by USGS colleagues. Experts within EPA assisted in interpreting data and authoring.	FALSE	FALSE
4/1/2018	4/13/2018	No; EPA acted as technical consultation for the paper and NCSU conducted the real-time sample collection and data	FALSE	FALSE
11/28/2017	3/19/2018	No; This manuscript is a descriptive white paper of a database website and does not contain EPA-generated data.	FALSE	FALSE

12/22/2017	1/22/2018	No; Summary of Webinars and Associated Workshop	FALSE	FALSE
4/9/2018	4/16/2018	Yes	TRUE	TRUE
2/14/2018	2/14/2018	Yes; NAGE Exempt	FALSE	FALSE

3/10/2018	1/10/2018	No; This study was performed in China.	FALSE	FALSE
2/7/2018		No; This is a review article	FALSE	FALSE
11/9/2017	4/2/2018	No; letter to the editor with no data	FALSE	FALSE
4/1/2018	5/3/2018	Yes	TRUE	TRUE

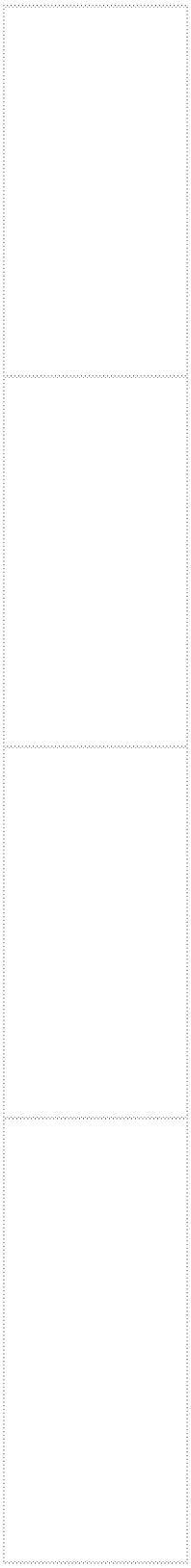
1/25/2018	1/25/2018	No; PI at the University of Cincinnati	FALSE	FALSE
1/2/2018	1/5/2018	No; no EPA generated data	FALSE	FALSE
3/30/2018		No; Commentary from a recent workshop.	FALSE	FALSE
1/1/2018	2/22/2018	No; the product is a white paper, it reviews the state of the science.	FALSE	FALSE
4/1/2018	2/12/2018	Yes	TRUE	TRUE

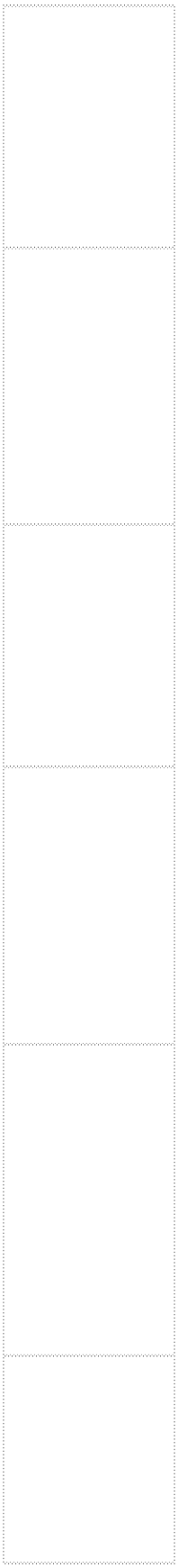
4/15/2018	2/26/2018	Yes	TRUE	TRUE
4/27/2018		No; Review article	FALSE	FALSE
1/22/2018	2/13/2018	Yes	TRUE	TRUE
3/5/2018	3/9/2018	No; no data used - meeting report based on workshop held at NASA Goddard	FALSE	FALSE
3/1/2018	4/9/2018	No; This is a concept paper, so there are no data generated by EPA or any other organizations	FALSE	FALSE

3/16/2018	3/26/2018	Yes	TRUE	TRUE
2/28/2018	2/22/2018	No; meeting report, no data	FALSE	FALSE
10/17/2017	3/26/2018	No; KreisÂ¿s review/consultation on work not related to any current milestones or deliverables in ORD RAPs.	FALSE	FALSE
3/14/2018	3/16/2018	No; there is no epa-generated data in this article	FALSE	FALSE
4/9/2018	4/16/2018	Yes	FALSE	FALSE

3/20/2018	5/4/2018	No; Inter-laboratory study - I particpated with a group located at a local university - no work performed at AED.	FALSE	FALSE
5/1/2018	5/4/2018	No; This is a review article. No new data is presented.	FALSE	FALSE

Sent to PMC?





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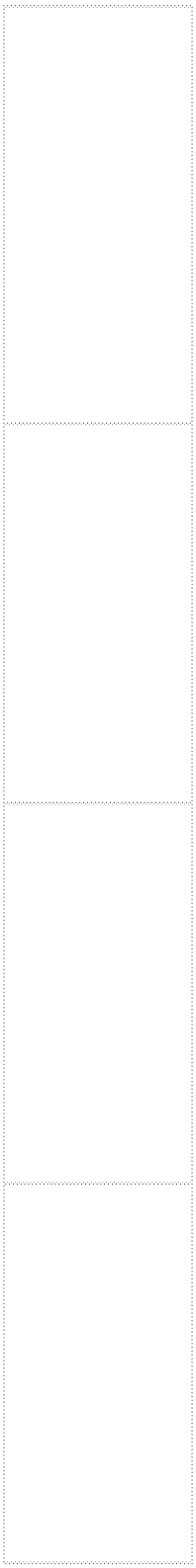
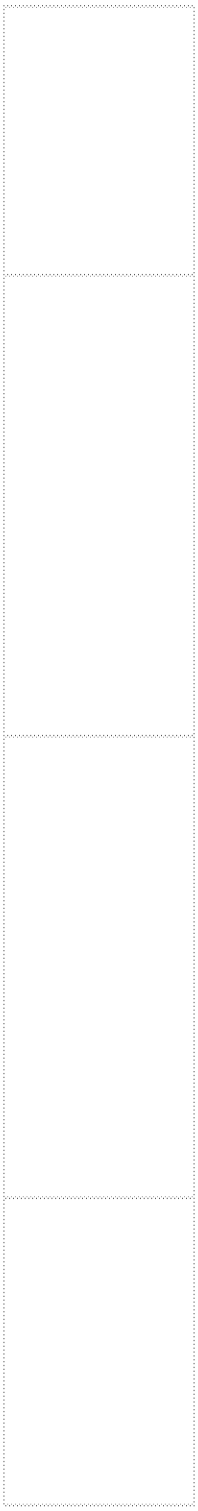
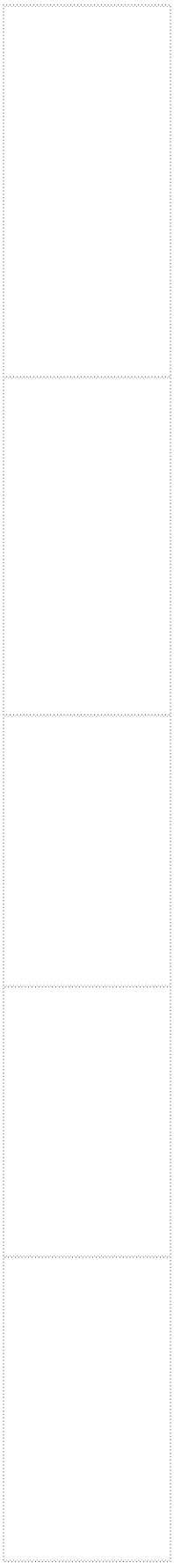


Yes

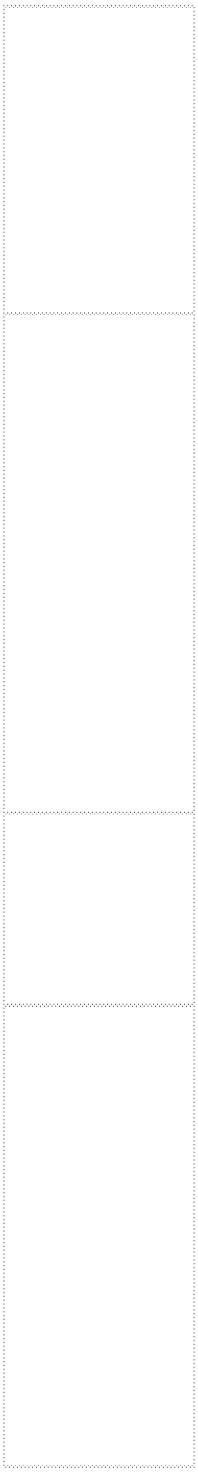


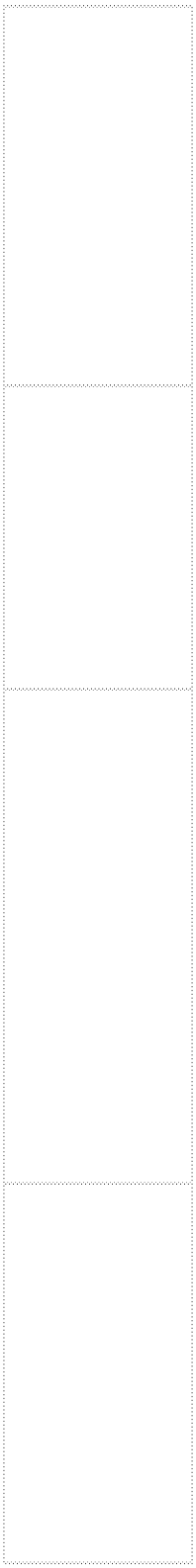
No

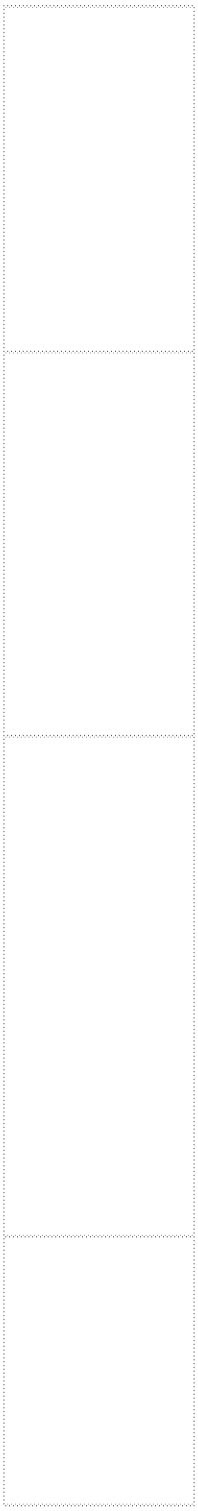


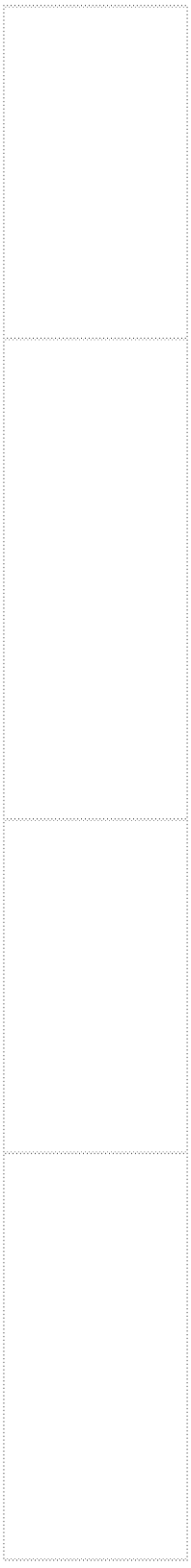
Yes

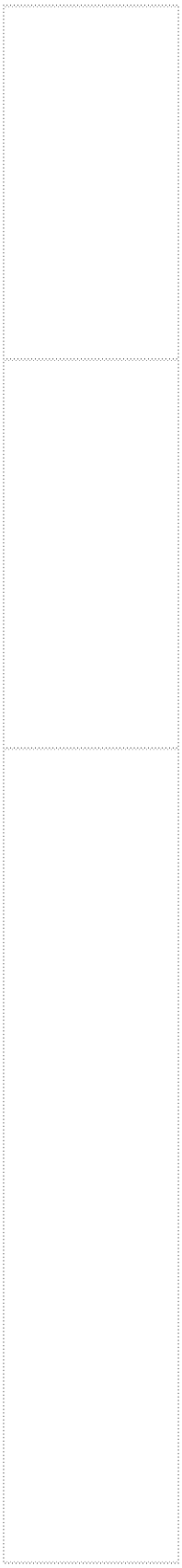
No

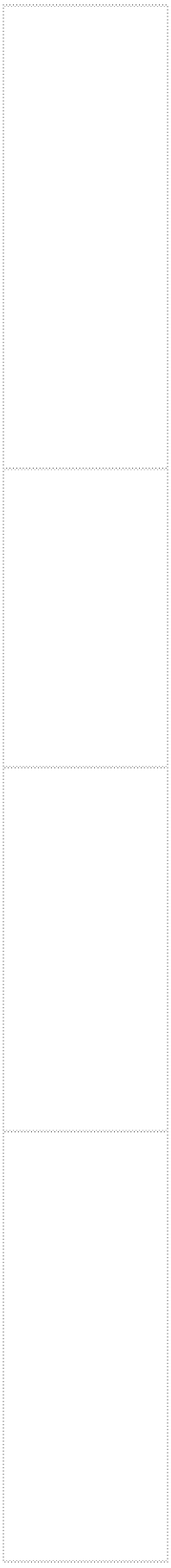


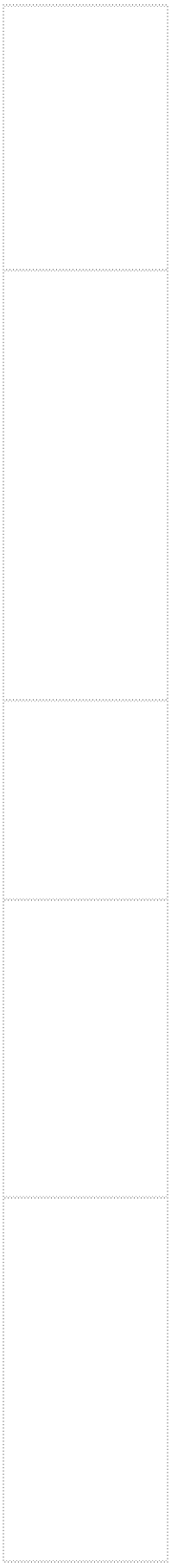


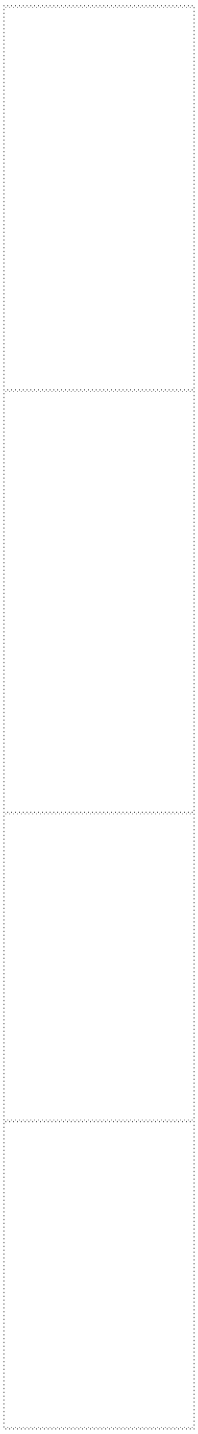












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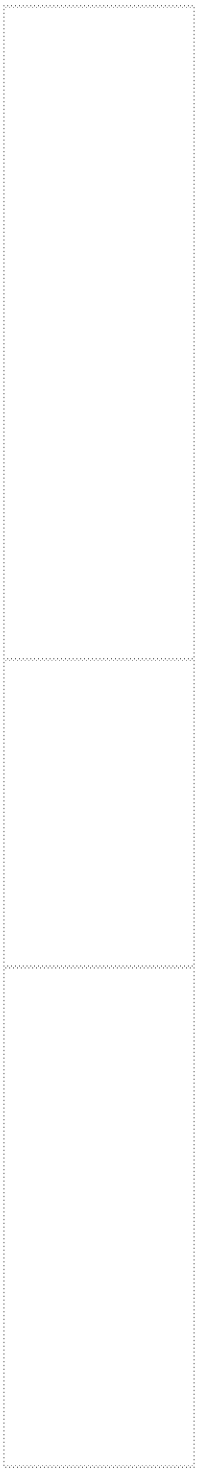

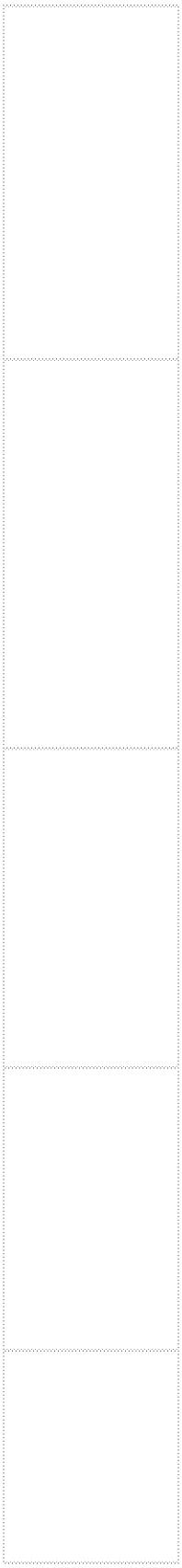

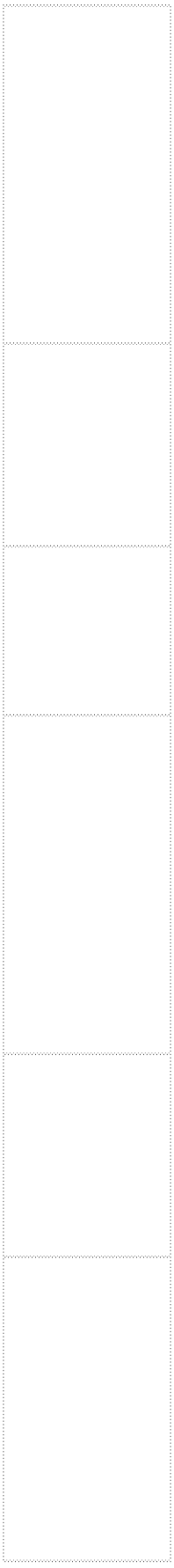

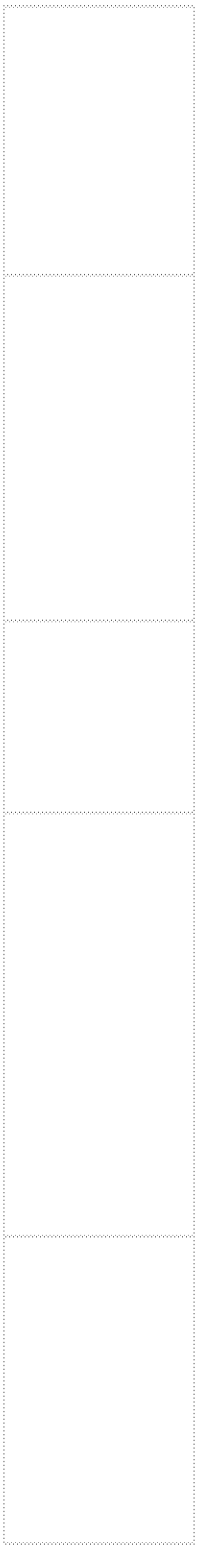

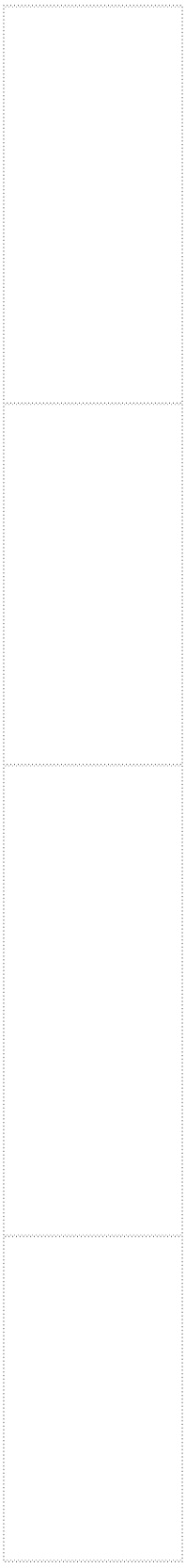

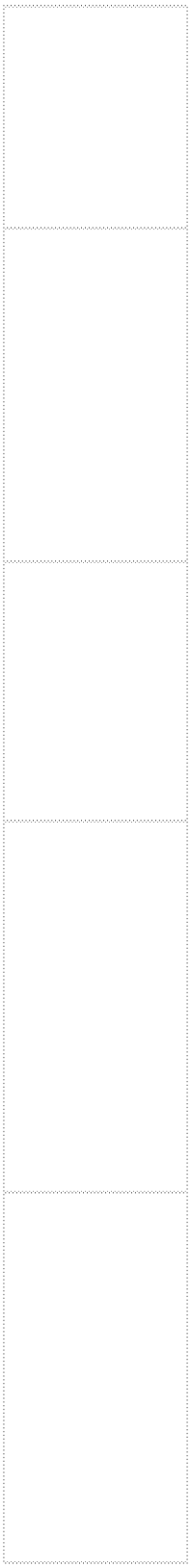

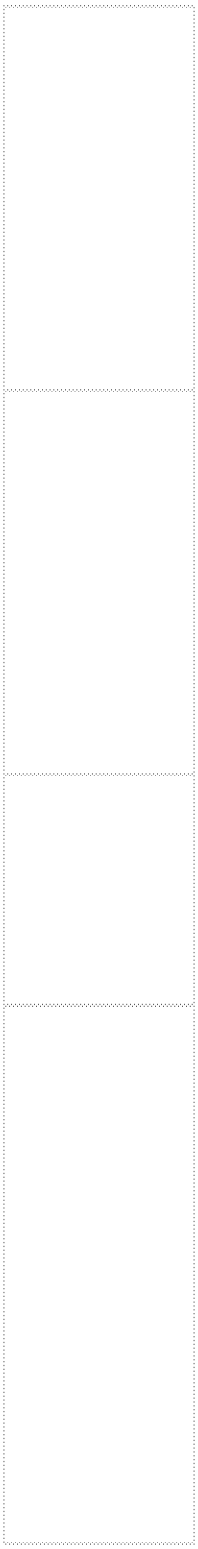

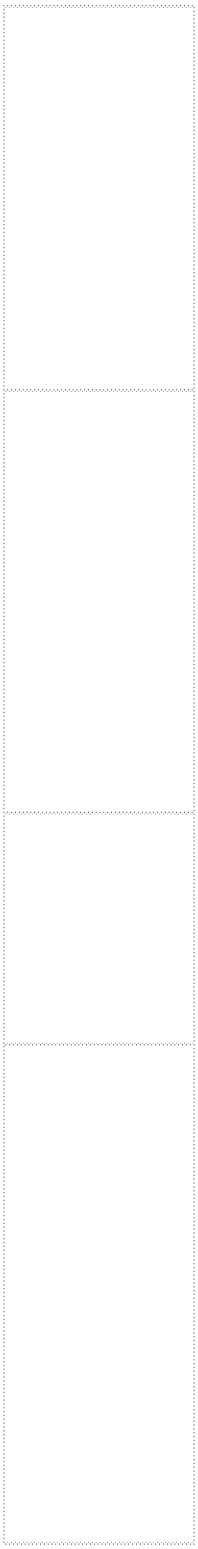

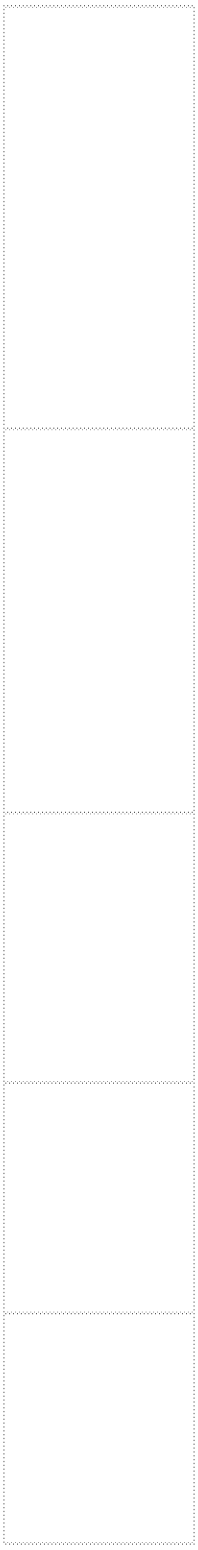

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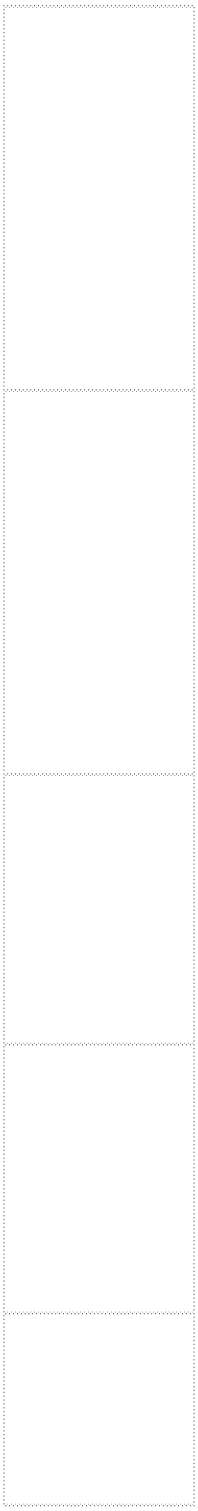

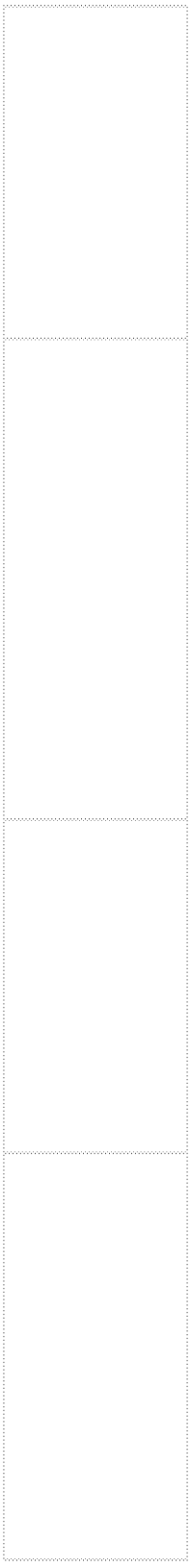

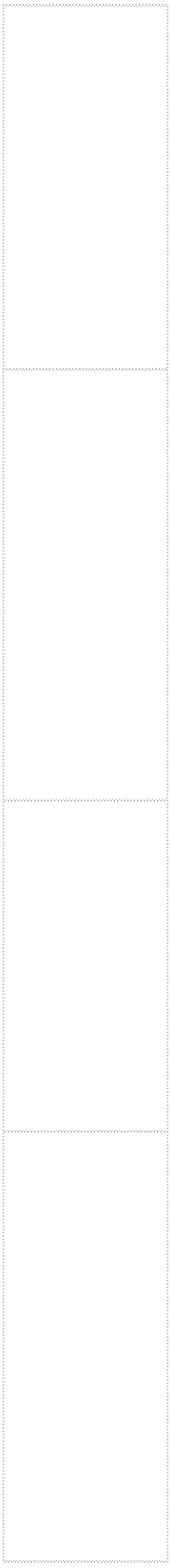

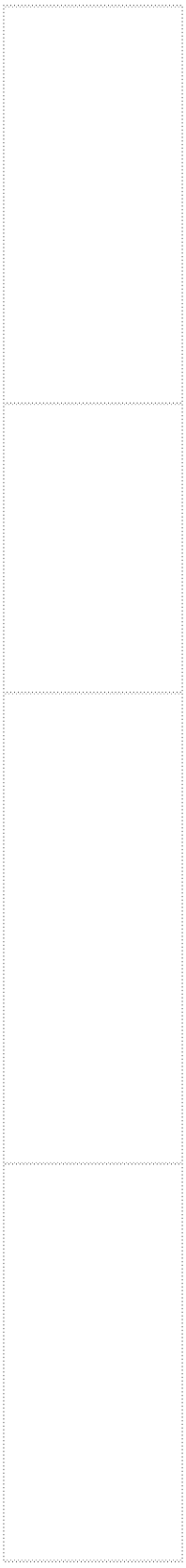

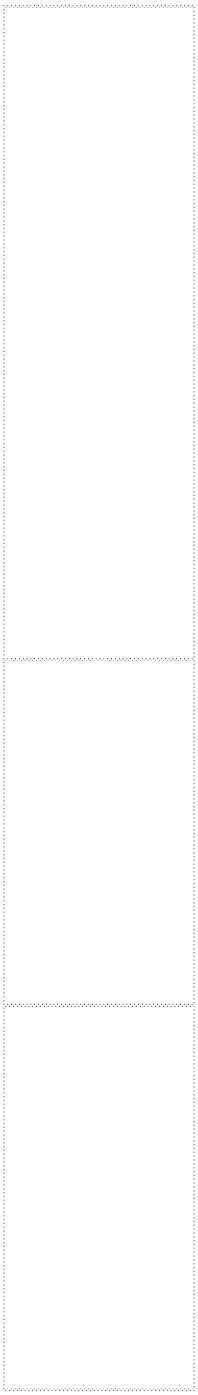

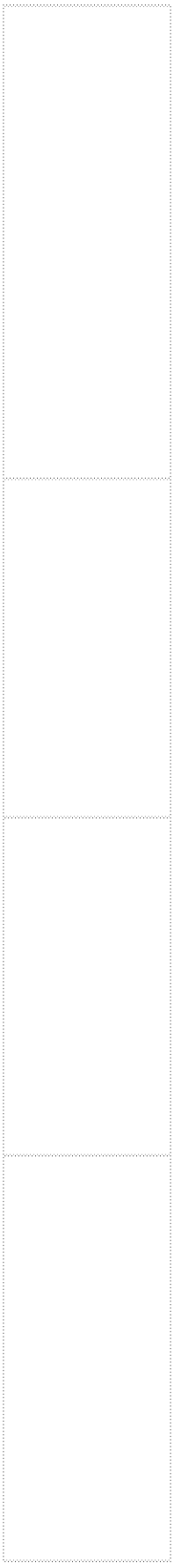

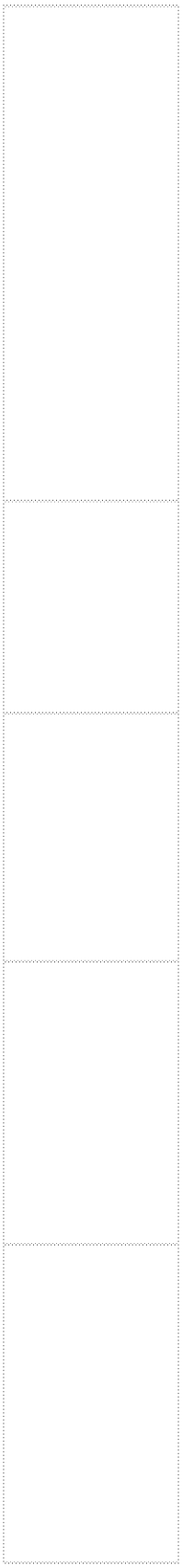

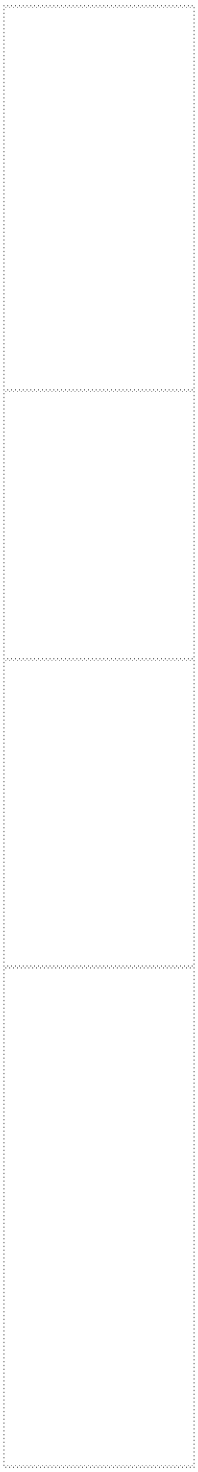

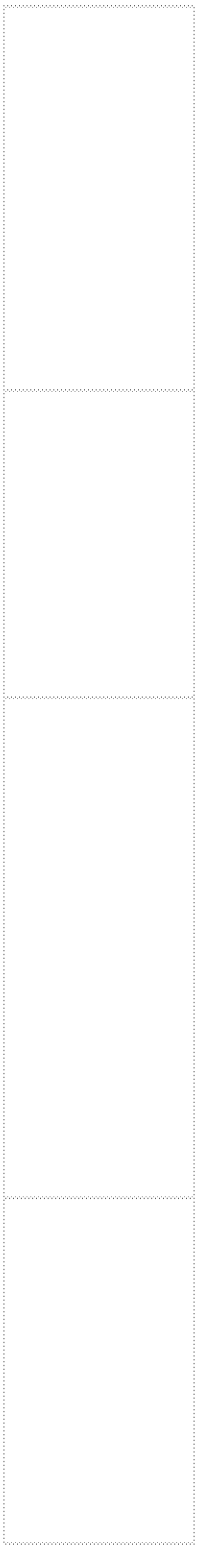

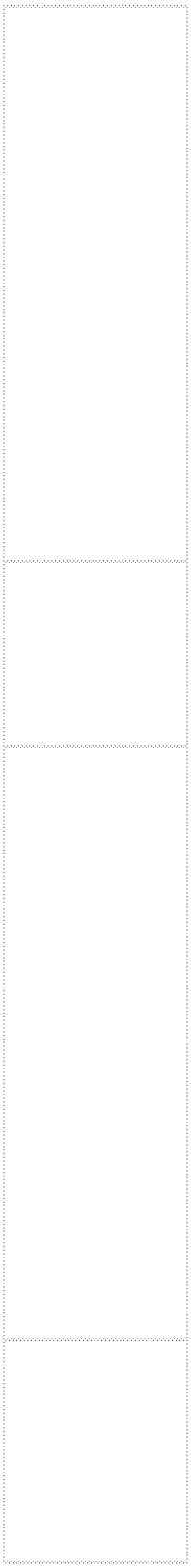

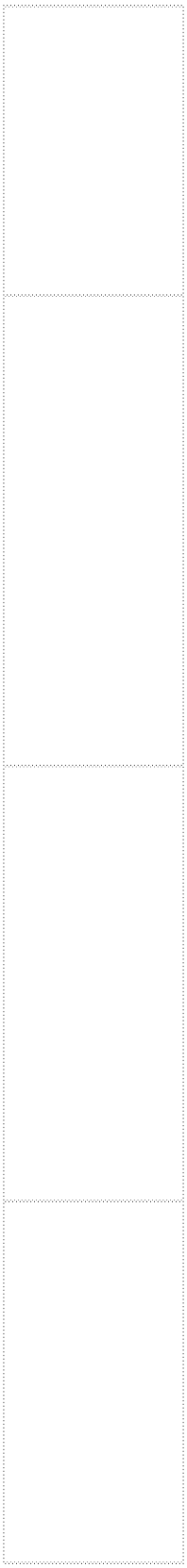

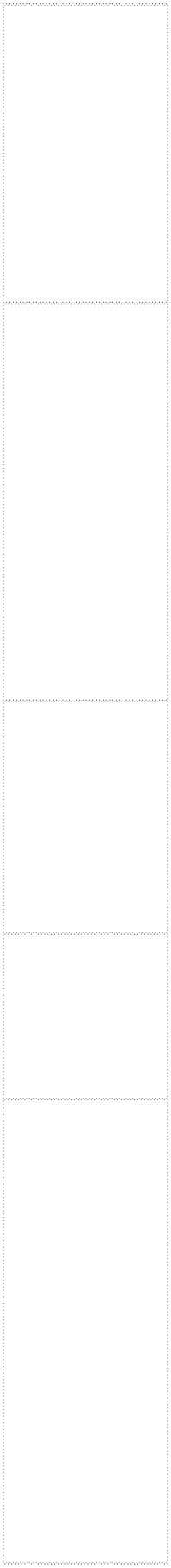

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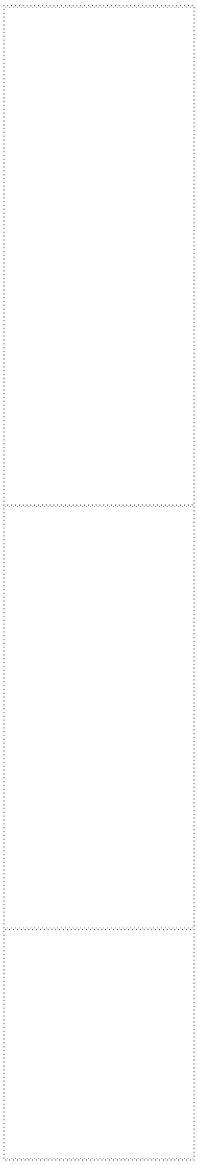

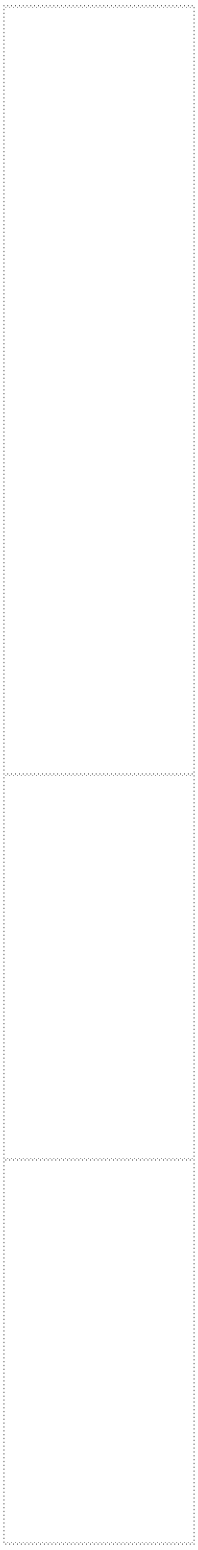

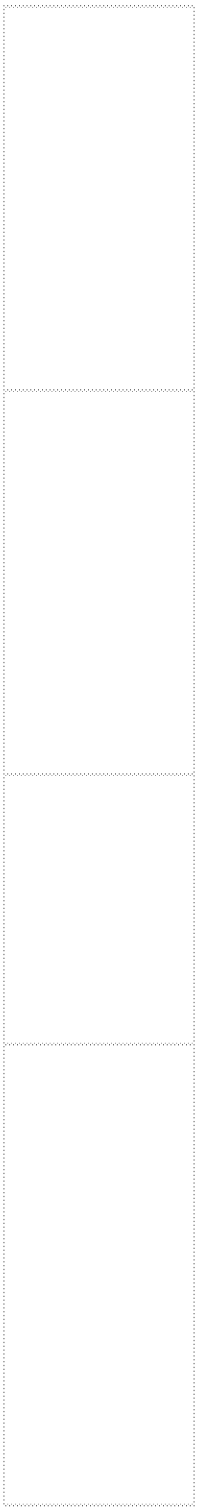

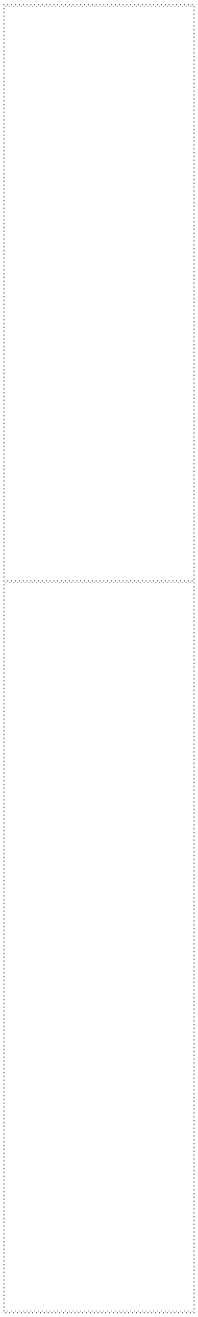

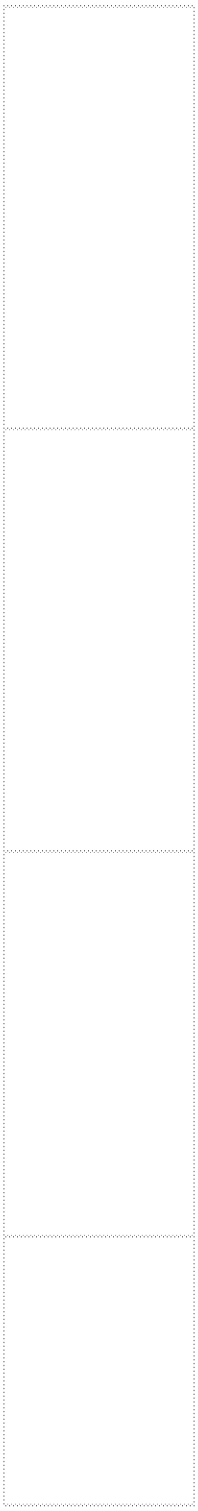

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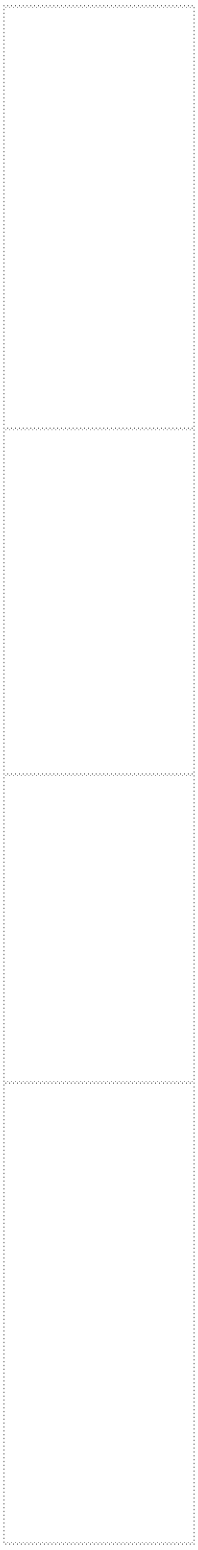

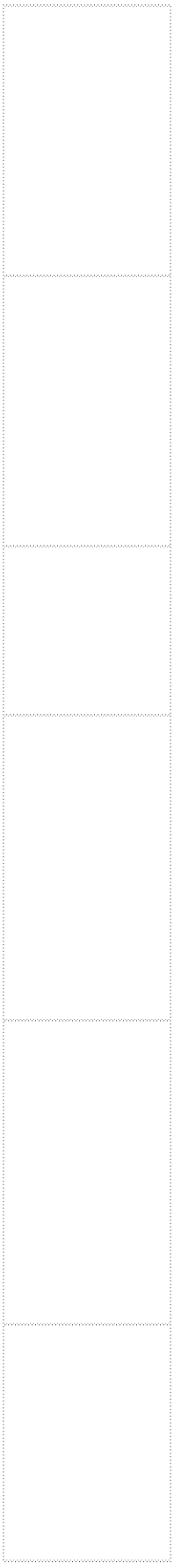

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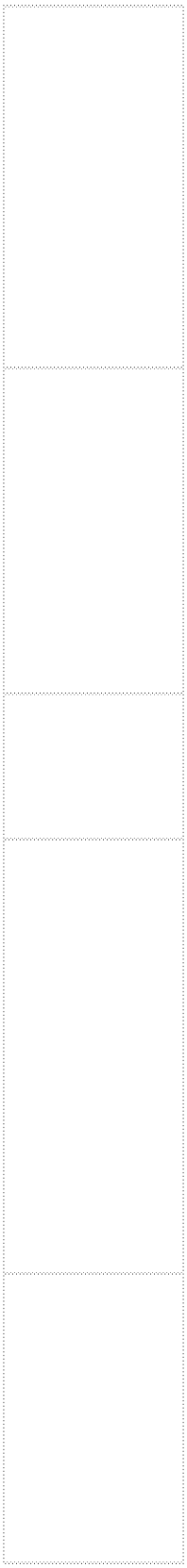

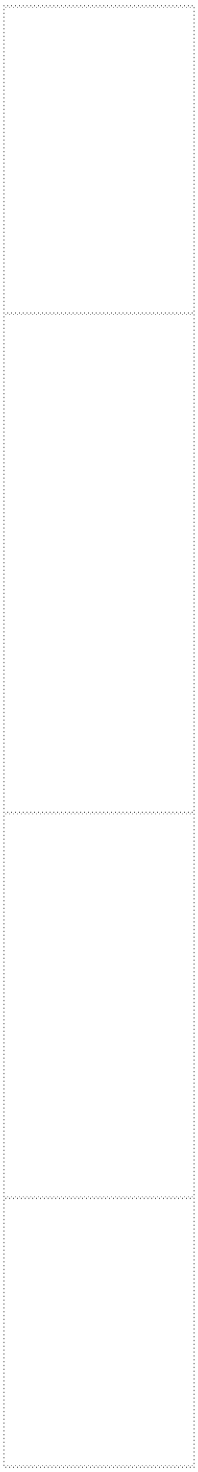

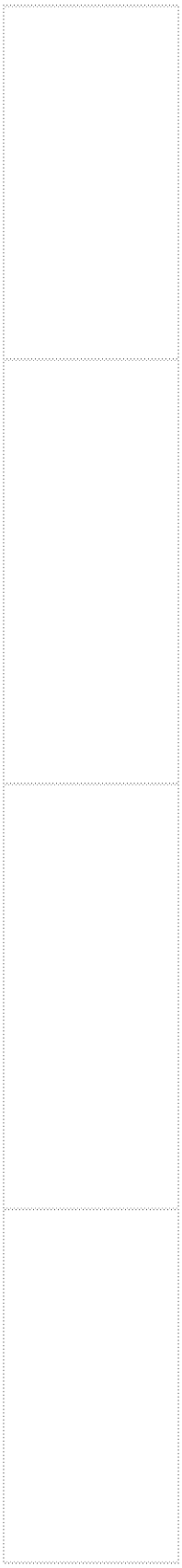

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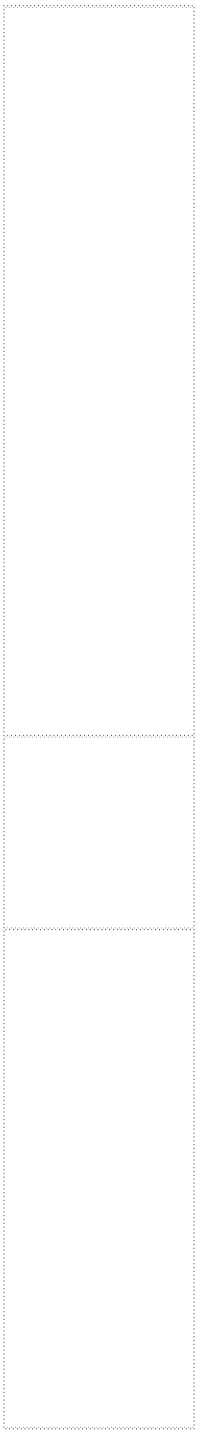

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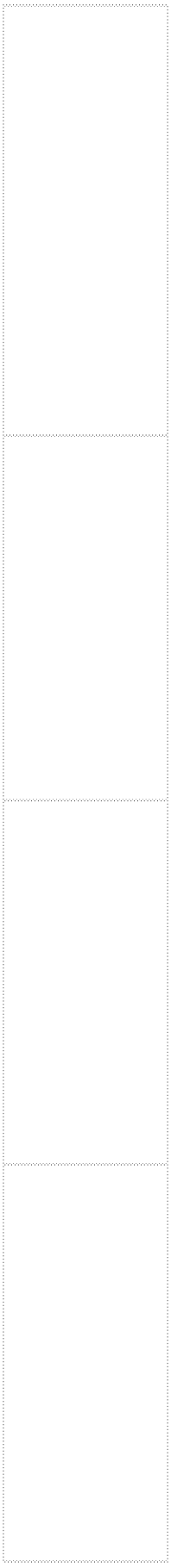

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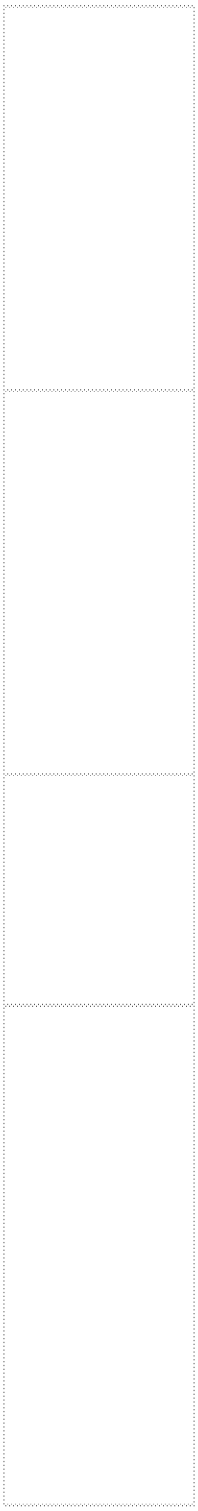

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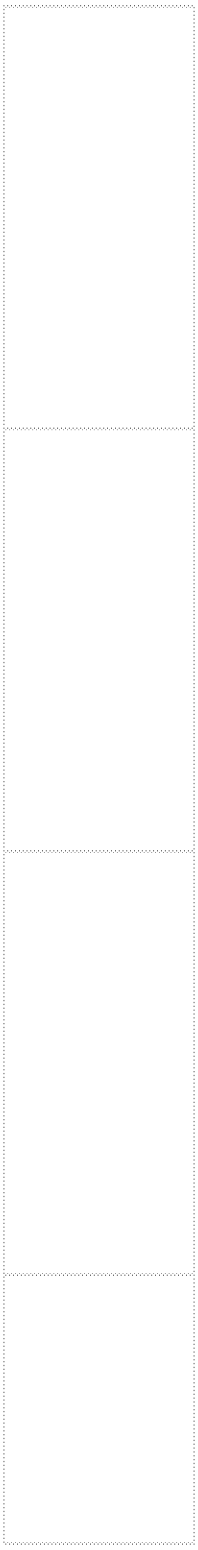

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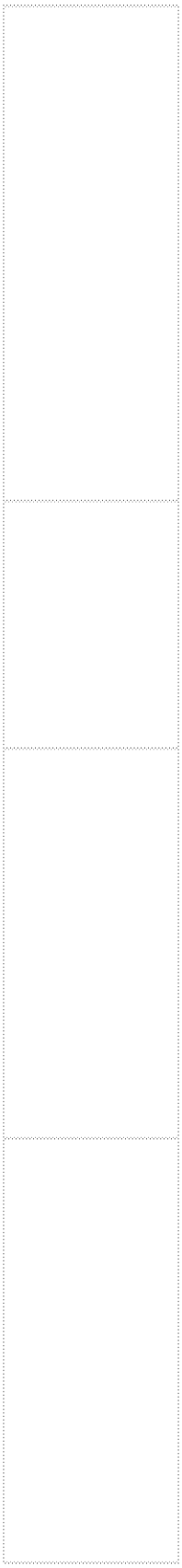

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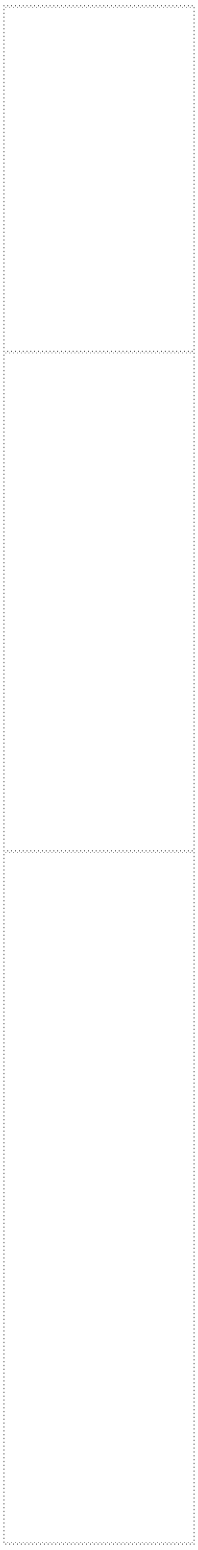

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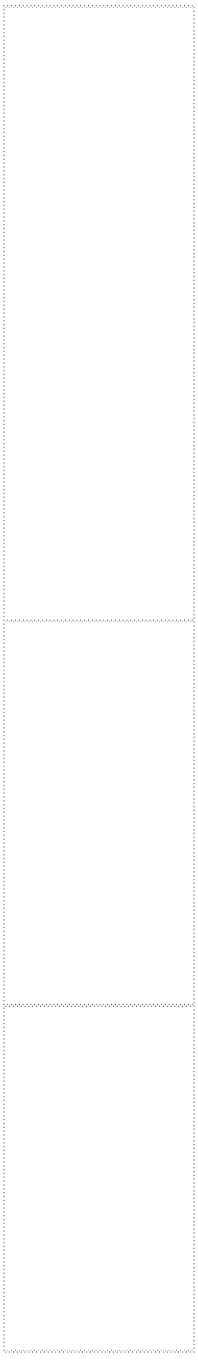

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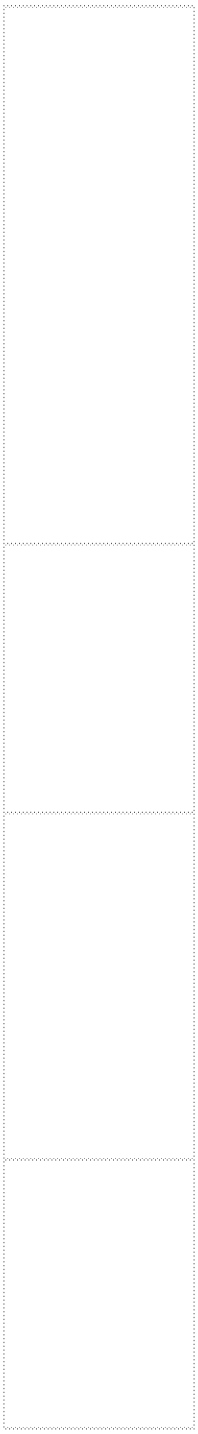

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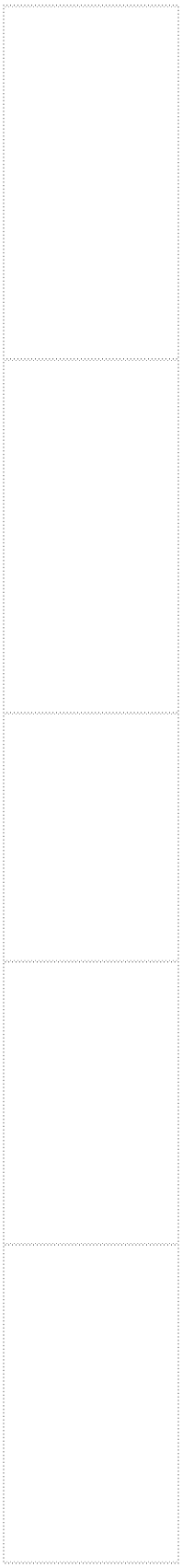

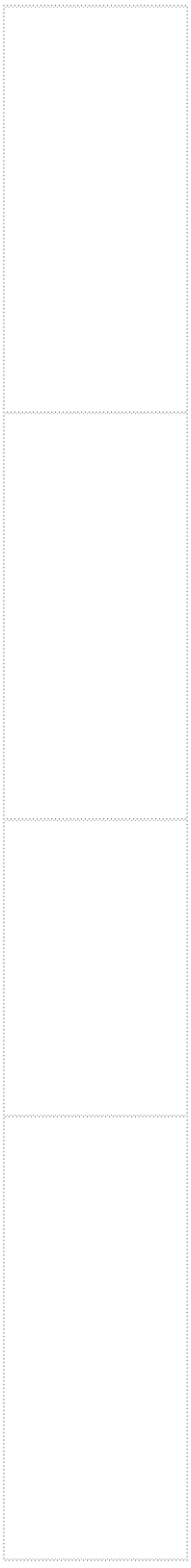

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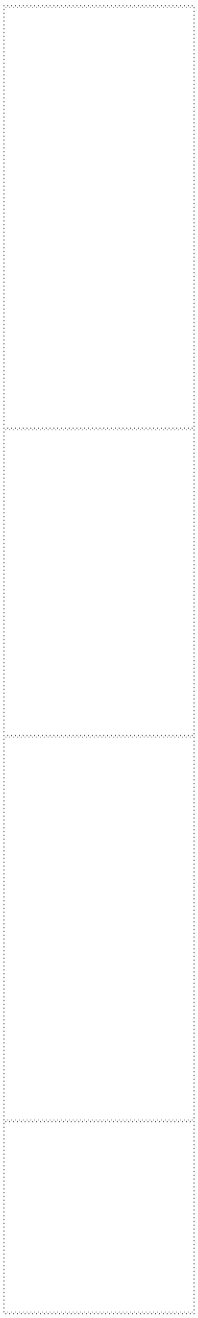

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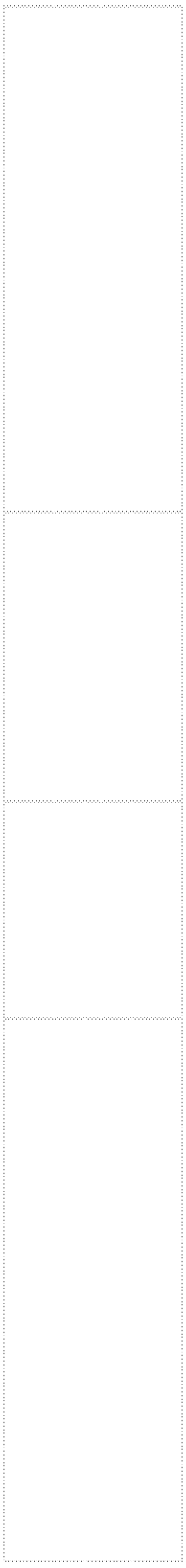

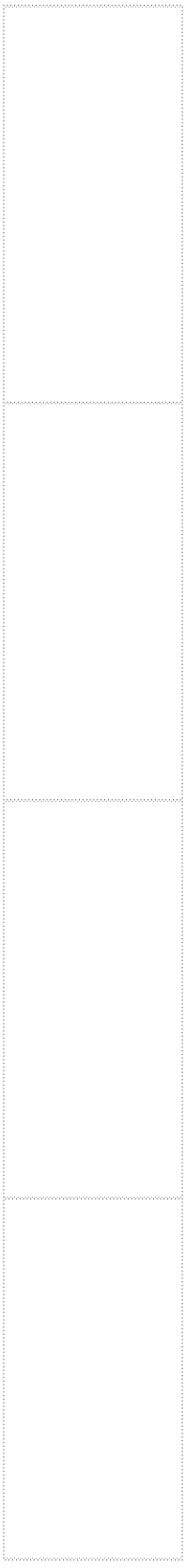

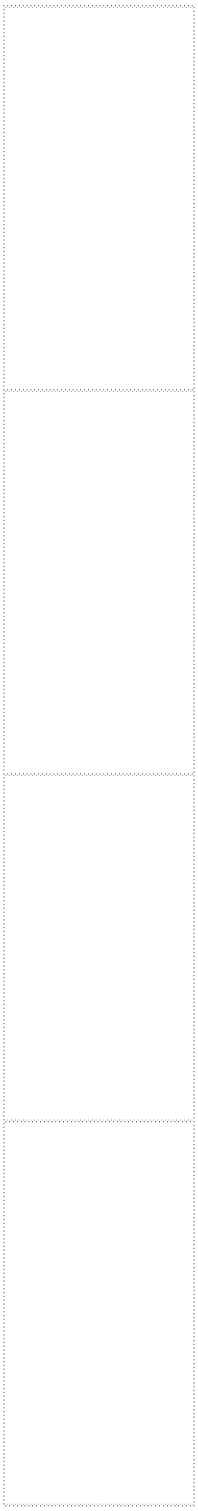

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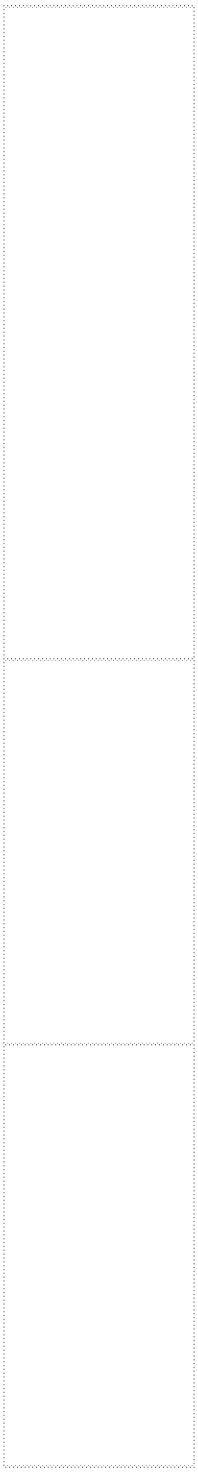

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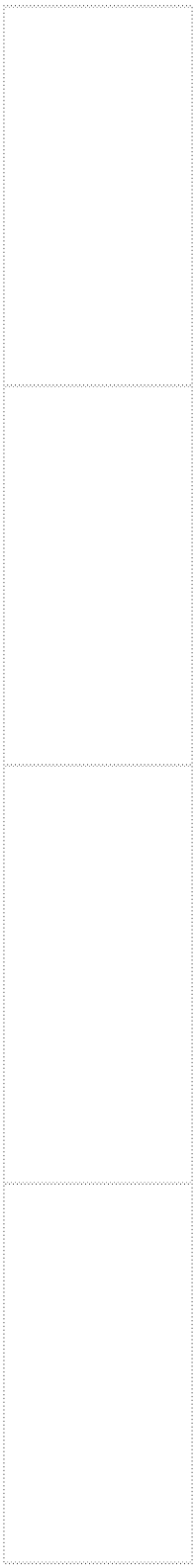

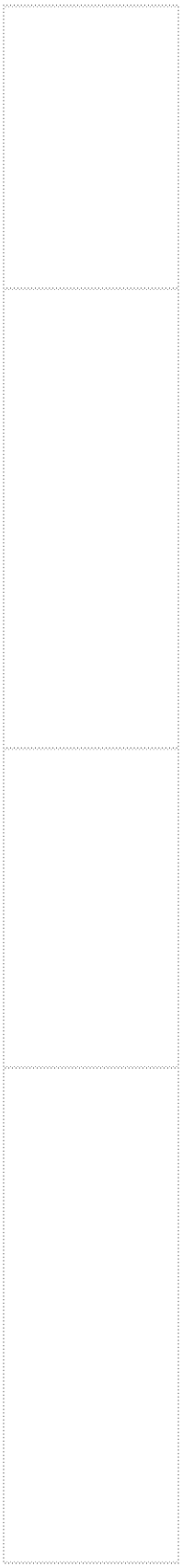

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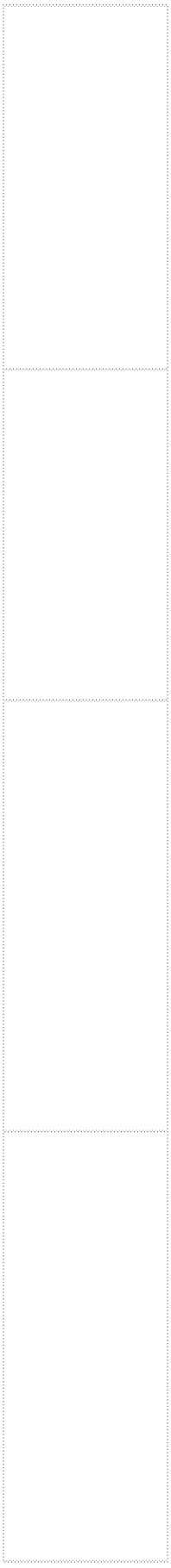

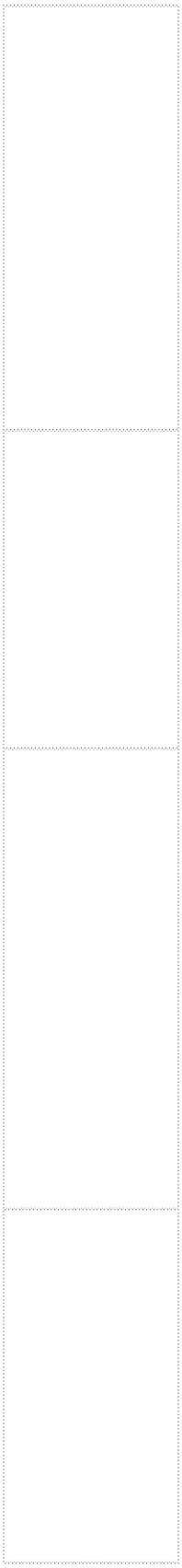

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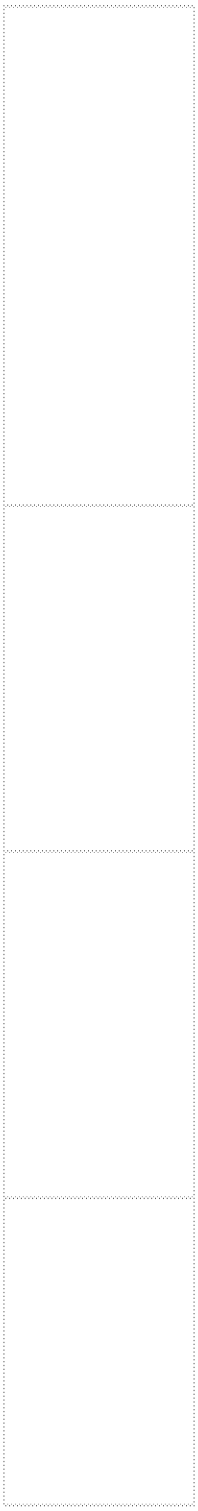

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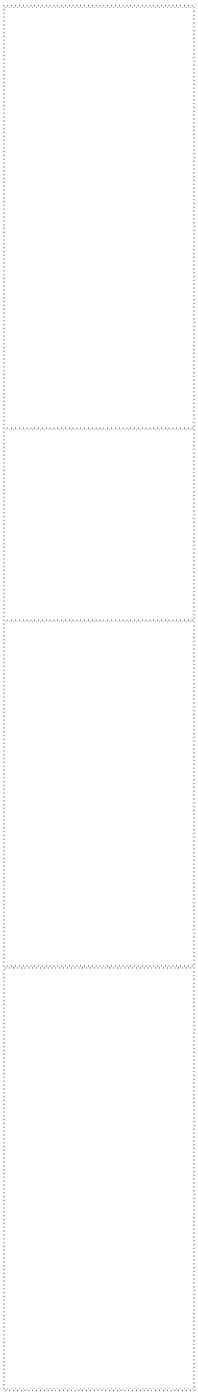

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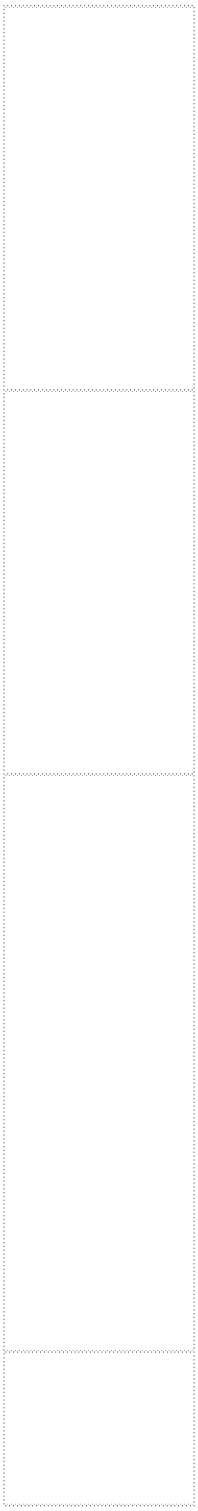

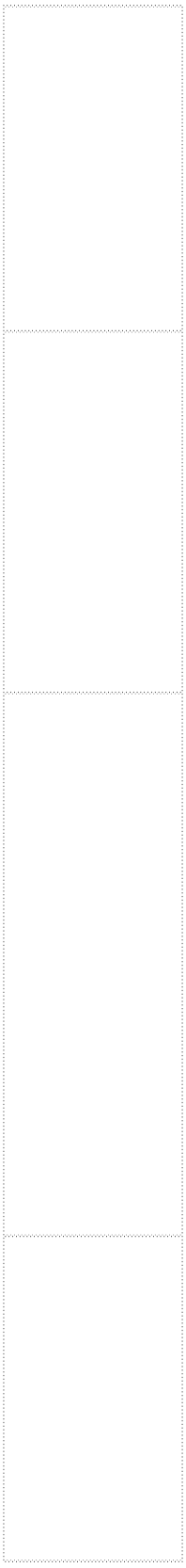

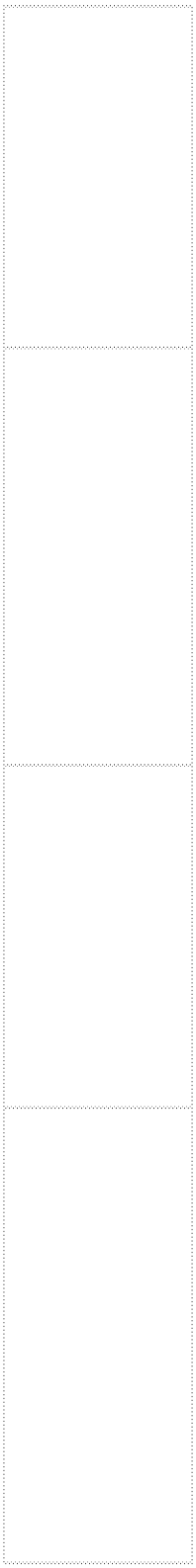

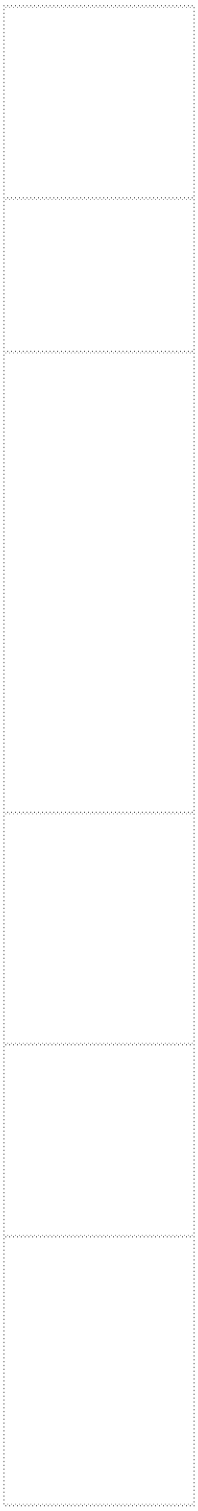

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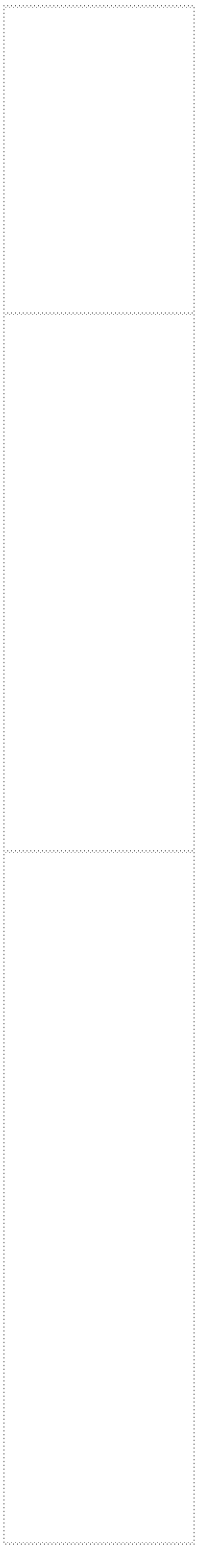

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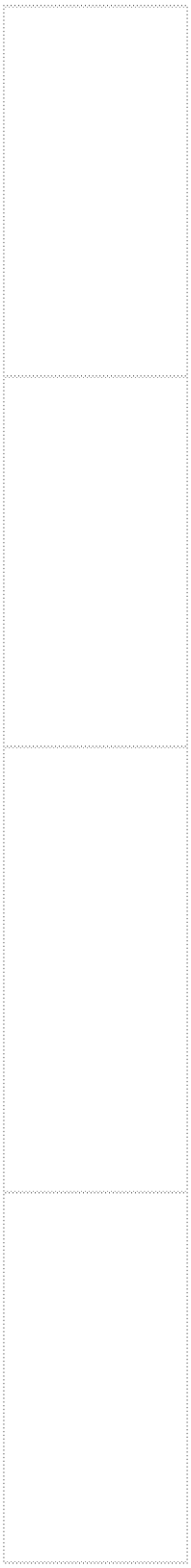

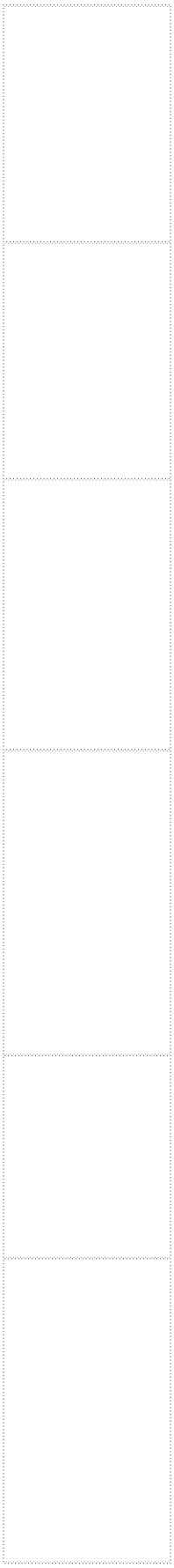

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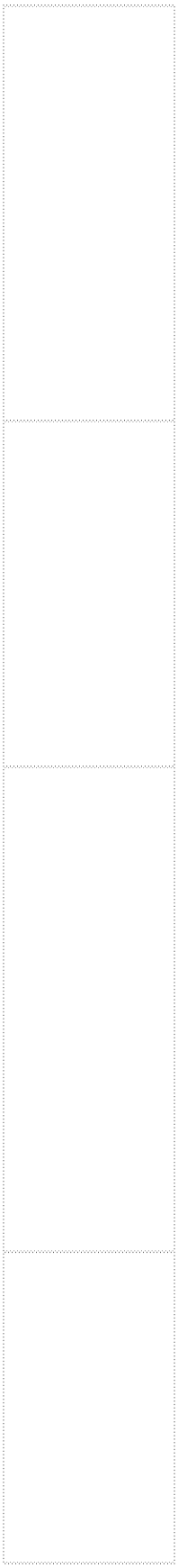

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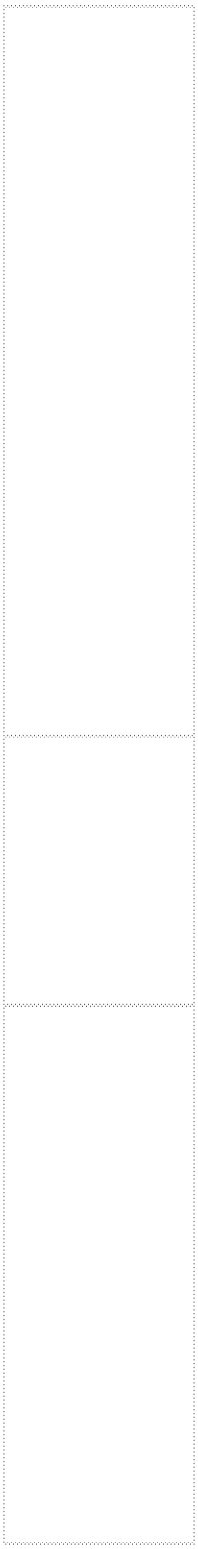

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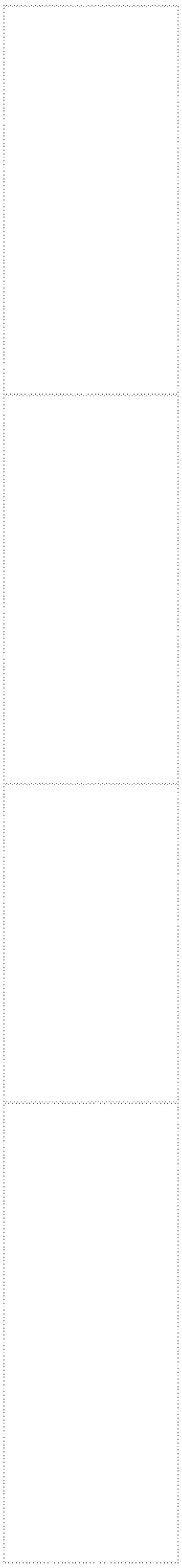

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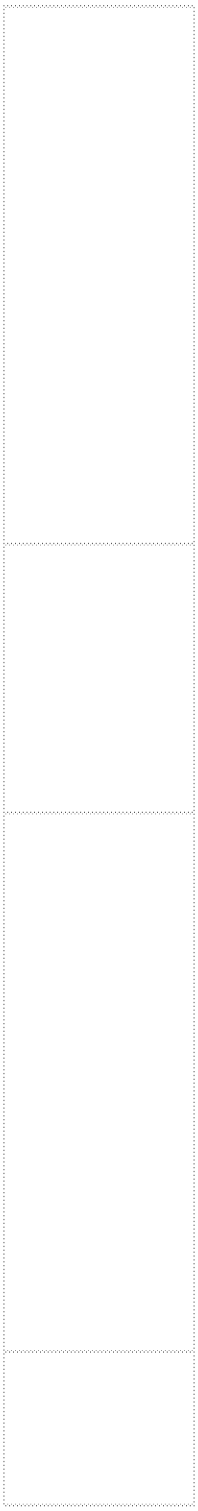

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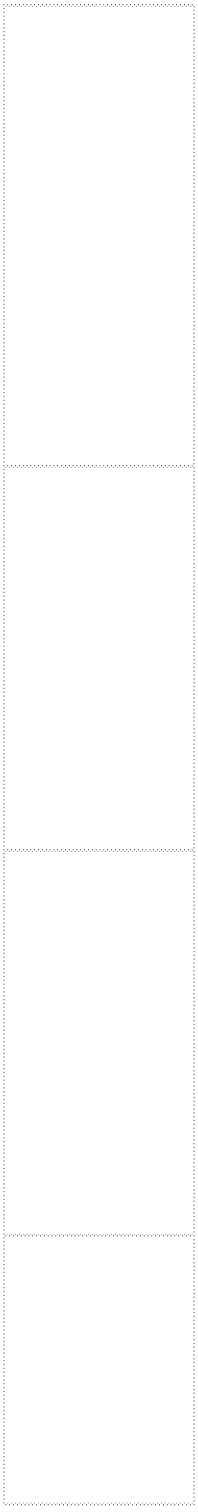

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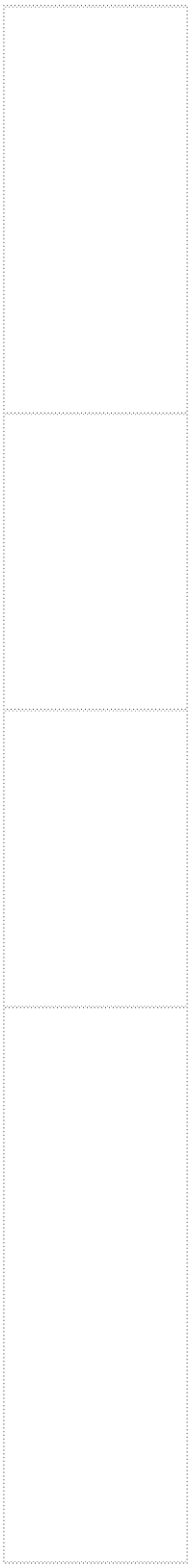

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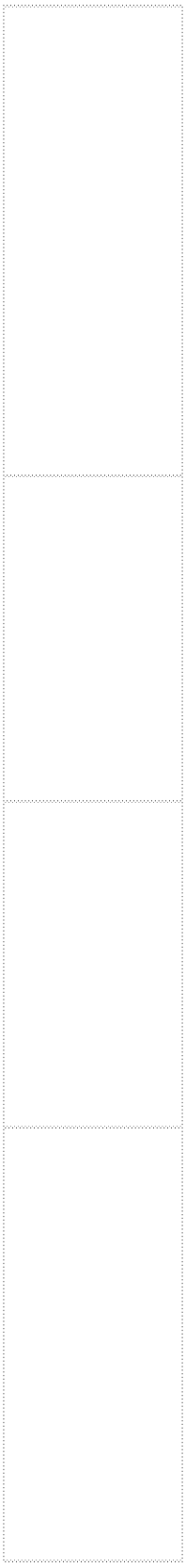

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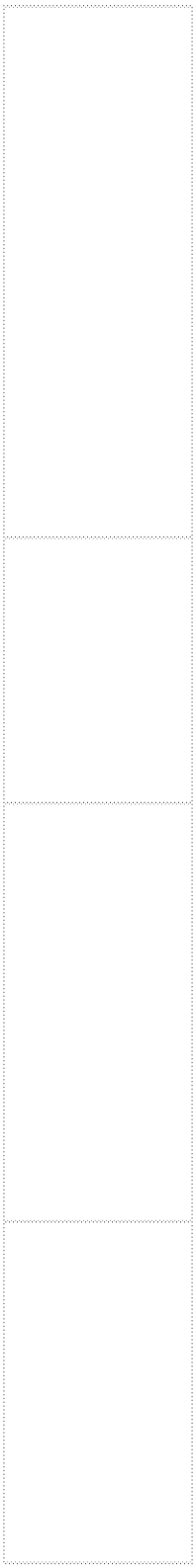

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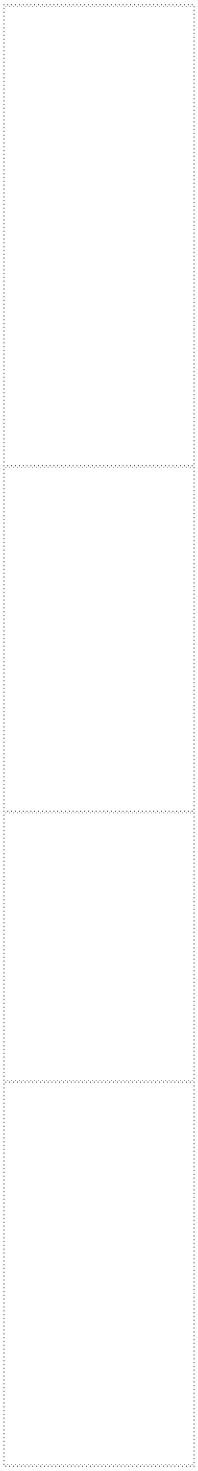

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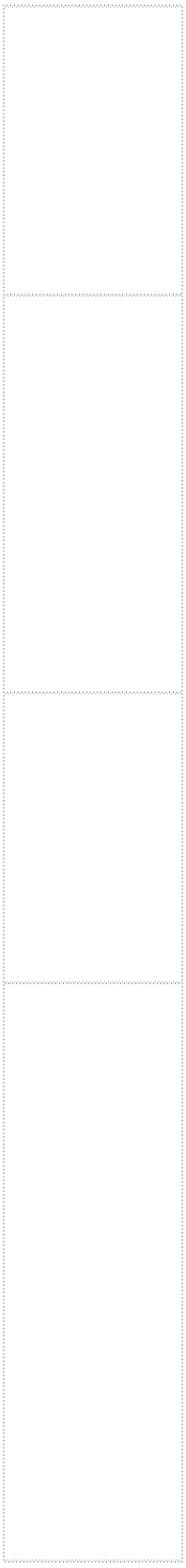

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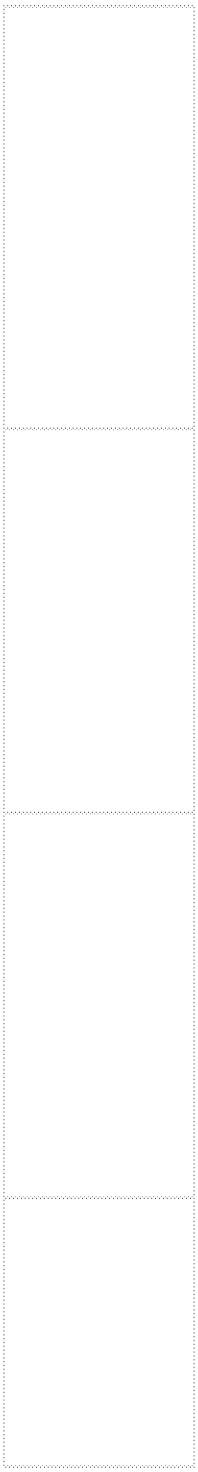

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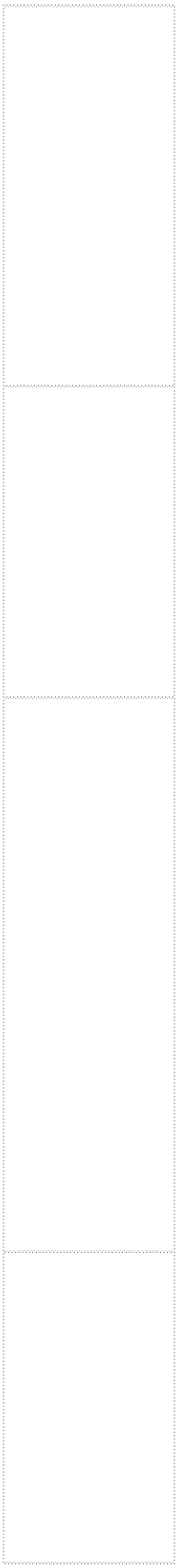

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Biomarker analysis of liver cells exposed to surfactant-wrapped and oxidized multi-walled carbon nanotubes (MWCNTs)
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Air Pollution Abatement Performances of Green Infrastructure in Different Urban Environments – A Review

PI/PO	Cleared Date	Published Date	Completed Date
Shay Fout	1/7/2015	1/1/2016	4/12/2016
Heriberto Cabezas	5/12/2014	6/1/2016	4/5/2017
Mike Borst	6/20/2014	11/15/2015	3/3/2016
Thomas Knudsen	7/12/2016	5/11/2016	7/18/2016
Alan Lindquist	7/24/2014	4/28/2016	12/8/2016
Marina Evans	6/10/2014	3/1/2016	6/8/2016
Betty Kreakie	7/7/2014	2/1/2016	3/29/2016
Imran Shah	7/22/2014	10/16/2015	12/16/2015
Walter Berry	11/6/2014	12/1/2015	12/1/2015
Joseph Flotemersch	4/28/2016	12/1/2015	4/28/2016
James Wickham	8/17/2015	1/5/2016	1/5/2016
Matthew Hopton	8/20/2012	3/1/2016	3/3/2016
Matthew Hopton	8/22/2012	3/3/2016	3/3/2016
Joseph Flotemersch	4/6/2016	5/16/2016	6/1/2016
Lucas Neas	9/19/2012	4/15/2016	4/27/2016
Regan Murray	1/25/2016	7/1/2016	7/5/2016
Joseph Flotemersch	12/21/2012	8/2/2016	8/26/2016
Matthew Hopton	12/7/2012	3/3/2016	3/3/2016
Jim Lazorchak	4/26/2013	11/1/2015	10/22/2015
Nathan Schumaker	2/13/2013	7/3/2016	11/14/2016
Matthew Etterson	2/19/2013	5/1/2016	7/13/2016
Adam Biales	5/24/2016	10/1/2015	5/24/2016
E Hilborn	4/23/2013	4/1/2016	5/17/2016
Heriberto Cabezas	5/2/2013	12/1/2015	6/22/2016
Eric Waits	5/15/2015	3/31/2016	4/12/2016
Yu-Sheng Lin	5/6/2013	4/19/2016	
Matt Heberling	5/14/2013	4/1/2016	6/22/2016
Sean Collins	10/28/2014	12/1/2015	1/15/2016
Sue Kimbrough	4/22/2015	1/5/2016	8/29/2016
Xiaoyu Liu	2/12/2015	12/16/2015	2/9/2016
Michael McManus	9/24/2013	4/1/2016	12/13/2016
Danelle Lobdell	9/6/2013	10/30/2015	11/16/2015
Mark Gabriel	11/18/2015	10/7/2015	11/18/2015
Swinburne Augustine	1/19/2016	10/1/2015	1/25/2016
Autumn Oczkowski	10/25/2013	10/28/2015	10/28/2015
Stephen Edwards	9/23/2013	11/25/2015	1/11/2016
Urmila Kodavanti	1/21/2014	12/15/2015	2/2/2016
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Jeff Yang	3/18/2014	2/15/2016	2/29/2016
Leisha Vance	10/29/2013	10/1/2015	12/22/2016
Heriberto Cabezas	11/5/2013	12/5/2015	11/4/2015
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Marc Russell	11/26/2013	8/1/2016	4/13/2017
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Lisam Smith	1/13/2014	10/1/2015	10/16/2015
Jeff Yang	3/6/2015	10/1/2015	12/9/2015
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Yongping Yuan	10/6/2014	3/15/2016	3/15/2016
Gene Whelan	5/25/2016	2/11/2016	5/25/2016
Lawrence Burkhard	6/4/2014	1/5/2016	1/5/2016
Richard Fulford	2/5/2014	2/1/2016	12/3/2015
Ahjond Garmestani	2/6/2014	3/1/2016	5/5/2016
Cathleen Wigand	4/14/2014	11/1/2015	12/1/2015
Kirk Kitchin	2/11/2014	12/1/2015	5/27/2016
Troy Hawkins	2/19/2014	4/20/2016	3/22/2017
Haiyan Tong	2/26/2014	11/30/2015	1/6/2016
Nathan Schumaker	3/21/2014	2/29/2016	5/25/2016
Matthew Landis	7/13/2015	1/15/2016	11/4/2015
Tim Shafer	3/12/2014	6/1/2016	5/31/2016
William Mundy	4/18/2014	11/1/2015	6/1/2016
Yu-Sheng Lin	3/20/2014	4/19/2016	4/20/2016
Autumn Oczkowski	6/10/2014	1/1/2016	1/5/2016
Chris Nolte	10/8/2015	11/13/2015	11/18/2015
Jorge Santodomingo	6/13/2014	11/10/2015	3/8/2016
Eric Villegas	9/2/2015	12/1/2015	10/20/2015
Philip Bushnell	5/12/2014	11/1/2015	1/11/2016
Heather Golden	6/15/2015	1/1/2016	2/8/2016
Shay Fout	6/12/2017	9/11/2016	6/21/2017
David Holland	8/20/2014	12/14/2015	12/14/2015
Bob Sonawane	5/23/2014	7/7/2016	7/7/2016
Steve Paulsen	8/21/2015	5/1/2016	5/31/2016
Rajender Varma	5/12/2014	11/1/2015	10/21/2015
Danelle Lobdell	7/16/2014	10/1/2015	10/14/2015
Shibin Li	7/10/2014	10/1/2015	6/30/2015
Kirk Scheckel	7/11/2014	1/15/2016	1/5/2016
James Wickham	4/14/2015	11/16/2015	11/16/2015
Ariamalar Selvakumar	9/5/2014	11/2/2015	10/26/2015
Danelle Lobdell	7/15/2014	11/18/2015	1/13/2016
Robert Luebke	9/5/2014	1/1/2016	11/12/2015
Mohamed Hantush	8/27/2014	2/12/2016	2/18/2016
Matthew Hopton	7/15/2014	5/1/2016	5/26/2016
Thomas Knudsen	6/30/2015	12/11/2015	1/22/2016
Deborah Segal	8/4/2014	4/21/2016	4/21/2016
Rajender Varma	8/11/2014	10/1/2015	9/30/2015
Kenneth Rygwelski	9/29/2014	2/1/2016	2/17/2016
Jim Hagy	8/12/2014	12/1/2015	1/25/2016

Stacy Pfaller	9/25/2014	6/1/2016	6/17/2016
David Meyer	9/4/2014	1/1/2016	1/14/2016
Dan Villeneuve	9/22/2014	6/30/2016	10/25/2016
Charles Lane	8/17/2015	2/1/2016	4/20/2016
Andrew Kraft	9/5/2014	4/15/2016	4/15/2016
Gary Norris	7/9/2015	10/1/2015	7/10/2015
Endalkachew Sahle-Demessie	9/4/2014	11/1/2015	11/2/2015
Jon Sobus	11/18/2015	10/1/2015	12/1/2015
Orin Shanks	9/19/2014	10/1/2015	9/23/2015
Jianping Xue	6/22/2015	11/15/2015	12/21/2015
Cheryl Brown	9/18/2014	2/5/2016	1/12/2016
Richard Pruell	10/28/2014	1/20/2016	1/20/2016
Robyn Conmy	9/19/2014	2/29/2016	6/16/2017
Terra Haxton	10/2/2014	1/6/2016	1/11/2016
Christian Daughton	6/3/2015	1/26/2016	1/26/2016
Wesley Ingwersen	9/29/2014	2/22/2016	4/4/2016
Mace Barron	9/12/2014	6/30/2016	6/16/2016
Bart Faulkner	9/15/2014	11/24/2015	6/10/2016
Michael Nye	8/4/2016	2/19/2016	8/4/2016
Joseph Flotemersch	4/28/2016	10/23/2015	5/27/2016
Mary Moffett	9/22/2014	10/30/2015	11/4/2015
Matt Heberling	9/15/2014	11/1/2015	12/16/2015
James Pauer	6/29/2016	8/16/2016	8/31/2016
Johnt Walker	9/24/2014	6/17/2016	6/30/2016
Stephen Edwards	10/6/2014	11/1/2015	3/31/2016
Susan Hester	10/6/2014	2/18/2016	6/20/2017
Nathan Smucker	6/19/2015	11/27/2015	2/9/2016
Tiffany Yelverton	10/10/2014	10/27/2015	11/30/2015
Wesley Ingwersen	9/30/2014	10/1/2015	12/21/2015
Katherine King	10/6/2014	4/6/2016	5/26/2016
Vlad Isakov	1/11/2016	12/15/2015	2/5/2016
Darren Lytle	9/26/2014	4/1/2016	3/2/2016
Rochelle Araujo	12/11/2014	11/10/2015	5/27/2016
Brian Gullett	3/10/2015	6/15/2016	6/28/2016
Urmila Kodavanti	10/6/2014	12/15/2015	2/3/2016
Sarah Taft	10/16/2014	4/26/2016	6/16/2016
Scott Leibowitz	10/2/2014	10/1/2015	9/15/2015
Paul Solomon	6/29/2015	10/1/2015	9/24/2015
Cathleen Wigand	6/18/2015	9/1/2016	7/28/2016
Christopher Gordon	10/14/2014	11/1/2015	11/23/2015
Raymond Smith	10/28/2014	11/1/2015	11/25/2015
Raymond Smith	10/20/2014	11/1/2015	11/25/2015
Matthew Magnuson	10/29/2014	5/17/2016	5/17/2016
Joel Hoffman	1/28/2015	1/1/2016	1/4/2016
E Hilborn	11/3/2014	4/5/2016	4/26/2016
Ken Fritz	4/28/2015	7/5/2016	7/13/2016
Todd Luxton	2/9/2015	10/1/2015	7/15/2015

Susan Makris	2/13/2015	4/26/2016	4/26/2016
Cecilia Tan	5/19/2015	1/1/2016	1/7/2016
Souhail Al-Abed	5/7/2015	3/29/2016	7/28/2016
Steve Jackson	11/17/2014	5/6/2016	5/17/2016
Christopher Clark	2/16/2016	1/16/2016	2/22/2016
E Hilborn	12/2/2014	12/31/2015	2/4/2016
Andy Ghio	2/2/2015	12/1/2015	2/3/2016
Christopher Clark	12/10/2014	4/12/2016	4/28/2016
Jingrang Lu	2/8/2016	2/1/2016	2/8/2016
Robyn Conmy	2/12/2015	12/15/2015	5/4/2017
Susan Makris	12/8/2014	4/26/2016	
Swinburne Augustine	4/28/2015	10/1/2015	11/13/2015
Marisa Mazzotta	2/24/2015	11/1/2015	10/22/2015
Peter Egeghy	12/17/2015	6/1/2016	6/3/2016
Richard Baldauf	1/23/2015	3/7/2016	9/1/2016
Dan Villeneuve	12/4/2014	1/1/2016	12/23/2015
Wayne Munns	3/6/2015	6/22/2016	6/27/2016
Matthew Magnuson	1/20/2015	11/18/2015	1/11/2016
Tim Wade	12/9/2014	6/1/2016	5/23/2016
Amanda Nahlik	12/10/2014	1/29/2016	5/25/2016
Sara Hughes	9/30/2015	12/23/2015	3/10/2016
Mary Gilbert	12/10/2014	12/1/2015	11/16/2015
Jeff Hollister	4/6/2015	3/21/2016	3/21/2016
Chris Corton	1/26/2015	3/9/2016	3/31/2016
Jay Garland	6/1/2016	9/1/2016	2/15/2017
Tim Wade	1/23/2015	1/1/2016	6/8/2016
Robyn Conmy	5/15/2015	2/29/2016	5/3/2017
David Herr	12/23/2014	12/1/2015	12/1/2015
Johnr Kelly	2/2/2015	12/22/2015	12/22/2015
Michael McManus	2/27/2015	4/6/2016	4/7/2016
Raymond Smith	1/5/2015	10/4/2015	10/1/2015
Jesse Bash	12/28/2015	11/19/2015	12/31/2015
Joachim Pleil	11/30/2015	11/30/2015	12/1/2015
Elizabeth Watson	1/8/2015	12/2/2015	12/2/2015
Tim Wade	1/23/2015	12/15/2015	11/16/2015
David Wahman	2/11/2015	6/21/2016	10/13/2016
Vickie Wilson	1/12/2015	2/28/2016	5/18/2016
Paul Solomon	2/11/2016	3/7/2016	4/12/2016
Peder Yurista	3/17/2015	4/1/2016	4/5/2016
Xiaoyu Liu	2/12/2015	10/13/2015	2/9/2016
David Thomas	2/3/2015	5/26/2016	8/25/2017
Kirk Scheckel	5/21/2015	1/11/2016	1/14/2016
Nathan Smucker	7/29/2015	11/24/2015	3/2/2016
James Wickham	10/26/2015	10/27/2015	10/27/2015
Jake Beaulieu	2/20/2015	10/21/2015	3/16/2016
EricS Hall	12/15/2015	12/1/2015	12/15/2015
Brian Gullett	2/23/2015	5/10/2016	10/12/2016

Chris Corton	3/2/2015	10/2/2015	4/4/2016
Nathan Smucker	4/14/2015	12/18/2015	3/2/2016
Andy Ghio	2/19/2015	11/16/2015	11/20/2015
Tara Greaver	2/10/2016	8/25/2016	10/21/2016
Joe Ebersole	1/29/2015	8/10/2016	11/14/2016
Jim Hagy	2/2/2015	12/1/2015	1/25/2016
Mallikarjuna Nadagouda	6/17/2015	1/15/2016	12/14/2015
Blake Schaeffer	2/2/2015	11/10/2015	4/13/2016
Ken Fritz	7/17/2015	2/10/2016	5/27/2016
Chun-Wai Lee	2/24/2015	2/8/2016	4/5/2016
Rita Schoeny	3/4/2015	10/9/2015	5/9/2016
Jim Kaldy	2/3/2015	6/1/2016	6/10/2016
Jim Lazorchak	6/17/2015	2/1/2016	4/22/2016
E Hilborn	6/12/2015	6/1/2016	6/22/2016
Tarsha Eason	2/10/2015	2/1/2016	8/2/2017
Xiaoyu Liu	6/12/2015	4/15/2016	6/7/2016
Paul Mayer	3/7/2015	12/15/2015	8/20/2015
Angela Batt	4/28/2016	4/1/2016	4/28/2016
David DeMarini	5/7/2015	2/19/2016	6/20/2017
Rick Mckinney	2/25/2015	12/14/2015	12/14/2015
Chris Corton	3/2/2015	3/9/2016	3/31/2016
Joel Hoffman	4/14/2015	11/1/2015	10/13/2015
Vlad Isakov	5/8/2017	9/1/2016	5/8/2017
Charles Lane	1/7/2016	4/1/2016	4/20/2016
Mike Borst	3/5/2015	12/1/2015	12/15/2015
Ahjond Garmestani	2/12/2015	12/30/2015	11/17/2016
Dan Campbell	4/24/2015	1/20/2016	10/5/2016
Rajender Varma	3/31/2015	11/1/2015	6/2/2015
Paul Mayer	10/1/2015	8/26/2016	1/11/2016
Erik Pilgrim	11/13/2015	1/1/2016	4/20/2016
William Boyes	3/6/2015	5/18/2016	5/18/2016
Marty Chintala	3/30/2015	12/31/2015	4/1/2016
Ahjond Garmestani	3/13/2015	3/1/2016	6/1/2016
Jorge Santodomingo	4/24/2015	3/1/2016	3/3/2016
Karen Bradham	5/26/2016	3/30/2016	5/27/2016
Kathleen Holm	11/2/2015	12/1/2015	11/18/2015
Michael Schock	9/1/2015	8/16/2016	7/24/2017
D Werkema	8/4/2015	6/13/2016	6/13/2016
Paul Mayer	11/17/2015	3/25/2016	4/4/2016
Xiaoyu Liu	5/15/2015	5/5/2016	3/14/2017
Cecilia Tan	11/25/2015	2/12/2016	2/16/2016
Richard Judson	6/16/2015	10/6/2015	10/26/2015
Matthew Hopton	3/13/2015	3/1/2016	5/11/2016
Yongping Yuan	8/22/2016	8/22/2016	8/22/2016
James Wickham	8/21/2015	5/12/2016	5/12/2016
Thabet Tolaymat	5/5/2015	11/15/2015	9/3/2015
Glenn Suter	4/20/2015	12/10/2015	12/18/2015

Brian Hill	4/14/2015	4/1/2016	2/4/2016
Lindsay Stanek	4/24/2015	9/1/2016	2/27/2017
Erin Silvestri	6/30/2015	2/17/2016	3/1/2016
David Wahman	5/18/2015	7/12/2016	10/20/2016
Kirk Kitchin	4/6/2015	9/9/2016	12/30/2016
John Washington	10/14/2015	11/11/2015	12/21/2015
Gerald Ankley	8/27/2015	3/1/2016	3/1/2016
Lucas Neas	4/30/2015	10/14/2015	10/27/2015
Tanya Spero	2/5/2016	1/1/2016	5/26/2016
Xiaoyu Liu	5/5/2015	1/8/2016	7/7/2016
Shaibal Mukerjee	7/2/2015	10/12/2015	12/2/2015
Mark Cantwell	9/15/2015	1/20/2016	1/20/2016
Joel Hoffman	12/10/2015	2/1/2016	3/9/2016
Jim Kaldy	4/16/2015	10/1/2015	7/15/2015
Shaibal Mukerjee	2/11/2016	2/1/2016	4/27/2016
Jorge Santodomingo	5/29/2015	10/26/2015	1/26/2016
Paul Mayer	4/16/2015	8/10/2016	8/26/2016
Lukas Oudejans	5/27/2015	4/12/2016	5/28/2015
Tanya Spero	1/11/2016	1/1/2016	2/5/2016
Joachim Pleil	4/27/2015	2/25/2016	4/12/2016
Christopher Nietch	4/24/2015	6/1/2016	10/21/2016
Rajender Varma	4/14/2015	1/25/2016	1/27/2016
Jim Lazorchak	5/13/2015	1/1/2016	1/29/2016
Reneej Brooks	4/22/2015	1/4/2016	5/18/2016
David DeMarini	6/3/2015	10/30/2015	6/9/2016
Richard Judson	3/31/2016	2/8/2016	4/7/2016
Paul Schlosser	6/9/2015	4/1/2016	7/5/2016
Jesse Bash	11/30/2015	11/19/2015	12/21/2015
Jesse Bash	7/22/2016	6/16/2016	7/22/2016
Elaina Kenyon	5/7/2015	9/1/2016	12/28/2016
Todd Luxton	7/10/2015	4/1/2016	4/26/2016
Eben Thoma	9/29/2015	3/1/2016	5/11/2016
Karen Bradham	9/15/2015	10/7/2015	5/27/2016
Jeanette VanEmon	11/25/2015	10/15/2015	4/27/2016
Randy Revetta	7/6/2015	7/12/2016	10/18/2016
Mace Barron	4/24/2015	1/1/2016	12/28/2015
E Hilborn	6/15/2015	1/18/2016	2/4/2016
David DeMarini	6/3/2015	10/30/2015	6/9/2016
Stephen Vesper	10/30/2015	8/1/2016	4/22/2016
Betty Kreakie	7/29/2015	8/19/2016	8/22/2016
Scott Leibowitz	4/22/2015	12/5/2015	12/16/2015
John Wambaugh	2/12/2016	9/16/2016	11/9/2016
Theodore Angradi	5/27/2015	6/1/2016	10/3/2016
John Nichols	6/12/2015	3/1/2016	3/8/2016
Ronald Williams	12/22/2015	12/1/2015	12/31/2015
Matthew Etterson	4/28/2015	10/1/2015	9/24/2015
Darren Lytle	5/18/2015	12/9/2015	8/17/2016

Rajender Varma	5/4/2015	1/1/2016	8/25/2015
Brian Hill	4/28/2015	2/28/2016	3/9/2016
Susan Hester	7/27/2015	2/29/2016	12/30/2016
Earl Gray	5/28/2015	12/30/2015	1/7/2016
Gene Rice	5/12/2015	10/31/2015	12/8/2016
Joachim Pleil	8/10/2015	12/11/2015	12/15/2015
William Shuster	7/23/2015	4/21/2016	5/2/2016
Joachim Pleil	5/26/2016	1/27/2016	5/27/2016
Ginger Moser	6/11/2015	11/1/2015	12/22/2015
Karen Bradham	9/21/2015	7/1/2016	2/28/2017
Kirk Scheckel	8/17/2015	10/1/2015	9/2/2015
Sandy Raimondo	5/7/2015	3/1/2016	3/7/2016
Marcus Beck	5/14/2015	8/1/2016	10/18/2016
Robert Devlin	7/1/2015	10/23/2015	11/23/2015
Heriberto Cabezas	5/14/2015	9/1/2016	12/14/2016
Vasudevan Namboodiri	5/20/2015	10/1/2015	5/18/2016
MichaelF Hughes	6/1/2015	12/1/2015	2/18/2016
Stephanie Padilla	6/11/2015	12/1/2015	12/1/2015
William Mundy	6/11/2015	12/1/2015	6/20/2017
Dan Loughlin	6/2/2015	2/10/2016	3/29/2016
Tim Wade	5/20/2015	7/26/2016	8/12/2016
Rajender Varma	7/15/2015	1/1/2016	1/21/2016
Rajender Varma	6/22/2015	12/17/2015	1/21/2016
Robert Gilliam	12/21/2015	12/16/2015	4/26/2016
Eric Rhodes	2/8/2016	2/1/2016	2/8/2016
Wayne Cascio	5/21/2015	9/30/2016	1/4/2016
Charles Wood	9/24/2015	11/25/2015	12/28/2016
Scott Leibowitz	6/19/2015	2/23/2016	4/21/2016
Timothy Dean	8/7/2015	10/1/2015	12/9/2015
Rajender Varma	6/22/2015	11/1/2015	11/30/2015
Gene Whelan	6/16/2015	4/25/2016	5/13/2016
Hisham El-Masri	12/17/2015	7/1/2016	12/6/2016
Jon Pleim	12/21/2015	11/3/2015	12/21/2015
Earl Gray	8/3/2015	1/1/2016	1/12/2016
Urmila Kodavanti	8/11/2015	6/15/2016	6/22/2016
Russell Thomas	8/14/2015	12/15/2015	12/16/2015
Karen Bradham	12/22/2015	11/2/2015	12/31/2015
Michael Breen	12/17/2015	11/2/2015	12/21/2015
John Washington	10/23/2015	10/20/2015	12/21/2015
Anett Trebitz	11/23/2015	12/21/2015	12/21/2015
Brenda Rashleigh	6/22/2015	3/30/2016	3/30/2016
Michael Lewandowski	12/14/2015	4/1/2016	4/13/2016
Jordan West	7/23/2015	3/1/2016	7/1/2016
Christian Andersen	6/8/2015	9/1/2016	4/13/2016
Laurie Alexander	9/11/2015	12/1/2015	1/6/2016
Rajender Varma	6/29/2015	4/21/2016	4/28/2016
Rajender Varma	6/29/2015	1/26/2016	1/25/2016

Mace Barron	8/26/2015	11/1/2015	10/30/2015
Stephen Gavett	7/28/2015	1/28/2016	2/17/2016
Mary Gilbert	6/22/2015	2/1/2016	4/21/2016
Brian McMinn	3/23/2016	5/1/2016	3/24/2016
John Washington	7/2/2015	11/3/2015	12/21/2015
Marisa Mazzotta	8/10/2015	9/1/2016	1/30/2017
Kent Thomas	9/1/2015	11/9/2015	12/21/2015
Nathan Schumaker	7/2/2015	12/15/2015	11/19/2015
Mark Rodgers	8/6/2015	11/17/2015	12/7/2015
Joel Hoffman	11/19/2015	6/2/2016	8/9/2016
Prasada Kodavanti	6/23/2015	12/30/2015	1/13/2016
Gerald Ankley	8/7/2015	12/1/2015	10/19/2015
E Hilborn	7/16/2015	6/1/2016	8/18/2016
Yue Ge	12/30/2016	9/14/2016	2/10/2017
Rajender Varma	8/14/2015	1/1/2016	12/22/2015
Eric Villegas	8/13/2016	6/1/2016	8/22/2016
Kate Sullivan	6/29/2015	5/13/2016	6/15/2016
David Herr	6/25/2015	3/17/2016	4/13/2016
Dan Campbell	6/24/2015	11/10/2015	10/16/2015
Daniel Heggem	3/8/2016	6/30/2016	6/30/2016
David Holland	12/2/2015	12/17/2015	12/17/2015
Jill Awkerman	7/23/2015	9/2/2016	10/6/2016
Tom Luben	8/20/2015	3/11/2016	5/31/2016
Brian Gullett	7/29/2015	6/7/2016	6/7/2016
Christopher Clark	9/2/2015	2/13/2016	9/14/2016
Paul Solomon	9/21/2015	10/27/2015	11/2/2015
Sheau-Fung Thai	7/15/2015	7/30/2016	6/21/2017
William Shuster	7/14/2015	9/7/2016	12/22/2016
Jeff Yang	9/2/2015	11/25/2015	12/14/2015
Vlad Isakov	1/11/2016	1/15/2016	4/13/2016
MichaelF Hughes	8/5/2015	1/28/2016	2/18/2016
Naomi Detenbeck	10/30/2015	9/20/2016	9/26/2016
Sandy Raimondo	7/8/2015	9/1/2016	9/6/2016
Scott Leibowitz	7/9/2015	4/1/2016	4/1/2016
John Stoddard	7/21/2015	2/25/2016	6/7/2016
Rong-Lin Wang	7/24/2015	1/1/2016	2/29/2016
Hisham El-Masri	9/3/2015	3/3/2016	12/28/2016
Rajender Varma	7/23/2015	11/2/2015	11/27/2015
Rajender Varma	7/30/2015	11/4/2015	10/13/2015
Charles Lane	8/24/2015	4/22/2016	6/1/2016
Ken Fritz	6/1/2016	5/11/2016	6/3/2016
Jesse Bash	1/11/2016	12/10/2015	4/27/2016
Thomas Long	8/20/2015	10/7/2015	10/12/2016
Rory Conolly	9/16/2015	5/31/2016	8/25/2017
David Wahman	9/1/2015	1/13/2016	1/13/2016
Rohit Mathur	12/17/2015	12/16/2015	4/25/2016
Johnt Walker	8/7/2015	11/24/2015	2/16/2016

Rajender Varma	8/26/2015	10/5/2015	11/17/2015
Michael Elovitz	1/6/2016	11/17/2015	1/6/2016
John Vandenberg	8/26/2015	3/19/2016	4/25/2016
Matthew Woody	5/26/2016	3/29/2016	5/27/2016
Dan Villeneuve	8/27/2015	4/1/2016	6/2/2016
Jon Sobus	12/14/2015	1/23/2016	1/25/2016
John Stanek	9/1/2015	4/6/2016	6/2/2016
Stephen Edwards	7/31/2015	1/1/2016	6/21/2017
JohnH Zimmerman	3/14/2016	3/14/2016	3/14/2016
Christopher Gordon	7/31/2015	3/1/2016	4/27/2016
Hisham El-Masri	10/14/2015	5/15/2016	6/3/2016
Rajender Varma	8/14/2015	5/1/2016	2/29/2016
Dan Villeneuve	8/27/2015	4/1/2016	2/26/2016
Dan Villeneuve	8/27/2015	4/1/2016	2/26/2016
Jim Lazorchak	8/28/2015	2/26/2016	4/26/2016
Havala Pye	11/30/2015	11/6/2015	12/21/2015
Matt Martin	8/19/2015	1/18/2016	4/7/2016
Stephen Edwards	8/7/2015	1/25/2016	2/18/2016
Jake Beaulieu	9/8/2015	6/24/2016	8/29/2017
Todd Martin	8/18/2015	1/19/2016	8/31/2016
Gayle Hagler	8/25/2015	5/10/2016	1/20/2017
Orin Shanks	10/19/2015	3/1/2016	2/29/2016
Don Betowski	12/1/2015	1/5/2016	1/5/2016
Orin Shanks	9/2/2015	11/23/2015	12/7/2015
Heath Mash	10/4/2015	5/15/2016	3/22/2016
Dan Villeneuve	9/25/2015	3/1/2016	3/1/2016
Teri Conner	5/19/2016	1/1/2016	5/19/2016
Timothy Dean	10/27/2015	6/28/2016	9/7/2016
Marsha Morgan	11/3/2015	1/1/2016	11/19/2015
Richard Judson	9/2/2015	5/20/2016	5/25/2016
Jorge Santodomingo	10/4/2015	3/1/2016	2/29/2016
Eric Villegas	10/30/2015	10/1/2015	4/21/2016
Imran Shah	9/10/2015	7/8/2016	7/8/2016
Mallikarjuna Nadagouda	1/5/2016	2/9/2016	1/10/2018
Amara Holder	9/28/2015	4/16/2016	5/12/2016
Nicolle Tulve	12/22/2015	2/3/2016	4/26/2016
Rajender Varma	8/28/2015	1/1/2016	12/22/2015
Eunice Varughese	2/8/2016	11/1/2015	2/8/2016
Grace Tier	10/5/2015	12/20/2015	4/6/2016
Stephen Edwards	9/28/2015	4/19/2016	6/21/2017
Stephen Edwards	9/21/2015	3/28/2016	6/21/2017
David Meyer	9/3/2015	9/6/2016	3/27/2017
DavidJ Williams	7/7/2016	7/11/2016	7/11/2016
Mallikarjuna Nadagouda	5/13/2016	8/5/2016	5/13/2016
William Mundy	9/16/2015	3/14/2016	3/23/2016
Tim Wade	9/2/2015	2/11/2016	6/1/2016
Alan Talhelm	11/6/2015	3/3/2016	6/1/2016

Andy Ghio	9/18/2015	4/19/2016	6/1/2016
Matthew Weber	9/8/2015	10/6/2015	10/14/2015
Matthew Magnuson	9/18/2015	2/3/2016	2/22/2016
Kirk Scheckel	1/14/2016	10/12/2015	1/14/2016
John Stanek	9/28/2015	5/12/2016	7/21/2016
David Lehmann	10/15/2015	9/1/2016	8/17/2016
Dale Hoff	11/16/2015	1/15/2016	11/16/2015
Vlad Isakov	11/5/2015	12/8/2015	6/9/2017
Joachim Pleil	3/16/2016	4/8/2016	4/27/2016
Shaibal Mukerjee	2/11/2016	1/15/2016	4/27/2016
Rich Haugland	1/19/2016	2/2/2016	4/26/2016
James Samet	6/2/2016	11/25/2015	6/2/2016
Matthew Landis	12/22/2015	2/1/2016	12/31/2015
Markg Johnson	9/29/2015	11/3/2015	1/25/2016
Christopher Gordon	9/15/2015	4/19/2016	4/22/2016
John Kenneke	10/14/2015	9/1/2016	2/28/2017
Stephen Vesper	11/12/2015	1/1/2016	2/29/2016
Randy Revetta	10/19/2015	1/7/2016	5/11/2016
Kirk Scheckel	12/11/2015	9/1/2016	9/14/2016
Richard Devereux	9/18/2015	1/15/2016	1/26/2016
Stephen Vesper	1/31/2017	4/20/2016	1/31/2017
Brian Chorley	9/23/2015	4/15/2016	6/13/2016
John Lehrter	9/23/2015	9/28/2016	3/23/2018
Dina Schreinemachers	10/2/2015	3/7/2016	4/26/2016
Randy Revetta	10/19/2015	1/21/2016	1/27/2016
Chris Nolte	4/5/2016	2/4/2016	4/27/2016
Tim Collette	10/14/2015	9/1/2016	2/28/2017
Kirk Scheckel	12/14/2015	9/28/2016	12/13/2016
Urmila Kodavanti	10/15/2015	4/1/2016	4/20/2016
Lukas Oudejans	10/20/2015	10/20/2015	11/2/2015
Rohit Mathur	6/20/2016	7/19/2016	7/22/2016
Joe Wood	10/13/2015	10/15/2015	10/15/2015
Rajender Varma	10/8/2015	12/29/2015	4/25/2016
EHenry Lee	10/9/2015	5/1/2016	3/7/2016
Stephen Vesper	10/30/2015	3/3/2016	3/16/2016
Florence Fulk	10/13/2015	5/11/2016	6/17/2016
Robert Devlin	10/1/2015	7/1/2016	6/14/2016
Ross Lunetta	3/1/2016	3/1/2016	3/1/2016
Chris Corton	11/23/2015	5/15/2016	6/20/2017
Jorge Santodomingo	10/26/2015	5/10/2016	10/18/2016
Steve Simmons	10/9/2015	2/15/2016	4/7/2016
Johnt Walker	11/9/2015	5/24/2016	8/9/2016
Rajender Varma	10/8/2015	2/26/2016	4/25/2016
Christopher Gordon	10/5/2015	1/1/2016	1/11/2016
Christopher Gordon	10/5/2015	1/1/2016	5/31/2016
Michael Lewandowski	7/22/2016	6/10/2016	7/22/2016
James Goodrich	12/7/2015	1/7/2016	9/20/2016

D Werkema	8/8/2016	8/8/2016	8/8/2016
Lawrence Burkhard	10/20/2015	6/16/2016	6/16/2016
Rajender Varma	10/22/2015	1/28/2016	4/25/2016
Joel Hoffman	10/20/2015	8/28/2016	8/1/2016
Shaun McCullough	10/30/2015	3/1/2016	3/3/2016
Swinburne Augustine	4/15/2016	9/12/2016	2/27/2017
Tim Shafer	11/10/2015	6/2/2016	12/28/2016
Mark Cantwell	12/21/2015	6/15/2016	6/16/2016
Phil Kaufmann	1/7/2016	5/1/2016	4/4/2016
Dan Campbell	10/22/2015	11/10/2015	10/22/2015
Orin Shanks	12/14/2015	5/2/2016	4/25/2016
Cecilia Tan	2/11/2016	1/13/2016	5/26/2016
Aimen Farraj	12/2/2015	3/17/2016	4/6/2016
Deborah Luecken	11/30/2015	10/23/2015	5/26/2016
Christopher Gordon	12/3/2015	5/10/2016	5/24/2016
Dan Campbell	12/10/2015	10/21/2015	12/15/2015
Alan Hecht	12/1/2015	2/25/2016	5/9/2016
Wesley Ingwersen	11/5/2015	9/10/2016	11/14/2016
Markg Johnson	11/16/2015	6/1/2016	5/23/2016
Ahjond Garmestani	10/29/2015	6/22/2016	4/28/2017
Gayle Hagler	12/9/2015	5/16/2016	5/2/2016
Stephen Gavett	11/30/2015	4/15/2016	4/26/2016
Dan Campbell	12/15/2015	4/15/2016	9/30/2016
David DeMarini	2/14/2016	7/5/2016	6/20/2017
Stephen Vesper	1/31/2017	8/15/2016	1/31/2017
Regan Murray	12/15/2015	1/12/2016	2/25/2016
Xiaoyu Liu	11/23/2015	9/8/2016	8/3/2016
Tim Wade	12/7/2015	9/1/2016	8/12/2016
Christian Hogrefe	3/16/2016	2/27/2016	5/26/2016
Havala Pye	2/9/2016	2/11/2016	4/12/2016
James Starr	4/26/2016	3/21/2016	4/27/2016
Jim Szykman	12/23/2015	7/18/2016	7/18/2016
Todd Luxton	12/14/2015	7/28/2016	10/17/2016
Dan Campbell	12/15/2015	11/11/2015	12/15/2015
Jay Garland	12/22/2015	1/11/2016	4/11/2016
Richard Zepp	4/7/2016	2/29/2016	4/27/2016
Eben Thoma	1/11/2016	7/25/2016	1/25/2017
Mace Barron	12/8/2015	4/30/2016	5/25/2016
Jim Lazorchak	12/14/2015	7/1/2016	4/12/2016
Rajender Varma	12/9/2015	4/1/2016	2/19/2016
Darryl Keith	3/2/2016	3/29/2016	3/30/2016
Laura Boczek	12/23/2015	3/8/2016	2/10/2016
Tiffany Yelverton	12/9/2015	1/28/2016	5/3/2016
Andrew Henderson	1/12/2016	2/1/2016	2/2/2017
Urmila Kodavanti	5/5/2016	6/1/2016	5/23/2016
Glenn Suter	12/2/2015	4/18/2016	4/28/2016
Chris Geron	8/11/2016	10/21/2015	1/31/2017

Dan Villeneuve	12/10/2015	2/1/2016	12/10/2015
Ana Rappold	12/24/2015	1/27/2016	2/4/2016
Paul Solomon	1/5/2016	1/6/2016	1/6/2016
Chris Geron	12/24/2015	3/8/2016	5/3/2016
Randy Revetta	1/11/2016	3/31/2016	6/3/2016
Joachim Pleil	6/3/2016	6/6/2016	6/6/2016
Annie Jarabek	4/8/2016	4/27/2016	6/1/2016
Joachim Pleil	4/4/2016	4/4/2016	4/4/2016
Tom Luben	4/28/2016	7/15/2016	7/21/2016
Elizabeth Chan	12/18/2015	5/21/2016	6/2/2016
Andrew Kraft	1/11/2016	4/15/2016	4/15/2016
William Boyes	12/14/2015	3/1/2016	3/3/2016
Robert Burgess	12/10/2015	1/5/2016	1/8/2016
Ronald Hines	12/9/2015	7/1/2016	5/22/2017
Rajender Varma	1/12/2016	4/20/2016	2/29/2016
Keith Houck	12/20/2015	6/1/2016	7/7/2016
Glenn Suter	2/9/2016	6/1/2016	7/20/2016
Stephen Gavett	12/15/2015	8/1/2016	8/17/2016
Prasada Kodavanti	12/30/2015	3/4/2016	4/8/2016
Jeff Hollister	1/25/2016	2/9/2016	4/13/2016
Grace Patlewicz	2/3/2016	6/10/2016	11/9/2016
Ahjond Garmestani	1/4/2016	6/2/2016	1/9/2017
Grace Patlewicz	5/20/2016	6/29/2016	9/29/2016
Markg Johnson	1/4/2016	6/1/2016	7/8/2016
Markg Johnson	1/4/2016	4/25/2016	7/8/2016
Gerald Ankley	12/31/2015	1/12/2016	1/28/2016
Dan Campbell	1/25/2016	2/15/2016	4/6/2016
John Rogers	1/28/2016	2/1/2016	2/4/2016
Charles Wood	1/12/2016	8/1/2016	12/28/2016
Joachim Pleil	3/11/2016	3/8/2016	3/16/2016
Chris Nolte	2/2/2016	5/7/2016	5/13/2016
Leland Vane	1/13/2016	7/7/2016	5/15/2017
Jeff Yang	6/8/2016	2/1/2016	10/18/2016
Heather Golden	1/19/2016	7/19/2016	7/22/2016
JohnH Zimmerman	5/6/2016	1/6/2016	5/6/2016
JohnM Johnston	1/20/2016	6/21/2016	6/21/2016
Bryan Bloomer	4/27/2016	4/1/2016	8/9/2016
Stephen Edwards	1/19/2016	4/15/2016	2/18/2016
Gayle Hagler	2/2/2016	3/17/2016	4/24/2018
Robert Burgess	2/1/2016	2/15/2016	3/24/2016
Autumn Oczkowski	2/15/2016	5/27/2016	5/27/2016
Elizabeth Chan	4/14/2016	9/19/2016	9/29/2016
Christian Daughton	4/19/2016	4/19/2016	4/19/2016
John Glaser	2/18/2016	2/1/2016	5/4/2016
Andrew Henderson	2/18/2016	8/1/2016	2/9/2017
Jorge Santodomingo	3/18/2016	8/9/2016	10/20/2016
MichaelF Hughes	3/31/2016	6/1/2016	6/20/2017

Thabet Tolaymat	4/13/2016	7/1/2016	4/26/2016
Ginger Moser	2/10/2016	4/21/2016	5/18/2016
Grace Tier	2/14/2016	2/11/2016	4/7/2016
Susan Glassmeyer	9/26/2016	9/22/2016	9/26/2016
John Lehrter	2/2/2016	5/5/2016	3/14/2016
Thomas Knudsen	2/12/2016	5/13/2016	5/17/2016
John Lehrter	3/10/2016	3/28/2016	5/18/2016
Jon Pleim	2/8/2016	3/16/2016	4/27/2016
Stuart Willison	2/25/2016	8/29/2016	4/24/2017
Cecilia Tan	5/9/2016	4/28/2016	6/17/2016
Golam Sarwar	7/1/2016	9/1/2016	7/22/2016
Nathan Schumaker	3/7/2016	2/22/2016	3/8/2016
Nathan Schumaker	3/7/2016	9/10/2016	6/7/2016
Markg Johnson	2/25/2016	9/28/2016	10/6/2016
Ahjond Garmestani	2/23/2016	8/11/2016	12/22/2016
Kirk Scheckel	7/8/2016	8/5/2016	7/20/2016
Michael Sierszen	2/16/2016	9/28/2016	9/28/2016
Rohit Mathur	2/10/2017	9/1/2016	2/10/2017
Robyn Conmy	3/15/2016	9/30/2016	6/13/2017
Randy Revetta	3/10/2016	5/10/2016	10/19/2016
Charles Wood	3/2/2016	9/1/2016	8/25/2017
Yongping Yuan	3/23/2016	2/1/2016	2/28/2017
Ann Richard	4/12/2016	7/1/2016	7/7/2016
Matthew Woody	5/6/2016	9/1/2016	7/22/2016
Gerardo Ruiz-Mercado	3/10/2016	7/1/2016	5/12/2016
Rajender Varma	4/6/2016	8/9/2016	9/7/2016
Diane Nacci	4/27/2016	9/20/2016	10/5/2016
Robert Burgess	3/1/2016	3/3/2016	3/3/2016
Brian Chorley	3/15/2016	5/19/2016	12/30/2016
Richard Judson	5/23/2016	7/5/2016	10/17/2016
Nicholas Anastas	3/25/2016	4/13/2016	2/21/2018
John Stanek	6/3/2016	9/22/2016	12/14/2017
Joachim Pleil	5/25/2016	9/2/2016	9/6/2016
Shannon Griffin	6/6/2016	9/1/2016	2/16/2017
Richard Zepp	5/3/2016	1/28/2016	5/27/2016
Cathleen Wigand	3/29/2016	3/2/2016	3/29/2016
Gerardo Ruiz-Mercado	4/6/2016	7/25/2016	9/8/2016
Glenn Suter	3/24/2016	6/1/2016	7/20/2016
Michael Papenfus	4/7/2016	8/1/2016	5/17/2016
Joe Ebersole	3/21/2016	9/2/2016	8/9/2016
Joachim Pleil	4/18/2016	6/2/2016	6/2/2016
Richard Baldauf	4/21/2016	9/9/2016	10/26/2016
Richard Judson	3/29/2016	3/15/2016	4/6/2016
Chunming Su	7/28/2016	7/1/2016	2/14/2017
Ken Fritz	4/15/2016	7/5/2016	7/13/2016
Paul Mayer	5/24/2016	9/9/2016	9/14/2016
James Starr	5/18/2016	5/18/2016	5/18/2016

Cathleen Wigand	4/18/2016	4/28/2016	7/29/2016
John Glaser	4/27/2016	4/1/2016	12/12/2016
Peter Egeghy	4/12/2016	7/22/2016	7/22/2016
Endalkachew Sahle-Demessie	5/20/2016	6/6/2016	6/16/2016
Swinburne Augustine	5/4/2016	5/12/2016	5/12/2016
Rick Wilkin	8/24/2016	8/27/2016	2/14/2017
Diane Nacci	4/28/2016	6/1/2016	8/16/2016
John Lehrter	4/27/2016	5/23/2016	7/27/2016
Joachim Pleil	5/26/2016	6/24/2016	7/11/2016
Mary Gilbert	5/5/2016	7/1/2016	11/17/2017
Joachim Pleil	6/29/2016	8/5/2016	8/9/2016
Jim Szykman	7/11/2016	6/23/2016	7/15/2016
Dan Campbell	5/27/2016	6/15/2016	6/16/2016
Urmila Kodavanti	5/26/2016	9/1/2016	8/12/2016
Ed Heithmar	5/26/2016	4/11/2016	6/3/2016
Andrew Whitehill	7/5/2016	8/1/2016	7/11/2016
Christopher Lau	6/9/2016	8/1/2016	11/17/2017
Daniel Vallero	6/27/2016	5/1/2016	3/29/2018
James Starr	6/1/2016	5/1/2016	6/3/2016
Orin Shanks	9/27/2016	12/9/2015	1/11/2018
Ellen Cooter	8/8/2016	9/16/2016	2/23/2017
Ahjond Garmestani	7/13/2016	8/26/2016	12/22/2016
Ahjond Garmestani	7/5/2016	8/1/2016	3/24/2017
Matthew Landis	7/12/2016	6/20/2016	7/15/2016
Peter Egeghy	7/12/2016	9/1/2016	8/29/2016
Rajender Varma	7/25/2016	9/1/2016	9/12/2016
David-C Wong	7/27/2016	9/1/2016	6/6/2017
Matthew Landis	7/18/2016	7/30/2016	8/1/2016
Rohit Mathur	7/28/2016	7/31/2016	6/6/2017
Chunming Su	8/19/2016	8/10/2016	2/14/2017
Matt Henderson	7/22/2016	9/15/2016	7/22/2016
Jim Latimer	8/3/2016	8/14/2016	4/18/2017
Mark Strynar	10/4/2016	8/1/2016	4/18/2017
Said Hilal	2/28/2017	9/1/2016	3/1/2017
Chunming Su	9/21/2016	9/5/2016	2/14/2017
Cissy Ma	9/26/2016	9/1/2016	3/12/2018
William Shuster	9/27/2016	9/7/2016	4/14/2017
Richard Judson	3/21/2017	1/15/2016	3/21/2017
Rajender Varma	12/13/2016	2/26/2016	1/30/2017
Richard Baldauf	4/25/2017	9/7/2016	4/24/2018

EPA Data?/Justification
Yes
Yes
No; Research data consisted of secondary data only
No; data are from 2002-2006 spatially balanced probabilistic stream survey data from W VA Dept of EPA
Yes

Yes

Yes

Yes

Yes

Yes

Yes

No; Review article

Yes

No; Secondary data used

No; Data belongs to another entity

Yes

Yes

Yes

No; All data for this article was generated at the University of Texas.

No; Data belongs to another entity

Yes

Yes

No; Research conducted was a literature review

No; The article is a review article outlining and discussing the conceptual basis for managing climate refugia

No; Review article with one figure from NOAA and NASA.

Yes

Yes

Yes

No; None of the papers has data that was generated by EPA. AG

No; Research data consisted of secondary data only

Yes

No; no data, software

Yes

Yes

Yes

Yes

No; Review Articles

Yes

No; No EPA Data, this is a review article

Yes

Yes

No; The date was not generated by EPA, but had an EPA coauthor

Yes

Yes

Yes

No; Review Articles

No; Review Articles

Yes

No; Manuscript describes a software package developed to retrieve, organize, and analyze estuary monitoring data

No; *

Yes

No; We helped with design, supplies, and writing but did not generate data

No; Used literature data

No; Based on summary of literature information and interviews, no lab or field gathering of data.

Yes

Yes

No; Data belongs to another entity
Yes
No; .

Yes; n/a

No; Used literature data only

Yes
Yes

No; Used publicly available data (non-EPA)

Yes

Yes

Yes

No; Used publicly available data (non-EPA)

No; Used publicly available data (non-EPA)

Yes

Yes

Yes

No; data belongs to Finnish Government

No; No EPA data, review only

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes; Primary data collected was classified as CBI. All other data used was secondary data.

Yes

No; Research data consisted of secondary data only.

Yes

No; This manuscript utilized previously published data.

Yes

No; No EPA Data, this is a review article

Yes

Yes

Yes

No; Data belongs to another entity

No; Review Articles

No; Review Articles

No; All data published in this manuscript were generated at the Medical College of Wisconsin

Yes

No; 2)No EPA data

Yes

No; This is a review article

No; Review Articles

Yes

Yes

Yes

Yes

Yes

No; No EPA Data, analysis of research methods

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

Yes

No; the lead author is not EPA and the data was not created by EPA, but is an analysis of publicly available data

No; Literature review

Yes

No; Review Articles

No; Review article

No; Review article

No; Review Articles

Yes

Yes

No; No EPA Data, this is a review article

No; *

Yes

No; Review Articles
Yes
No; Review Articles

No; Authorship granted only due to samples provided
No; introduction to special issue - no data

No; Information gathered by NIH, Univ. of Calif, and Harvard University.
Yes
Yes
Yes

Yes

No; highlights from a conference
Yes

No; I was intellectual contributor - not data contributor. I helpied primary author interpret data & gave advice.
Yes
No; All data is from University of Georgia
Yes
No; Data consisit of secondary data only
No; This journal article is observational based on analysis of existing population data.
No; This is a review article primarily by external non-EPA authors, and has no associated data.
Yes
No; Literature review only

completed_review	published_data	Sent to PMC?
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EPA Data?/Justification	(All)

Row Labels	Count of Initiator's L/C/O
Qtr1	**190**
Qtr2	**156**
Qtr3	**127**
Qtr4	**177**
Grand Total	**650**

published_data

Row Labels
Qtr1
Jan
Feb
Mar
Qtr2
Qtr3
Jul
Aug
Sep
Qtr4
Oct
Nov
Dec
Grand Total

(All)

Count of Initiator's L/C/O
190
73
61
56
156
127
34
34
59
177
56
58
63
650

Sent to PMC?	(All)

Row Labels	Count of Initiator's L/C/O
Qtr1	**190**
Qtr2	**156**
Qtr3	**127**
Jul	34
Aug	34
Sep	59
Qtr4	**177**
Grand Total	**650**

Row Labels	Count of Initiator's L/C/O
Qtr1	**190**
Jan	73
Feb	61
Mar	56
Qtr2	**156**
Apr	64
May	43
Jun	49
Qtr3	**127**
Jul	34
Aug	34
Sep	59
Qtr4	**177**
Oct	56
Nov	58
Dec	63
Grand Total	**650**

Initiator's L/C/O	Clearance Tracking Number
ord,nerl,sed,efab	ORD-003798
ord,nerl,ced	ORD-005847
ord,nheerl,aed,peb	ORD-006191
ord,nerl,sed,efab	ORD-006797
ord,nerl,esd,cmb	ORD-007145
ord,nrmrl,aemd,ensb	ORD-007478
ord,nerl,emmd,mieb	ORD-007759
ord,nerl,sed,efab	ORD-009125
ord,nerl,emmd,ieib	ORD-009206
ord,nerl,emmd	ORD-009383
ord,nrmrl,appcd,iemb	ORD-009388
ord,nheerl,ged	ORD-009695
ord,nrmrl,lrpcd,esmb	ORD-009933
ord,ncea,nceacin,brab	ORD-010003
ord,nrmrl,std,sab	ORD-010061
ord,nerl,ced	ORD-010125
ord,nerl,emmd,phcb	ORD-010139
ord,nerl,ced,web	ORD-010181
ord,nheerl,aed,heb	ORD-010685
ord,nrmrl,lrpcd,wmb	ORD-010708
ord,nheerl,aed,peb	ORD-010744
ord,nrmrl,aemd,ensb	ORD-010777
ord,nerl,sed,efab	ORD-010846
ord,nheerl,aed	ORD-010994
ord,ncct,N/A	ORD-011159
ord,nheerl,med	ORD-011208
ord,nheerl,med,stb	ORD-011209
ord,nheerl,ephd,eb	ORD-011272
ord,nerl,emmd,aqb	ORD-011274
ord,nheerl,aed,peb	ORD-011310
ord,ncea,nceacin,crab	ORD-011343
ord,nheerl,ged	ORD-011553
ord,nrmrl,appcd	ORD-011565
ord,nrmrl,wsd	ORD-011614
ord,nheerl,ged	ORD-011887
ord,nheerl,ged	ORD-011888
ord,nheerl,ephd,crb	ORD-011889
ord,nerl,emmd	ORD-011904
ord,nheerl,istd	ORD-011938
ord,nrmrl,wswrd	ORD-011988
ord,nerl,sed,efab	ORD-012121
ord,nheerl,med	ORD-012137
ord,nerl,ced	ORD-012149
ord,nerl,emmd	ORD-012218
ord,nheerl,med	ORD-012405
ord,nrmrl,appcd,apb	ORD-012408

ord,nrmrl,lrpcd,esmb	ORD-012562
ord,nerl,sed,eib	ORD-012664
ord,nrmrl,lrpcd,wmb	ORD-012696
ord,ncea,odd	ORD-012749
ord,nheerl,istd,pb	ORD-012827
ord,nhsrc,wipd	ORD-012929
ord,nheerl,aed,wdb	ORD-013005
ord,nheerl,aed,heb	ORD-013026
ord,nrmrl,appcd,aptb	ORD-013072
ord,nheerl,aed,peb	ORD-013102
ord,nheerl,ephd,eb	ORD-013124
ord,nheerl,med	ORD-013188
ord,nheerl,med	ORD-013205
ord,nrmrl,wswrd	ORD-013222
ord,nheerl,ephd,eb	ORD-013311
ord,nheerl,ged	ORD-013314
ord,nheerl,aed,peb	ORD-013330
ord,nheerl,ephd,cib	ORD-013422
ord,nheerl,wed,eeb	ORD-013447
ord,ncct,N/A	ORD-013503
ord,nrmrl,wsd,dwtdb	ORD-013508
ord,nerl,sed,eib	ORD-013607
ord,nerl,heasd,pmrb	ORD-013638
ord,nheerl,ephd,cib	ORD-013645
ord,nrmrl,appcd,apb	ORD-013646
ord,nerl,emmd	ORD-013657
ord,nhsrc,tcad	ORD-013659
ord,nrmrl,std,gcb	ORD-013682
ord,nrmrl,std,sab	ORD-013708
ord,nhsrc,wipd	ORD-013709
ord,nheerl,aed,peb	ORD-013732
ord,nerl,sed,efab	ORD-013736
ord,nheerl,med	ORD-013745
ord,nerl,heasd,emrb	ORD-013759
ord,nrmrl,lmmd,lcdsb	ORD-013782
ord,nheerl,istd,sbb	ORD-013788
ord,nrmrl,std,seb	ORD-013822
ord,nheerl,ephd,eb	ORD-013952
ord,nheerl,ephd,cib	ORD-013975
ord,ncea,nceartp,emag	ORD-014035
ord,nerl,ced	ORD-014052
ord,nrmrl,wswrd	ORD-014069
ord,nerl,esd	ORD-014081
ord,nerl,ced	ORD-014089
ord,nerl,ced	ORD-014105
ord,nerl,ced	ORD-014112
ord,ncct,N/A	ORD-014177

ord,nerl,sed,efab	ORD-014194
ord,nhsrc,wipd	ORD-014200
ord,nrmrl,aemd,dsbb	ORD-014219
ord,nerl,sed	ORD-014258
ord,nhsrc,wipd	ORD-014320
ord,nrmrl,lrpcd,wmb	ORD-014351
ord,nerl,emmd,mieb	ORD-014352
ord,nheerl,ephd,eb	ORD-014435
ord,nrmrl,wswrd,uwmb	ORD-014446
ord,nheerl,ged	ORD-014449
ord,nheerl,aed,peb	ORD-014496
ord,ncea,nceartp,emag	ORD-014499
ord,nheerl,ged	ORD-014509
ord,nheerl,N/A	ORD-014515
ord,nheerl,wed,feb	ORD-014521
ord,nheerl,istd,pb	ORD-014574
ord,nrmrl,std,seb	ORD-014605
ord,nheerl,ged	ORD-014647
ord,nrmrl,std,seb	ORD-014694
ord,nheerl,istd,sbb	ORD-014698
ord,nerl,emmd,phcb	ORD-014709
ord,nheerl,ephd,cib	ORD-014944
ord,nheerl,med	ORD-014967
ord,nheerl,med	ORD-014971
ord,nrmrl,appcd,ecpb	ORD-014973
ord,nerl,sed,iemb	ORD-014980
ord,nheerl,med	ORD-014981
ord,nerl,sed	ORD-014984
ord,nheerl,aed,heb	ORD-015001
ord,nheerl,wed,eeb	ORD-015004
ord,nheerl,wed,feb	ORD-015009
ord,nheerl,ephd,eb	ORD-015044
ord,ncea,nceartp,emag	ORD-015068
ord,nhsrc,wipd	ORD-015098
ord,nerl,ced	ORD-015118
ord,nheerl,ged	ORD-015119
ord,nheerl,aed,peb	ORD-015127
ord,nerl,ced	ORD-015131
ord,nrmrl,appcd,aptb	ORD-015165
ord,nerl,emmd	ORD-015166
ord,nerl,emmd,mieb	ORD-015167
ord,nheerl,ephd,eb	ORD-015169
ord,ncct,N/A	ORD-015175
ord,nheerl,wed,feb	ORD-015177
ord,ncct,N/A	ORD-015179
ord,nerl,sed	ORD-015180
ord,ncea,nceartp	ORD-015195

ord,nheerl,ephd,cib	ORD-015205
ord,nerl,sed,eib	ORD-015218
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ord,nheerl,adh	ORD-015254
ord,ncea,nceartp,emag	ORD-015279
ord,nrmrl,wswrd	ORD-015286
ord,nheerl,istd,pb	ORD-015289
ord,nheerl,aed	ORD-015297
ord,nheerl,med	ORD-015378
ord,nerl,sed,ehcab	ORD-015414
ord,nrmrl,wsd,wmb	ORD-015434
ord,nheerl,istd,sbb	ORD-015444
ord,nheerl,wed,eeb	ORD-015445
ord,nheerl,ephd,crb	ORD-015455
ord,ncea,nceartp,emag	ORD-015468
ord,nheerl,ephd,crb	ORD-015472
ord,nrmrl,lrpcd,wmb	ORD-015473
ord,nheerl,aed,wdb	ORD-015494
ord,ncea,nceacin,brab	ORD-015497
ord,nerl,sed,ehcab	ORD-015502
ord,nerl,emmd	ORD-015504
ord,ncea,nceartp,emag	ORD-015511
ord,nerl,emmd	ORD-015553
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ord,nrmrl,std,cpb	ORD-015633
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ord,nheerl,istd,cb	ORD-015685
ord,nrmrl,std,sab	ORD-015688
ord,nerl,ced	ORD-015709
ord,nheerl,tad,dtb	ORD-015710
ord,nheerl,aed,peb	ORD-015718
ord,nerl,sed	ORD-015721
ord,nheerl,med	ORD-015743
ord,nheerl,istd,cb	ORD-015757
ord,nheerl,istd	ORD-015759
ord,nrmrl,lrpcd,wmb	ORD-015772
ord,nrmrl,lrpcd,esmb	ORD-015782
ord,nerl,sed	ORD-015793
ord,nerl,sed	ORD-015817
ord,nhsrc,wipd	ORD-015834
ord,nerl,emmd,mieb	ORD-015836
ord,nrmrl,wswrd	ORD-015845

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ord,nerl,emmd,mieb	ORD-015957
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ord,nerl,emmd	ORD-015969
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ord,nheerl,med	ORD-016102
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ord,nheerl,aed,heb	ORD-016110
ord,nheerl,rpcs	ORD-016129
ord,nrmrl,std,seb	ORD-016134
ord,nheerl,wed,feb	ORD-016137
ord,nerl,emmd	ORD-016155
ord,nrmrl,wswrd,mccb	ORD-016157
ord,nrmrl,wsd,dwsb	ORD-016158
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ord,ncea,nceartp,emag	ORD-016177
ord,nheerl,med	ORD-016182
ord,nheerl,ced	ORD-016185
ord,nheerl,ephd,crb	ORD-016196
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ord,nrmrl,std,cpb	ORD-016220
ord,nrmrl,std,seb	ORD-016225
ord,nerl,ced	ORD-016226
ord,nrmrl,std,seb	ORD-016240
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ord,nheerl,tad	ORD-016277
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ord,nheerl,aed,heb	ORD-016293
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ord,nerl,emmd	ORD-016358
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ord,nheerl,istd,cb	ORD-016403

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ord,nrmrl,wswrd,tteb	ORD-016438
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ord,nheerl,med	ORD-016485
ord,ncct,N/A	ORD-016488
ord,nrmrl,wsd	ORD-016496
ord,nrmrl,wswrd,wqmb	ORD-016498
ord,ncct,N/A	ORD-016499
ord,nrmrl,wswrd,wqmb	ORD-016518
ord,nerl,emmd	ORD-016519
ord,nrmrl,wsd,dwsb	ORD-016523
ord,nheerl,ephd,crb	ORD-016532
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ord,nheerl,ged	ORD-016584
ord,ncct,N/A	ORD-016588
ord,nerl,ced	ORD-016595
ord,nhsrc,dcmd	ORD-016610
ord,nrmrl,wswrd,uwmb	ORD-016615
ord,nheerl,tad,rtb	ORD-016617
ord,nerl,sed	ORD-016620
ord,nerl,emmd,mieb	ORD-016626
ord,nerl,rpdis	ORD-016631
ord,nrmrl,std,seb	ORD-016648
ord,nrmrl,std,seb	ORD-016651
ord,nerl,rpdis	ORD-016660
ord,nrmrl,std,cpb	ORD-016690
ord,ncct,N/A	ORD-016691
ord,nheerl,wed,eeb	ORD-016701
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ord,nheerl,ged	ORD-016779
ord,nheerl,istd,pb	ORD-016796
ord,nerl,emmd	ORD-016798
ord,nheerl,med,esab	ORD-016806
ord,nheerl,med	ORD-016811
ord,nheerl,istd,sbb	ORD-016816
ord,ncct,N/A	ORD-016848
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ord,nheerl,ephd,crb	ORD-016869
ord,nerl,ced	ORD-016876

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ord,nerl,emmd	ORD-016932
ord,nheerl,wed,eeb	ORD-016948
ord,nrmrl,wswrd	ORD-016959
ord,nrmrl,wsd	ORD-016978
ord,ncea,nceacin,crab	ORD-016980
ord,nheerl,istd,gctb	ORD-017004
ord,nrmrl,lrpcd,wmb	ORD-017029
ord,nhsrc,tcad	ORD-017045
ord,nerl,sed,efab	ORD-017046
ord,ioaa,N/A	ORD-017069
ord,nrmrl,appcd	ORD-017073
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ord,nheerl,med	ORD-017107
ord,nheerl,med	ORD-017110
ord,nerl,emmd	ORD-017120
ord,nheerl,ephd,eb	ORD-017121
ord,nheerl,ephd,eb	ORD-017126
ord,nheerl,med	ORD-017129
ord,nerl,ced	ORD-017143
ord,nrmrl,lrpcd,wmb	ORD-017171
ord,nheerl,ephd,cib	ORD-017203
ord,nheerl,ged	ORD-017213
ord,nheerl,wed,eeb	ORD-017216
ord,nerl,ced	ORD-017217
ord,nerl,emmd	ORD-017222
ord,nrmrl,appcd,apb	ORD-017241
ord,nerl,ced	ORD-017242
ord,nheerl,aed,heb	ORD-017250
ord,nheerl,med	ORD-017261
ord,nheerl,aed,wdb	ORD-017268
ord,nerl,ced	ORD-017272
ord,nhsrc,dcmd	ORD-017288
ord,nerl,ced	ORD-017289
ord,nheerl,ephd,crb	ORD-017292
ord,ncct,N/A	ORD-017304
ord,nrmrl,std,sab	ORD-017314
ord,nrmrl,std,sab	ORD-017315
ord,nrmrl,wsd	ORD-017339
ord,nrmrl,lrpcd,wmb	ORD-017350
ord,nheerl,aed,peb	ORD-017357
ord,nheerl,ged	ORD-017368
ord,nerl,ced	ORD-017370
ord,nerl,ced	ORD-017372
ord,nheerl,med	ORD-017374
ord,nheerl,med	ORD-017375

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ord,nerl,sed,ehcab	ORD-017388
ord,nrmrl,std,cpb	ORD-017390
ord,nerl,emmd	ORD-017400
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ord,nrmrl,lmmd,rteb	ORD-023628

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A sustainable approach to empower the bio-based future: upgrading of biomass via process intensification
Linking physiological parameters to perturbations in the human exposome: Environmental exposures modify blood press
The Significant Surface-Water Connectivity of “Geographically Isolated Wetlands”
Comprehensive target-chemical assessment reveals extensive mixed-organic-contaminant exposure in USA streams
Acute Sensitivity of the Vernal Pool Fairy Shrimp, Branchinecta Lynchi (Anostraca; Branchinectidae), and Surrogate Specie
Ecdysone receptor agonism leading to lethal molting disruption in arthropods: Review and adverse outcome pathway de
Ecosystem services in the Great Lakes
Modification of an Existing In vitro Method to Predict Relative Bioavailable Arsenic in Soils
Reevaluating the significance of estrone as an environmental estrogen (article)
Uptake of Nickel by Synthetic Mackinawite
Sample Processing Approach for Detection of Ricin in Surface Samples [HS7.52.04 - 0671]
Light-absorbing organic carbon from prescribed and laboratory biomass burning and gasoline vehicle emissions
A supplementary tool to existing approaches for assessing ecosystem community structure
(SAR AND QSAR IN ENVIRONMENTAL RESEARCH) Application of IATA - A case study in evaluating the global and local per
Sorption of cesium onto the mineral phases and cement of concrete and desorption into simple salt solutions
Marginal abatement cost curve for NOx incorporating controls, renewable electricity, energy efficiency and fuel switchin
IMPACTS OF MATERNAL DIET AND EXERCISE ON OFFSPRING BEHAVIOR AND GROWTH
Ecosystem Services Deserve Better than “Dirty Paper”
Delineating wetland catchments and modeling hydrologic connectivity using lidar data and aerial imagery
LCIA framework and cross-cutting issues guidance within the UNEP/SETAC Life Cycle Initiative
(Journal of Chemical Information and Modeling) In Silico Prediction of Physicochemical Properties of Environmental Cher
Integrating exhaled breath diagnostics by disease-sniffing dogs with instrumental laboratory analysis
Adrenal-derived stress hormones modulate ozone-induced lung injury and inflammation
Pilot Plant Demonstration of Stable and Efficient High Rate Biological Nutrient Removal with Low Dissolved Oxygen Cond
Relative Sensitivity of Arctic Species to Physically and Chemically Dispersed Oil Determined from Three Hydrocarbon Mea
Evaluation of estrogen receptor alpha activation by glyphosate-based herbicide constituents
Particulate-phase mercury emissions from biomass burning and impact on resulting deposition: a modelling assessment
Impact of Work Task-Related Acute Occupational Smoke Exposures on Select Proinflammatory Immune Parameters in W
Fixation of carbon dioxide into dimethyl carbonate over titanium-based zeolitic thiophene-benzimidazolate framework
Developmental Neurotoxicants Disrupt Activity in Cortical Networks on Microelectrode Arrays: Results of Screening 86 C
Bayesian Monte Carlo and Maximum Likelihood Approach for Uncertainty Estimation and Risk Management: Applicatior
The value of nature: Economic, intrinsic, or both?
Dynamic evaluation of two decades of WRF-CMAQ ozone simulations over the contiguous United States
Hydroxylation of Benzene via C-H Activation Using Bimetallic CuAg@g-C3N4
A WEIGHT OF EVIDENCE FRAMEWORK FOR ECOLOGICAL ASSESSMENTS: INFERING QUALITIES
A WEIGHT OF EVIDENCE FRAMEWORK FOR ENVIRONMENTAL ASSESSMENTS: INFERING QUANTITIES
Prediction of pesticide acute toxicity using two-dimensional chemical descriptors and target species classification
Advancing the adverse outcome pathway framework - An international horizon scanning approach
Relationship Between Total and Bioaccessible Lead on Children’s Blood Lead Levels in Urban Residential Philadelp
Effects of triclosan on bacterial community composition and Vibrio populations in natural seawater microcosms
An "EAR" on environmental surveillance and monitoring: A case study on the use of exposure-activity ratios t

(Computational Toxicology) Navigating through the minefield of read-across tools: A review of in silico tools for grouping
Chronic nitrogen deposition influences the chemical dynamics of leaf litter and fine roots during decomposition
Roadside vegetation design characteristics that can improve local, near-road air quality
Agglomeration Determines Effects of Carbonaceous Nanomaterials on Soybean Nodulation, Dinitrogen Fixation Potentia
EFFECTS OF MATERNAL HIGH FAT DIET AND SEDENTARY LIFESTYLE ON SUSCEPTIBILITY OF ADULT OFFSPRING TO OZONE
Impacts of aerosol direct effects on tropospheric ozone through changes in atmospheric dynamics and photolysis rates
Prioritization of contaminants of emerging concern in wastewater treatment plant discharges using chemical: Gene inter
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A global database of nitrogen and phosphorus excretion rates of aquatic animals
A Conceptual Model to Assess Stress-Associated Health Effects of Multiple Ecosystem Services Degraded by Disaster Ever
Overcoming Global Pressures to Achieve a Healthy, Resilient and Sustainable Society
Semivolatile POA and parameterized total combustion SOA in CMAQv5.2: impacts on source strength and partitioning
Interaction between Soil Moisture and Air Temperature in the Mississippi River Basin
Framework for Optimizing Selection of Interspecies Correlation Estimation Models to Address Species Diversity and Toxic
Advanced error diagnostics of the CMAQ and Chimere modelling systems within the AQMEII3 model evaluation framewo
Influences of Coal Ash Leachates and Emergent Macrophytes on Water Quality in Wetland Microcosms
A Nitrogen Physical Input-Output Table (PIOT) Model for Illinois
Factors that influence vital rates of Seaside and Saltmarsh sparrows in coastal New Jersey, USA
Screening the ToxCast phase II libraries for alterations in network function using cortical neurons grown on multi-well mi
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Temperature and driving cycle significantly affect semi-volatile organic compound emissions from diesel trucks
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Mode of Action (MOA) Assignment Classifications for Ecotoxicology: An Evaluation of approaches
Dollars and Deadlines: Rule Reforms in Short Time Frames
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Impact of intercontinental pollution transport on North American ozone air pollution: an HTAP phase 2 multi-model stud
Population-Based Case–Control Study of the Association between Weather-Related Extreme Heat Events and Neu
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Effect of nutrient pollution on dinoflagellate cyst assemblages across estuaries of the NW Atlantic
Factors contributing to the hydrologic effectiveness of a rain garden network (Cincinnati OH USA)
On-road Emissions and Chemical Transformation of Nitrogen Oxides
Bioaccumulation and Biological Effects of Dietary Exposure to the Alternative Brominated Flame Retardant, Bis(2-ethylhe
Commentary: Should All Tests of Cognitive Function – Learning, Memory, Attention – be Eliminated From t
Cross Validation of Two Partitioning-Based Sampling Approaches in Mesocosms Containing PCB Contaminated Field Sedi
Riparian spiders as sentinels of PCB contamination across heterogeneous aquatic ecosystems

PI/PO	Cleared Date	Published Date	Completed Date
Lisa Melnyk	6/15/2016	11/1/2016	4/20/2017
JohnM Johnston	6/6/2017	9/1/2017	11/6/2017
Lesley Mills	9/30/2013	11/7/2016	11/9/2016
Nichole Brinkman	11/9/2016	6/14/2017	12/7/2017
Daniel Heggem	9/15/2014	3/20/2017	3/20/2017
Gurbakhash Bhander	9/22/2016	8/4/2017	4/23/2018
Dennis Lye	8/27/2014	11/1/2016	1/31/2017
Susan Glassmeyer	9/25/2014	3/1/2017	2/27/2017
Mitchell Kostich	5/5/2016	2/1/2017	2/6/2017
Jon Sobus	2/23/2017	11/1/2016	2/23/2017
Clyde Owens	9/28/2016	9/1/2017	9/12/2017
Johne Rogers	8/29/2014	7/1/2017	8/22/2017
Ronald Herrmann	9/19/2014	3/30/2017	6/2/2017
Michael Griffith	9/30/2014	3/1/2017	3/10/2017
Cissy Ma	9/19/2014	3/1/2017	12/6/2016
JohnM Johnston	6/13/2017	3/10/2017	6/23/2017
Jody Shoemaker	3/20/2016	10/17/2016	2/28/2017
JohnM Johnston	4/27/2017	6/24/2017	5/23/2017
Cathleen Wigand	2/13/2015	5/1/2017	4/4/2017
Souhail Al-Abed	4/9/2015	2/15/2017	12/15/2016
Jason Grear	11/18/2014	10/1/2016	3/30/2017
Gurbakhash Bhander	11/30/2016	9/1/2017	11/1/2017
Angela Batt	4/28/2016	2/1/2017	2/27/2017
Wayne Munns	12/17/2015	1/1/2017	12/19/2016
John Wambaugh	2/19/2015	7/1/2017	9/27/2017
Sigmund Degitz	1/28/2015	12/1/2016	11/18/2016
Dan Villeneuve	3/7/2016	1/1/2017	7/19/2017
Danelle Lobdell	2/11/2015	10/1/2016	2/15/2017
Paul Solomon	1/20/2017	9/1/2017	6/9/2017
Diane Nacci	4/13/2015	11/1/2016	1/5/2017
Jack Creed	2/6/2015	5/30/2017	8/4/2017
Mace Barron	2/9/2015	7/1/2017	6/20/2017
Gayle Hagler	2/23/2015	11/1/2016	11/7/2017
Jeff Yang	3/6/2015	5/15/2017	3/26/2018
Sandy Raimondo	3/11/2015	11/1/2016	1/20/2017
Susan Yee	4/24/2015	3/1/2017	12/30/2016
Ana Rappold	6/12/2015	1/18/2017	2/13/2017
Mark Strynar	2/27/2017	11/1/2016	2/27/2017
MichaelF Hughes	4/30/2015	6/8/2017	8/25/2017
Jeff Yang	4/15/2015	5/15/2017	7/6/2017
Jay Garland	4/2/2015	4/1/2017	6/9/2017
Dan Villeneuve	9/9/2015	2/28/2017	3/20/2017
Lisa Baxter	2/27/2017	2/1/2017	2/27/2017
John Washington	4/17/2015	10/1/2016	7/22/2016
Sigmund Degitz	11/13/2015	12/1/2016	11/18/2016
Carol Lenox	6/15/2015	11/15/2016	3/14/2017

Robyn Conmy	11/10/2015	10/31/2016	5/4/2017
Randy Bruins	5/22/2015	1/1/2017	2/27/2017
Kirk Scheckel	8/17/2015	11/1/2016	8/11/2016
Ila Cote	6/9/2015	11/2/2016	1/23/2017
Marina Evans	6/2/2015	6/6/2017	6/20/2017
Jeff Szabo	8/31/2015	2/1/2017	6/28/2017
Autumn Oczkowski	7/30/2015	11/1/2016	10/3/2016
Cathleen Wigand	9/10/2015	5/1/2017	5/23/2017
Bill Linak	8/7/2015	1/2/2017	5/5/2017
Jason Grear	6/29/2015	5/5/2017	4/5/2017
James Crooks	7/7/2015	11/30/2016	12/27/2016
Gerald Ankley	9/10/2015	11/1/2016	10/26/2016
Matthew Etterson	7/2/2015	1/31/2017	2/23/2017
Jake Beaulieu	9/14/2015	11/1/2016	8/29/2017
Tim Wade	7/16/2015	10/14/2016	11/21/2016
Richard Fulford	7/27/2015	11/1/2016	10/6/2016
Diane Nacci	12/17/2015	7/24/2017	8/21/2017
Aimen Farraj	9/22/2015	4/1/2017	9/19/2017
Nathan Schumaker	8/11/2015	10/3/2016	10/27/2016
Imran Shah	9/18/2015	3/1/2017	9/29/2017
Jonathan Pressman	9/17/2015	1/1/2017	3/20/2018
Heather Golden	12/4/2015	10/3/2016	1/10/2017
Rachelle Duvall	8/25/2016	10/13/2016	12/6/2016
Mehdi Hazari	10/10/2015	4/1/2017	8/29/2017
Rebecca Dodder	9/29/2015	10/19/2016	12/16/2016
Drew Ekman	10/6/2015	10/3/2016	2/28/2017
Sarah Taft	7/20/2017	5/1/2017	7/20/2017
Gerardo Ruiz-Mercado	9/2/2015	1/10/2017	5/5/2017
Jane Bare	9/2/2015	11/1/2016	2/2/2017
Gene Rice	9/29/2015	12/8/2016	6/19/2017
Mark Cantwell	10/13/2015	10/25/2016	10/27/2016
Lisa Melnyk	7/12/2016	10/1/2016	8/26/2016
Dan Villeneuve	9/9/2015	4/1/2017	4/18/2017
Kathie Dionisio	11/29/2016	12/1/2016	11/29/2016
David Meyer	9/3/2015	11/1/2016	12/5/2017
Tamara Tal	10/16/2015	6/1/2017	8/25/2017
Ahjond Garmestani	9/14/2015	12/1/2016	10/24/2016
Tim Wade	9/15/2015	4/21/2017	
Janice Dye	9/18/2015	11/1/2016	8/11/2016
Tom Luben	11/4/2015	10/25/2016	8/11/2017
Christian Hogrefe	6/20/2017	9/1/2017	6/23/2017
Darren Lytle	3/18/2016	10/15/2016	10/31/2016
John Iiames	1/17/2017	4/3/2017	4/3/2017
Tom Purucker	10/6/2015	10/25/2016	2/28/2017
John Kenneke	10/14/2015	4/1/2017	6/9/2017
Kristin Isaacs	2/8/2017	12/1/2016	5/31/2017
Thomas Knudsen	8/10/2016	6/1/2017	9/29/2017

Florence Fulk	12/1/2015	2/1/2017	2/28/2017
Robert Janke	9/12/2016	12/8/2016	8/23/2017
Sue Kimbrough	11/29/2016	9/7/2017	11/2/2017
Florence Fulk	12/16/2016	11/24/2016	2/27/2017
James Goodrich	3/14/2016	7/21/2017	7/31/2017
Souhail Al-Abed	9/30/2016	8/31/2017	6/13/2017
Stephen Vesper	10/30/2015	4/13/2017	4/24/2017
Tim Wade	10/15/2015	2/1/2017	5/10/2017
Thomas OConnor	5/17/2016	5/16/2017	4/13/2017
Kevin Summers	11/12/2015	10/1/2016	6/13/2016
David Katz	5/31/2016	7/1/2017	8/8/2017
Jennifer Richmond-Bryant	11/16/2015	1/5/2017	5/25/2017
Mace Barron	10/27/2015	5/1/2017	4/20/2017
William Benson	10/22/2015	10/1/2016	9/28/2016
Phil Kaufmann	11/25/2015	10/1/2016	11/15/2016
Jane Simmons	11/24/2015	2/1/2017	8/28/2017
Ahjond Garmestani	10/29/2015	12/1/2016	2/22/2017
Susan Yee	10/30/2015	3/1/2017	3/3/2017
Ahjond Garmestani	11/5/2015	12/1/2016	1/6/2017
Tim Shafer	11/10/2015	5/3/2017	2/12/2018
Maura Donohue	10/4/2016	12/1/2016	6/9/2017
David Lehmann	12/17/2015	3/1/2017	2/7/2017
Russell Erickson	6/29/2016	12/8/2016	12/13/2016
John Nichols	2/9/2016	12/1/2016	11/15/2016
Eben Thoma	12/11/2015	10/4/2016	11/22/2016
Kent Thomas	4/26/2016	3/1/2017	6/9/2017
Dale Hoff	3/7/2016	10/4/2016	10/26/2016
Kent Thomas	4/25/2016	4/1/2017	9/21/2017
Stephen Hale	1/26/2016	11/29/2016	11/30/2016
Reneej Brooks	1/9/2016	4/1/2017	8/28/2017
Marc Weber	12/14/2015	7/1/2017	6/5/2017
Danelle Lobdell	1/11/2016	8/1/2017	8/28/2017
Erin Hines	6/23/2016	6/27/2017	7/5/2017
Matthew Magnuson	1/28/2016	1/1/2017	12/14/2017
Steven Perry	8/24/2016	10/3/2016	8/26/2016
Mace Barron	1/11/2016	10/4/2016	12/9/2016
Robert Burgess	3/1/2016	11/1/2016	11/1/2016
Rohit Mathur	4/26/2016	3/1/2017	5/31/2017
Bill Linak	12/24/2015	2/1/2017	2/28/2017
Jon Sobus	4/20/2016	11/14/2016	11/14/2016
Jingrang Lu	7/24/2017	7/5/2017	7/25/2017
Tim Wade	1/30/2016	10/1/2016	11/21/2016
Thomas Knudsen	1/25/2016	10/19/2016	10/27/2016
Phil Kaufmann	1/7/2016	7/1/2017	8/10/2017
Thomas Knudsen	1/25/2016	10/21/2016	10/27/2016
EricS Hall	3/15/2016	11/1/2016	6/9/2017
Alan Talhelm	2/15/2016	7/7/2017	12/14/2017

Colette Miller	5/24/2016	2/1/2017	8/28/2017
Jim Lazorchak	1/5/2016	11/1/2016	2/15/2017
Mehdi Hazari	2/16/2016	6/1/2017	8/30/2017
Ronald Hines	1/4/2016	5/1/2017	2/12/2018
Jason Sacks	2/15/2016	12/9/2016	6/21/2017
Jeff Yang	3/2/2016	12/14/2016	7/6/2017
MichaelF Hughes	2/17/2016	11/15/2016	6/20/2017
Wayne Munns	2/19/2016	1/1/2017	1/9/2017
Greg Peterson	1/5/2017	2/1/2017	3/10/2017
James Wickham	9/22/2016	11/1/2016	12/6/2016
Christopher Nietch	3/15/2016	5/8/2017	1/10/2018
Tim Shafer	1/25/2016	3/1/2017	8/25/2017
Christian Andersen	2/8/2016	1/31/2017	2/6/2017
Andy Ghio	2/17/2016	12/1/2016	12/22/2016
Tom Luben	2/15/2016	2/13/2017	7/17/2017
James Samet	2/16/2016	12/1/2016	12/22/2016
Kirk Scheckel	3/9/2016	12/29/2016	2/23/2017
Mohamed Abdelrhman	4/4/2016	7/1/2017	6/14/2017
Michael McManus	2/24/2016	9/5/2017	9/6/2017
John Darling	2/16/2016	12/1/2016	2/23/2017
Robert Willis	10/13/2016	10/17/2016	10/17/2016
Erin Hines	4/28/2016	1/19/2017	6/30/2017
Mark Strynar	10/13/2016	10/13/2016	10/13/2016
Paul Solomon	5/23/2017	9/11/2017	9/11/2017
Danelle Lobdell	3/13/2016	3/1/2017	5/10/2017
Gayle Hagler	3/18/2016	11/1/2016	11/28/2016
Peg Pelletier	3/3/2016	1/24/2017	2/13/2017
Rajender Varma	2/24/2016	12/1/2016	12/19/2016
Urmila Kodavanti	2/16/2016	3/1/2017	8/28/2017
Urmila Kodavanti	5/24/2016	12/1/2016	12/22/2016
Jeff Yang	3/22/2016	1/16/2017	3/15/2017
Brian Chorley	2/19/2016	12/15/2016	12/30/2016
Wesley Ingwersen	2/23/2016	4/1/2017	3/13/2017
Timothy Barzyk	9/27/2016	12/28/2016	6/15/2017
Christopher Lau	3/16/2016	3/1/2017	1/17/2017
Mark Cantwell	2/15/2016	4/1/2017	9/5/2017
Erik Pilgrim	5/13/2016	4/1/2017	6/23/2017
Kevin Flynn	8/10/2016	11/4/2016	11/4/2016
Yue Ge	2/22/2016	12/15/2016	1/6/2017
Rory Conolly	2/22/2016	11/1/2016	8/25/2017
Kirk Scheckel	7/8/2016	11/1/2016	7/20/2016
Robyn Conmy	3/15/2016	1/30/2017	6/8/2017
Jay Garland	3/7/2016	11/1/2016	2/28/2017
Kiran Alapaty	3/27/2017	4/3/2017	4/19/2017
Matthew Magnuson	3/24/2016	12/1/2016	12/14/2017
Jingrang Lu	6/22/2017	7/15/2017	8/14/2017
Darren Lytle	5/10/2016	10/1/2016	6/16/2016

Peter Beedlow	2/23/2016	8/15/2017	5/24/2017
Wayne Cascio	2/27/2016	12/1/2016	9/22/2016
Kristen Rappazzo	3/10/2016	2/1/2017	2/15/2017
Michael Wright	3/10/2016	2/1/2017	2/2/2017
Nichole Brinkman	3/7/2016	11/15/2016	6/21/2017
Jingrang Lu	10/26/2016	3/14/2017	3/14/2017
Barbara Abbott	3/21/2016	5/1/2017	6/5/2017
Paul Solomon	2/21/2017	3/14/2017	3/14/2017
Dermont Bouchard	8/19/2016	11/15/2016	11/15/2016
John Nichols	4/7/2016	2/28/2017	3/27/2017
Cathleen Wigand	3/21/2016	5/1/2017	5/8/2017
Cathleen Wigand	6/18/2016	10/27/2016	11/9/2016
Lisa Baxter	4/12/2016	1/4/2017	1/10/2017
Ahjond Garmestani	3/22/2016	3/1/2017	4/3/2017
Matthew Weber	3/18/2016	10/1/2016	8/9/2016
D Werkema	12/12/2016	12/13/2016	12/13/2016
Mark Rodgers	5/23/2016	11/1/2016	12/15/2016
Mark Rodgers	5/23/2016	12/6/2016	1/10/2018
Rick Mckinney	5/31/2016	1/1/2017	11/14/2016
Tom Luben	5/16/2016	7/11/2017	7/24/2017
Chelsea Hatzenbuhler	4/12/2016	4/13/2017	5/5/2017
Matthew Etterson	6/10/2016	5/3/2017	7/19/2017
David Diaz-Sanchez	3/23/2016	3/30/2017	4/14/2017
David Diaz-Sanchez	4/9/2016	5/1/2017	8/28/2017
Matthew Hopton	4/6/2016	6/1/2017	7/7/2017
Rajender Varma	10/27/2016	1/7/2017	1/11/2017
Ahjond Garmestani	4/7/2016	6/30/2017	6/26/2017
George Pouliot	3/8/2017	5/1/2017	5/5/2017
Bayou Demeke	4/27/2016	11/17/2016	2/8/2017
Megan Mehaffey	11/17/2016	2/1/2017	1/31/2017
Theodore Angradi	4/27/2016	2/1/2017	1/30/2017
Marcus Beck	5/17/2016	2/1/2017	2/10/2017
Earl Gray	5/13/2016	10/1/2016	2/9/2017
Joachim Pleil	6/1/2016	1/12/2017	1/12/2017
Ellen Cooter	4/6/2016	5/1/2017	6/6/2017
Dan Villeneuve	4/7/2016	2/1/2017	7/7/2017
Cathleen Wigand	4/19/2016	5/1/2017	3/31/2017
Robert Burgess	4/4/2016	8/26/2017	9/8/2017
Rajender Varma	4/6/2016	12/19/2016	2/1/2017
James Samet	5/5/2016	12/1/2016	9/30/2017
Kay Ho	8/23/2016	2/7/2017	2/10/2017
Matthew Magnuson	4/28/2016	11/1/2016	10/25/2017
Blake Schaeffer	12/13/2016	12/13/2016	12/13/2016
Jeff Yang	6/8/2016	11/1/2016	
Thomas Sorg	6/8/2016	5/10/2017	5/3/2017
David Diaz-Sanchez	4/19/2016	10/1/2016	12/22/2016
Charles Wood	5/12/2016	12/1/2016	12/28/2016

John Offenberg	2/7/2017	2/7/2017	2/7/2017
Andrew Lindstrom	8/26/2016	1/12/2017	1/12/2017
Thomas Sorg	6/7/2016	5/10/2017	5/3/2017
Maliha Nash	12/5/2016	3/21/2017	5/2/2017
Jim Jetter	6/14/2016	1/14/2017	5/23/2017
Scott Leibowitz	5/3/2016	12/31/2016	2/8/2017
Tom Hollenhorst	11/7/2016	10/1/2016	11/8/2016
John Wambaugh	2/28/2017	6/16/2017	9/27/2017
Jorge Santodomingo	8/17/2016	5/17/2017	1/17/2018
Jorge Santodomingo	9/28/2016	10/1/2016	1/4/2017
John Wambaugh	5/4/2016	2/1/2017	3/21/2017
Jorge Santodomingo	9/30/2016	5/10/2017	5/2/2017
Paul Solomon	5/23/2016	12/28/2016	1/3/2017
Hodon Ryu	7/8/2016	2/1/2017	7/13/2017
Haiyan Tong	5/9/2016	12/1/2016	11/21/2016
John Lehrter	5/2/2016	9/15/2017	4/2/2018
David Thomas	5/24/2016	11/1/2016	12/30/2016
Mary Gilbert	6/2/2016	11/2/2016	11/14/2016
Danelle Lobdell	6/8/2016	10/24/2016	11/21/2016
Mace Barron	5/2/2016	5/1/2017	4/12/2017
Russell Thomas	5/20/2016	5/1/2017	8/28/2017
Matthew Woody	5/31/2016	12/1/2016	2/27/2017
Joe Wood	6/13/2016	11/14/2016	11/16/2016
Jake Beaulieu	8/5/2016	4/11/2017	8/29/2017
Earl Gray	5/18/2016	2/27/2017	11/17/2017
Nicolle Tulve	10/14/2016	10/14/2016	6/15/2017
Shay Fout	2/15/2017	5/22/2017	5/22/2017
John Kenneke	7/11/2016	1/2/2017	5/8/2017
Ahjond Garmestani	6/9/2016	3/1/2017	6/23/2017
Ahjond Garmestani	5/11/2016	3/17/2017	4/3/2017
Jennifer Cashdollar	7/11/2016	11/1/2016	11/6/2017
Rajender Varma	5/17/2016	9/21/2017	8/29/2017
Matt Martin	6/20/2016	10/26/2016	11/9/2016
Reneej Brooks	5/12/2016	2/1/2017	1/11/2017
Brandall Ingle	5/24/2016	11/28/2016	2/27/2017
David Diaz-Sanchez	6/1/2016	11/1/2016	8/15/2016
Jianyong Wu	5/24/2016	11/15/2016	8/12/2016
Jim Hagy	6/29/2016	2/1/2017	11/23/2016
Elaina Kenyon	7/19/2016	10/27/2016	
Matthew Landis	5/15/2017	5/18/2017	5/18/2017
Dan Villeneuve	6/9/2016	10/4/2016	10/26/2016
Dan Villeneuve	6/9/2016	11/7/2016	5/5/2017
Tim Shafer	6/15/2016	10/10/2016	12/28/2016
Keith Houck	2/28/2017	6/15/2017	9/29/2017
Janet Burke	9/26/2016	11/1/2016	1/10/2017
Michael Madden	5/27/2016	12/1/2016	9/22/2016
Nicholas Heath	6/10/2016	1/24/2017	5/1/2017

Rochelle Araujo	4/11/2017	7/1/2017	6/6/2017
Rick Wilkin	11/10/2016	12/28/2016	2/8/2017
Matthew Landis	2/7/2017	2/14/2017	2/14/2017
Reneej Brooks	6/8/2016	9/1/2017	8/24/2017
Orin Shanks	7/19/2016	11/15/2016	10/19/2016
Jeff Yang	8/25/2016	3/27/2017	4/11/2018
Glenn Rice	1/27/2017	8/1/2017	8/4/2017
David DeMarini	10/13/2016	3/28/2017	6/29/2017
Souhail Al-Abed	8/18/2016	4/30/2017	2/13/2017
Erin Silvestri	6/30/2016	11/1/2016	7/24/2017
Angela Batt	10/10/2016	3/7/2017	6/15/2017
Kathleen Deener	6/9/2016	3/1/2017	3/2/2017
Brian Gullett	1/23/2017	4/15/2017	5/5/2017
Mary Gilbert	8/25/2016	3/1/2017	11/17/2017
Gerald Ankley	8/16/2016	3/1/2017	3/14/2017
Gerald Ankley	8/16/2016	3/1/2017	3/14/2017
D Werkema	2/7/2017	2/1/2017	2/16/2017
Tim Wade	7/27/2016	9/1/2017	8/28/2017
Danelle Lobdell	6/16/2016	3/1/2017	5/10/2017
Michael Hornung	8/8/2016	6/14/2017	6/16/2017
Christian Hogrefe	6/21/2016	12/20/2016	12/20/2016
Souhail Al-Abed	9/30/2016	1/1/2017	12/28/2016
Ian Gilmour	6/22/2016	11/1/2016	11/22/2016
Mace Barron	6/22/2016	12/20/2016	8/23/2017
Paul Mayer	7/14/2016	8/1/2017	8/29/2017
Limei Ran	8/8/2016	2/16/2017	2/23/2017
Joachim Pleil	10/26/2016	10/26/2016	10/26/2016
Johnt Walker	7/27/2016	10/18/2016	4/27/2017
Christian Hogrefe	9/20/2016	3/14/2017	3/14/2017
Walter Berry	7/6/2016	1/1/2017	1/26/2017
Gerald Ankley	7/22/2016	11/1/2016	11/28/2016
Mohamed Abdelrhman	7/15/2016	11/24/2016	1/4/2017
Matthew Woody	8/9/2016	3/30/2017	5/8/2017
Anne Mikelonis	9/21/2016	11/10/2016	
Kathie Dionisio	7/1/2016	7/28/2017	8/25/2017
Andy Ghio	8/1/2016	10/1/2016	9/29/2016
Thomas Knudsen	7/7/2016	10/25/2016	10/27/2016
Tarsha Eason	7/25/2016	11/9/2016	4/5/2017
Tarsha Eason	7/18/2016	1/1/2017	4/5/2017
Orin Shanks	8/15/2016	10/13/2016	2/5/2018
Kirk Scheckel	10/14/2016	1/31/2017	12/14/2016
Mark Cantwell	8/23/2016	7/1/2017	7/28/2017
Mace Barron	7/18/2016	11/1/2016	10/6/2016
David Heist	3/2/2017	4/3/2017	5/25/2017
Steven Perry	8/9/2016	2/1/2017	2/23/2017
Russell Erickson	11/28/2016	6/1/2017	5/31/2017
Teresa Norberg-King	8/24/2016	11/1/2016	11/4/2016

Phil Kaufmann	8/12/2016	1/1/2017	9/19/2016
James Wickham	11/29/2016	3/15/2017	2/16/2017
Rajender Varma	8/12/2016	11/7/2016	12/14/2016
JohnH Zimmerman	5/3/2017	3/3/2017	7/26/2017
Kevin Crofton	8/3/2016	10/29/2016	11/7/2016
Marc Mills	10/11/2016	4/21/2017	6/26/2017
Brian Gullett	8/15/2016	6/15/2017	9/14/2017
Souhail Al-Abed	10/14/2016	9/1/2017	5/31/2017
Brian Gullett	8/15/2016	4/6/2017	3/14/2017
Joachim Pleil	9/1/2016	11/22/2016	11/28/2016
Robert Devlin	7/28/2016	3/29/2017	4/14/2017
Golam Sarwar	2/22/2017	2/7/2017	6/6/2017
Don Betowski	4/27/2017	8/1/2017	6/6/2017
Alan Talhelm	10/7/2016	2/16/2017	5/3/2017
Richard Zepp	2/7/2017	3/1/2017	2/16/2017
Todd Luxton	12/12/2016	3/31/2017	2/8/2017
Tom Purucker	8/2/2016	1/1/2017	12/2/2016
MichaelF Hughes	10/7/2016	10/28/2016	8/23/2017
Vincente Gallardo	9/6/2016	6/23/2017	8/23/2017
Christian Hogrefe	8/19/2016	2/28/2017	6/6/2017
Rajender Varma	8/17/2016	11/7/2016	12/19/2016
Earl Gray	8/9/2016	3/1/2017	11/17/2017
Havala Pye	8/9/2016	1/6/2017	2/10/2017
Souhail Al-Abed	9/26/2016	7/1/2017	5/10/2017
Jay Garland	8/29/2016	4/1/2017	6/6/2017
Gerry Laniak	8/23/2016	1/2/2017	2/23/2017
John Lehrter	8/22/2016	1/27/2017	3/6/2017
Andrew Henderson	9/23/2016	1/1/2017	2/8/2017
Shaibal Mukerjee	5/25/2017	8/1/2017	5/31/2017
Matthew Weber	8/19/2016	9/1/2017	9/8/2017
Ginger Moser	8/22/2016	12/15/2016	11/2/2016
Jake Beaulieu	2/2/2017	6/13/2017	3/14/2018
Ken Fritz	9/11/2016	2/1/2017	2/24/2017
Scott Leibowitz	8/24/2016	7/1/2017	8/29/2017
Carol Lenox	11/23/2016	9/21/2017	11/1/2017
Christopher Gordon	8/22/2016	3/1/2017	11/17/2017
Souhail Al-Abed	10/14/2016	2/15/2017	2/23/2017
John McKernan	11/30/2016	12/8/2016	2/15/2017
Jay Garland	9/7/2016	4/3/2017	5/9/2017
Christopher Nietch	9/12/2016	6/12/2017	1/22/2018
David Herr	8/30/2016	3/1/2017	11/17/2017
Dixon Landers	10/19/2016	5/9/2017	5/10/2017
Dixon Landers	9/29/2016	5/2/2017	5/10/2017
John Darling	8/28/2017	5/16/2017	9/29/2017
Marsha Morgan	11/3/2016	11/23/2016	2/23/2017
Hosein Foroutan	9/20/2016	3/3/2017	6/15/2017
Tom Luben	2/2/2017	8/8/2017	8/9/2017

Heather Golden	9/11/2016	8/1/2017	8/1/2017
Kirk Scheckel	10/5/2016	3/1/2017	2/23/2017
Mace Barron	8/26/2016	1/6/2017	8/23/2017
Autumn Oczkowski	9/6/2016	12/9/2016	12/12/2016
Regan Murray	10/16/2016	7/7/2017	8/16/2017
Steven Dutton	12/30/2016	5/17/2017	6/8/2017
Brad Barnhart	9/13/2016	8/16/2017	9/6/2017
Ahjond Garmestani	8/31/2016	9/1/2017	12/19/2017
Shaun McCullough	8/25/2016	2/10/2017	2/10/2017
Michael Lewandowski	7/19/2017	9/5/2017	9/7/2017
Andy Ghio	9/6/2016	6/15/2017	6/28/2017
Andy Ghio	9/6/2016	12/1/2016	2/10/2017
Sandy Raimondo	8/25/2016	3/1/2017	2/8/2018
Gerald Ankley	9/22/2016	2/1/2017	3/14/2017
Ana Rappold	9/19/2016	6/20/2017	8/28/2017
Alan Talhelm	10/7/2016	1/10/2017	12/14/2017
Jonathan Krug	5/15/2017	5/18/2017	5/18/2017
Reneej Brooks	9/7/2016	5/15/2017	5/9/2017
Todd Martin	9/13/2016	5/1/2017	12/18/2017
John Davis	5/16/2017	5/16/2017	5/16/2017
Joel Hoffman	11/28/2016	7/1/2017	7/7/2017
Caroline Stevens	5/16/2017	5/2/2017	6/6/2017
Chunming Su	9/21/2016	11/17/2016	2/14/2017
Alfred Dufour	7/31/2017	5/26/2017	4/16/2018
Vincente Gallardo	11/8/2016	2/23/2017	5/31/2017
Susan Glassmeyer	9/13/2016	2/1/2017	6/23/2017
Wyat Appel	9/23/2016	4/21/2017	5/8/2017
Raymond Smith	9/7/2016	3/20/2017	5/5/2017
Christopher Gordon	9/7/2016	1/1/2017	11/17/2017
Richard Baldauf	10/18/2016	5/4/2017	4/24/2018
Diane Nacci	10/25/2016	12/9/2016	12/12/2016
Richard Judson	2/21/2017	11/25/2016	9/27/2017
Katherine Phillips	9/19/2016	2/21/2017	2/24/2017
Woodrow Setzer	12/19/2016	8/24/2017	9/27/2017
Richard Judson	9/12/2016	4/17/2017	9/7/2017
Paul Ringold	9/29/2016	10/1/2016	10/6/2016
Swinburne Augustine	4/1/2017	5/1/2017	4/23/2018
Antony Williams	12/19/2016	12/16/2016	12/21/2016
Susan Laws	9/29/2016	4/1/2017	12/30/2016
Thomas Knudsen	2/28/2017	4/17/2017	9/7/2017
Heriberto Cabezas	9/26/2016	11/1/2016	5/5/2017
Stephen Vesper	5/24/2017	5/25/2017	5/25/2017
Alan Hecht	9/28/2016	12/22/2016	1/4/2017
Carlie LaLone	1/5/2017	4/1/2017	7/7/2017
Allen Brookes	9/22/2016	8/1/2017	5/10/2017
Kevin Summers	10/26/2016	6/1/2017	8/23/2017
Val Garcia	3/1/2017	5/15/2017	3/1/2017

William Boyes	10/19/2016	6/29/2017	11/17/2017
Christian Andersen	9/22/2016	4/1/2017	3/17/2017
Gerald Ankley	10/13/2016	6/1/2017	7/7/2017
Kirk Scheckel	12/13/2016	2/6/2017	4/13/2017
Kirk Scheckel	12/12/2016	2/23/2017	3/9/2018
Joseph Flotemersch	10/10/2016	7/12/2017	7/26/2017
Scott Wesselkamper	9/16/2016	5/1/2017	7/28/2017
Deborah Luecken	9/27/2016	2/13/2017	6/6/2017
Randy Bruins	10/13/2016	4/1/2017	6/9/2017
Maryann Cairns	10/10/2016	3/1/2017	6/9/2017
Mace Barron	9/22/2016	7/1/2017	2/8/2018
Chandra Giri	11/8/2016	11/8/2016	11/8/2016
Richard Judson	2/28/2017	6/1/2017	9/25/2017
Kathie Dionisio	9/26/2016	6/1/2017	6/9/2017
Tonya Nichols	11/2/2016	8/24/2017	9/21/2017
Mark Strynar	1/25/2017	2/2/2017	2/16/2017
Tim Watkins	9/26/2016	11/1/2016	6/15/2017
Ron Williams	6/12/2017	4/1/2017	6/12/2017
Jeff Yang	1/24/2017	1/4/2017	3/15/2017
Regan Murray	11/8/2016	4/5/2017	5/31/2017
Andrew Lindstrom	10/7/2016	12/13/2016	2/6/2017
Mark Strynar	10/12/2016	6/12/2017	6/12/2017
John Glaser	12/13/2016	1/1/2017	5/10/2017
Richard Pruell	11/22/2016	5/15/2017	5/9/2017
Tammy Stoker	11/1/2016	6/1/2017	9/11/2017
Walt Nelson	10/3/2016	8/1/2017	8/29/2017
Walt Nelson	10/3/2016	3/1/2017	2/9/2017
Kirk Scheckel	12/13/2016	12/16/2016	4/19/2017
Reneej Brooks	10/11/2016	4/1/2017	3/6/2017
Daniel Vallero	10/28/2016	7/31/2017	8/1/2017
Dan Campbell	10/26/2016	2/1/2017	1/25/2017
John Nichols	1/17/2017	5/22/2017	
D Werkema	1/31/2017	8/16/2017	8/16/2017
Shaun McCullough	10/11/2016	5/2/2017	5/8/2017
Terry Keating	10/20/2016	1/31/2017	2/8/2018
Blake Schaeffer	3/27/2017	9/1/2017	6/6/2017
Rajender Varma	10/21/2016	9/20/2017	8/28/2017
Chris Corton	2/14/2017	5/27/2017	10/4/2017
Chris Corton	3/21/2017	6/7/2017	9/28/2017
Jim Jetter	11/17/2016	6/12/2017	9/14/2017
Rajender Varma	10/20/2016	7/1/2017	6/15/2017
Endalkachew Sahle-Demessie	12/5/2016	12/1/2016	2/8/2017
Joachim Pleil	11/28/2016	11/28/2016	11/28/2016
Joachim Pleil	12/15/2016	1/9/2017	1/12/2017
Charles Wood	12/12/2016	7/20/2017	12/7/2017
Chris Corton	2/3/2017	9/28/2017	9/28/2017
Ahjond Garmestani	10/24/2016	3/17/2017	4/19/2017

Markg Johnson	10/31/2016	5/20/2017	8/29/2017
Wesley Ingwersen	12/5/2016	7/1/2017	11/21/2017
Jim Lazorchak	12/15/2016	5/1/2017	6/9/2017
John Nichols	11/18/2016	10/24/2016	3/15/2017
Jana Compton	11/14/2016	4/13/2017	5/8/2017
Jana Compton	11/14/2016	4/13/2017	5/8/2017
David Diaz-Sanchez	12/2/2016	12/1/2016	12/22/2016
Brian McMinn	3/8/2017	7/1/2017	6/21/2017
Chandra Giri	11/8/2016	11/28/2016	11/28/2016
Earl Gray	11/1/2016	10/20/2016	11/27/2017
Dan Campbell	12/2/2016	9/10/2017	6/14/2017
Mary Moffett	11/7/2016	2/2/2017	5/5/2017
Jana Compton	11/14/2016	4/1/2017	5/8/2017
EricS Hall	11/8/2016	3/1/2017	1/3/2018
DavidM Martin	3/2/2017	9/24/2017	12/14/2017
Erin Urquhart	5/25/2017	7/14/2017	9/7/2017
Stacy Pfaller	11/12/2016	2/23/2017	5/8/2017
Jon Sobus	2/8/2017	9/1/2017	9/7/2017
Havala Pye	5/2/2017	5/2/2017	6/6/2017
Walt Nelson	11/21/2016	7/1/2017	8/29/2017
Russell Erickson	11/18/2016	4/1/2017	5/5/2017
Dan Campbell	12/12/2016	8/1/2017	5/25/2017
Gerald Ankley	11/18/2016	8/1/2017	10/30/2017
Nathan Schumaker	12/1/2016	9/1/2017	9/13/2017
Mark Strynar	8/17/2017	6/1/2017	8/18/2017
Prasada Kodavanti	11/29/2016	8/15/2017	9/11/2017
Christian Hogrefe	12/20/2016	7/1/2017	6/6/2017
Kathleen Fahey	3/13/2017	4/13/2017	4/19/2017
Vickie Wilson	11/23/2016	5/2/2017	11/17/2017
Urmila Kodavanti	2/10/2017	5/24/2017	7/31/2017
Lawrence Martin	12/2/2016	4/7/2017	4/24/2017
Mark Strynar	12/2/2016	3/14/2017	6/9/2017
Leland Vane	11/30/2016	3/8/2017	11/7/2017
Robert Burgess	12/2/2016	1/15/2017	12/19/2016
Hodon Ryu	1/24/2017	12/20/2016	1/11/2018
Jeffrey Ross	12/12/2016	5/1/2017	6/29/2017
Wesley Ingwersen	1/5/2017	8/1/2017	5/16/2017
Kirk Scheckel	1/5/2017	5/8/2017	3/12/2018
Thomas Knudsen	7/5/2017	6/1/2017	9/29/2017
Peter Egeghy	12/14/2016	2/10/2017	2/16/2017
Daniel Vallero	4/16/2018	12/1/2016	4/20/2018
Matthew Landis	2/6/2017	2/10/2017	2/15/2017
Worth Calfee	2/8/2017	1/12/2017	2/9/2017
JohnM Johnston	12/15/2016	5/10/2017	6/9/2017
Brian Chorley	12/19/2016	9/10/2017	
Eben Thoma	1/25/2017	4/19/2017	5/17/2017
Valerie Zartarian	5/22/2017	9/30/2017	11/6/2017

Amanda Nahlik	12/19/2016	12/13/2016	12/21/2016
Rory Conolly	3/24/2017	4/18/2017	4/19/2017
Maureen Gwinn	1/3/2017	7/1/2017	8/9/2017
Jay Christensen	11/14/2017	3/1/2017	12/15/2017
JohnM Johnston	2/8/2017	6/15/2017	6/15/2017
Laura Erban	1/24/2017	6/1/2017	6/22/2017
Rajender Varma	1/5/2017	4/7/2017	4/12/2017
Joachim Pleil	7/26/2017	9/1/2017	9/7/2017
Charles Lane	1/30/2017	8/1/2017	11/6/2017
Dan Villeneuve	1/4/2017	5/2/2017	10/27/2017
Sandy Raimondo	1/18/2017	3/1/2017	4/2/2018
Dan Villeneuve	1/4/2017	4/1/2017	6/12/2017
Theodore Angradi	1/4/2017	6/1/2017	8/22/2017
Kirk Scheckel	3/1/2017	8/31/2017	5/11/2017
Gerald Ankley	1/31/2017	4/1/2017	4/18/2017
David Jewett	1/31/2017	5/2/2017	5/30/2017
Sanjiv Shah	4/17/2017	8/30/2017	9/28/2017
Amara Holder	2/23/2017	8/4/2017	
Matthew Hopton	2/3/2017	7/10/2017	8/2/2017
Grace Patlewicz	2/28/2017	4/20/2017	9/27/2017
Matthew Magnuson	3/2/2017	11/1/2016	10/16/2017
Dan Loughlin	3/13/2017	6/30/2017	2/22/2018
Christopher Gordon	3/1/2017	9/1/2017	11/17/2017
Wayne Munns	2/7/2017	3/28/2017	3/30/2017
Charles Lane	2/23/2017	7/14/2017	7/19/2017
Jane Bare	6/12/2017	9/10/2017	4/10/2018
Richard Judson	7/28/2017	1/9/2017	9/27/2017
Joachim Pleil	4/18/2017	9/7/2017	9/7/2017
Urmila Kodavanti	2/21/2017	8/15/2017	6/28/2017
Jorge Santodomingo	3/7/2017	9/15/2017	1/10/2018
Mace Barron	2/10/2017	9/15/2017	2/8/2018
Chris Corton	4/6/2017	7/12/2017	9/28/2017
Matthew Landis	2/17/2017	2/21/2017	2/21/2017
David Diaz-Sanchez	3/6/2017	7/1/2017	8/28/2017
Rajender Varma	3/17/2017	4/17/2017	4/13/2017
Tim Shafer	3/20/2017	8/16/2017	
Mohamed Hantush	2/22/2017	1/1/2017	3/1/2017
Anne Rea	2/27/2017	9/1/2017	12/13/2017
Christian Hogrefe	3/2/2017	9/1/2017	6/8/2017
Rajender Varma	3/17/2017	3/21/2017	5/9/2017
Glenn Suter	3/28/2017	7/21/2017	11/8/2017
Glenn Suter	3/28/2017	7/21/2017	11/8/2017
Todd Martin	3/17/2017	7/13/2017	12/19/2017
Carlie LaLone	3/29/2017	6/1/2017	5/30/2017
Karen Bradham	9/12/2017	9/5/2017	9/19/2017
Matt Henderson	4/7/2017	5/24/2017	6/6/2017
Dan Villeneuve	3/29/2017	8/1/2017	8/1/2017

Grace Patlewicz	3/30/2017	5/29/2017	9/27/2017
Alan Talhelm	3/24/2017	4/17/2017	5/3/2017
Richard Baldauf	4/6/2017	5/9/2017	4/4/2018
Dermont Bouchard	12/20/2017	6/27/2017	12/20/2017
Christopher Gordon	3/8/2017	8/18/2017	11/17/2017
Rohit Mathur	3/14/2017	8/22/2017	8/25/2017
Dan Villeneuve	3/7/2017	8/1/2017	8/22/2017
Richard Zepp	5/22/2017	1/26/2017	6/6/2017
Mace Barron	3/8/2017	8/1/2017	2/8/2018
Matthew Hopton	3/17/2017	5/1/2017	12/4/2017
Lisam Smith	3/16/2017	3/1/2017	4/2/2018
Alan Hecht	3/17/2017	5/6/2017	5/9/2017
Benjamin Murphy	4/3/2017	9/20/2017	11/6/2017
Chunling Tang	8/23/2017	9/15/2017	11/6/2017
Mace Barron	3/20/2017	7/18/2017	2/8/2018
Christian Hogrefe	9/29/2017	9/7/2017	10/30/2017
Clay Nelson	9/25/2017	9/22/2017	9/26/2017
Jana Compton	3/23/2017	9/24/2017	9/22/2017
Matthew Etterson	3/29/2017	6/1/2017	1/3/2018
Tim Shafer	5/1/2017	8/2/2017	
Matthew Woody	4/7/2017	4/4/2017	4/19/2017
Michael Hays	4/28/2017	9/11/2017	4/24/2018
Barbara Abbott	4/26/2017	9/12/2017	11/20/2017
Matthew Magnuson	7/11/2017	8/2/2017	
Joachim Pleil	5/8/2017	8/4/2017	8/10/2017
Ariel Wallace	7/26/2017	9/22/2017	9/6/2017
Mace Barron	5/10/2017	9/5/2017	2/9/2018
Daniel Nelson	4/27/2017	7/1/2017	9/30/2017
Erin Hines	6/16/2017	5/31/2017	
Terry Keating	10/19/2017	5/8/2017	2/6/2018
Tom Luben	5/25/2017	8/2/2017	8/7/2017
Orin Shanks	8/11/2017	7/12/2017	8/29/2017
Shaun McCullough	6/29/2017	7/1/2017	9/1/2017
EricS Hall	8/24/2017	8/18/2017	8/25/2017
Jim Latimer	7/13/2017	8/15/2017	7/26/2017
William Shuster	8/2/2017	9/6/2017	1/22/2018
Richard Baldauf	9/14/2017	8/14/2017	9/27/2017
Diane Nacci	8/30/2017	9/7/2017	9/7/2017
David Herr	8/18/2017	1/2/2017	11/20/2017
Robert Burgess	10/3/2017	9/5/2017	11/3/2017
Marc Mills	9/28/2017	5/1/2017	3/21/2018

EPA Data?/Justification
Yes
Yes
Yes; n/a
Yes
Yes
Yes
Yes
Yes
Yes
No; No EPA data used in this analysis/paper
Yes
No; Data from swfwmd and other published sources
Yes
No; This is a literature review.
No; -
Yes
Yes
Yes
No; Research was the development of a management framework which was not data driven
Yes
Yes; n/a
Yes
Yes
Yes; N/A
Yes
Yes
Yes
Yes
No; EPA did not collect the data nor did EPA direclty fund the research effort described in the paper.
Yes; N/A
Yes
No; No data generated for this review paper discussing future research directions for ecological risk assessment
Yes
Yes
Yes
No; Analysis is all based on secondary data (publicly available GIS files obtained from other agencies/lit review)
No; Reveiw of existing NMMAPS data
Yes
Yes
Yes
No; literature review
Yes
Yes
Yes
Yes

Yes
No; SETAC lit review from workshop to set practical guidance for the application of the ecosystem services

No; A perspective article, utilizing publically available data for illustrating a point. No data generated.
No; the modeling was already published and the human data came directly from the published dissertation
Yes
No; Based on pre-esisting datasets collected by others. All data available publically, refs & links in the text.
Yes
Yes
Yes
Yes
No; Primary Review Article
Yes
No; Graduate students led research.
Yes
No; Manuscript describes model-based analysis that used secondary data only.Original results are model output
Yes
Yes
No; Secondary data
No; this research was not done at EPA and does not contain data generated by EPA. There is one EPA coauthor.
No; Oak Ridge Institute for Science and Education completed the research.
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes; n/a

Yes
Yes
Yes
Yes
No; No the paper doesn't have EPA data, and for that matter it doesn't have any data at all ahjond
No

No; All of the data were generated as part of the National Birth Defects Prevention Study (NBDPS) led by CDC.
No; No EPA data was used in this analysis, see SciHub entry for more info
Yes
Yes
Yes
Yes
Yes
No; no EPA data; all the data generated by external organizations; EPA coauthors

Yes
Yes
Yes
No; Data produced by UNC not EPA
Yes
Yes
No; The data was generated by researchers at the Univeristy of Michigan.
Yes
Yes

Yes; n/a
Yes
No; Data and analyses were generated and retained by the PI (Univ. S. Alabama)
No; The journal article builds upon a conceptual model developed in a 2000 Pellston Workshop.
No; Research done independently by Brazilian coauthors using EPA methods/designs but no EPA funding or agreement
No; used published EPA health values
No; Papers do not have any data in them.
Yes
No; 2)No EPA data
Yes
No; State Health Department Data
No; A discussion section - no data provided.
Yes
Yes
Yes
No; Review Article
Yes
No; Lead authorship from another federal agency.
Yes; n/a
No; all data is Oregon State University data.
No; Only data analyzed are from the Bureau of Water, South Carolina Department of Health and Environmental Control
Yes
No; This publication was a review article and did not generate new data
Yes

Yes
Yes; n/a
Yes
Yes
No; Review article, no data
No; Non EPA data - Data generated by Zhejiang University, China
Yes
No; this paper uses EPA public data to build new datasets and analysis by non-EPA authors
No; Data collected/interpreted by Brazilian universities using designs, field & analytical procedures adapted from
No; this paper uses EPA public data to build new datasets and analysis by non-EPA authors
Yes
No; Assisted in the data interpretation and the writing of the manuscript.

No; review of existing data
No; No data, a review article
Yes
No; All work, including data analysis, was done outside of EPA
No; This paper is a review article.
Yes
Yes
No; No new data presented. Paper presents consensus views about advances that could improve risk assess. & mgmt.
Yes
Yes
Yes
Yes
Yes
Yes
No; Study relied on data collected by CDCÂ¿s NBDPS. All data variables were collected as part of the NBDPS' CATI.
Yes
Yes
No; Using existing data.
Yes
No; No, this is a literature review article with no EPA-generated or other data or analysis associated with it.
Yes
No; UNC hospital created data that were used in the publication but EPA did not.
Yes
No; EPA did not collect the data nor did EPA directly fund the research effort described in the paper.
Yes
Yes
Yes
No; *
Yes
Yes
Yes
No; contains literature data
Yes
Yes
Yes
Yes
Yes
Yes
Yes
No; The manuscript describes a computational model.

Yes
Yes
Yes
Yes
No; no EPA generated data is associated with this article.

Yes
No; it is a review
Yes
No; No EPA-generated data was used; project is exempted from Science Hub because of personally identifiable info
Yes
Yes
No; Review article - no new data.
No; EPA did not collect the data nor did EPA directly fund the research effort described in the paper.
Yes
Yes
No; EPA author provided technical expertise and interpretation of existing data.
Yes; n/a
Yes
No; Papers do not have any data in them.

No; This is a review article.
Yes
Yes
Yes; n/a
No; This is a review article that is synthesizing the results of previously published analyses.
Yes
Yes
No; all work and anaylsis performed at UNC
Yes
No; There are not data associated with the paper
Yes
No; Papers do not have any data in them.
Yes
Yes
Yes
Yes
No; Study evaluated 2 methods for analysis of water quality trends. We used monitoring data from existing programs
Yes
No; Review Article
Yes
No; All experiments and data generation were conducted by collaborators at Nanjing University.
No; This is a review article.
No; The article does not contain any new U.S. EPA data, only data is cited from the literature.
Yes
No; this is a review of already published data
Yes
No; .
No; Concept only, no EPA dataset created
No
Yes
Yes
Yes

No; Data belongs to UNC
Yes
Yes
Yes
Yes
No; all analysis was based on USGS data
No; This paper resulted from some university collaboration and advisement. The university scientist generated all of the
Yes
Yes
Yes
No; this is a non-EPA workshop summary and review paper. There is no EPA data associated with the paper.
Yes
No; EPA did not collect the data nor did EPA direclty fund the research effort described in the paper.
Yes
No; The article is a review paper which has no data associated with it.
No; Data generated by DISL
Yes
Yes
Yes
No; Rsrch led by Rep of Tajikistan scientists, w/ EPA tech overview. All data generated/owned by Tajik scientists
No; The research which produced this data was not funded by EPA. The EPA coauthor helped write the manuscript.
Yes
Yes
No; Graduate student was lead for this article.
No; SETAC Workshop summary
No; No EPA Data, review article.
Yes
Yes
No; Papers do not have any data in them.
No; Papers do not have any data in them.
No; published before requirement
Yes
Yes
No; A review of published literature
Yes

No; No data was collected; all data are from analysis of textual statements in published reports and articles
Yes
Yes
No; The papers contribute to research being conducted through an agreement between the Chinese Ministry of Science a
No; The papers contribute to research being conducted through an agreement between the Chinese Ministry of Science a
Yes
No; The paper has data generated by NIH and the EPA coauthors provided input into the prepartion of the manuscript
Yes
No; review only
Yes

Yes
Yes
Yes
No; All data generated by Oregon State University
Yes
Yes
No; No. This is a methods paper. There is no data - it is all secondary data.
Yes
Yes
Yes
Yes
No; This manuscript is a commentary, and it does not use EPA generated data.
Yes
Yes
No; Workshop that did not employ any EPA data.
No; Workshop that did not employ any EPA data.
Yes
Yes
No; opinion of outcomes of NIH-Bethesda, MD workshop
Yes
Yes
Yes
Yes
Yes
No; Data is from drinking water pland and the Baltimore long term ecological research site
Yes
No; Review Article
Yes
Yes
No; Book Review in a Journal
Yes
No; Published ocean data (Hemsley et al. 2015) is used in the journal article.
Yes
No
Yes
Yes
No; workshop summary manuscript presented as journal Forum article with no EPA generaged data
Yes
Yes
No; Data was generated by Stanford University, Stanford, California.
Yes
Yes
Yes
Yes
Yes
Yes
Yes

No; Data collected by Brazilian coauthors in Brazil using published guidance cited in text and references
Yes
No; .
Yes
No; This paper is a workshop review and contains no EPA data and therefore needs no SDM plan or associated QAPP.
Yes
Yes
Yes
Yes
No; Math Tutorial
Yes
Yes
Yes
No; Secondary data only
Yes
Yes
Yes
Yes
Yes
Yes
No; -
No; Review article
Yes
Yes
Yes
No; Review paper on integrated modeling systems.
Yes
Yes
Yes
Yes
Yes
No; Data was generated by Lead Author at the University of Maryland. The EPA provided advice and data interpretat
No; A review/Database/analysis
Yes
Yes
Yes
Yes
No; All the data in this manuscript is generated by the Romanian couthors.
No; All data represented in this article is contained in the manuscript and/or its associated Supplemental Material.
No; No data associated with this article. This paper introduced GIFMod and provided some example applications.
Yes
No; Data was gathered during a US Park Service led workshop
No; No data collected - paper is an intellectual application of FEGS to a problem
Yes
Yes
Yes
No; Data were collected as part of the National Birth Defects Prevention Study (NBDPS) through the CDC.

No; Review article, no data
No; This product is a literature review.
Yes
Yes
Yes
No; Journal article is a review of EPA documents and assessment processes and did not use EPA-generated data.
No; The paper focuses on an already existing model called EXP-HYDRO from Patil and Stieglitz (2014)
No; No data in article
Yes
Yes
Yes
Yes
No; Data were generated by USGS and are publically available through their process
Yes
Yes
No; Helped with writing, provided expertise in tree physiology that helped data be interpreted by Univ of Idaho
Yes
Yes
No; There was no EPA generated data for this article (data was taken from literature)
Yes
No; ORD-018108 was led by a graduate student and the data are hers as part of her dissertation.
Yes
Yes
No; revisiting for 2002 publication by same author
Yes
Yes
Yes
Yes
Yes
No; Review of previously published article results only
Yes
Yes
Yes
Yes
Yes
No; Product is being cleared for completion-work prior to EPA
Yes
Yes
Yes
Yes
No; All calculations were performed using published data on chemical manufacturing processes from the scientific literat
No; The data was generated by researchers in Australia
No; Secondary data only
Yes
No; Paper describes the modeling enviornment.
No; The manuscript reviews existing available models, indicators, and metrics for climate event resilience.
Yes

No; Review paper, no data to report
Yes
Yes
Yes
Yes
No; Research data consisted of secondary data only
No; Publicly available datasets were reanalyzed They are identified and described appropriately within the article
Yes
No; This article proposes a new conceptual approach to modeling of ecotoxicological effects.
No; It does not have any data because it describes an outreach activity conducted in the Western Balkans
No; This is a review paper - no data, just summary and interpretation
No; Data does not belong to the EPA. Started prior to joining EPA
Yes
Yes
Yes
Yes
No; Research data consisted of secondary data only
Yes
Yes
Yes
Yes
Yes
No; This is a news column of recent technology reports.
Yes
Yes
No; Article is a review of published literature
No; Review article, utilizes secondary data from the literature
Yes
No; Data was generated at Oregon State University. EPA was a collaborator.
Yes
No; Study by a laboratory in China
Yes
No; USGS owns the datasets that were used to build the software.
No; This manuscript contains a small amount of methodological data that were only used to optimize** see comments
No; EPA did not generate any of the model inputs described in the journal article.
Yes
No; Research Consisted of secondary data only
Yes
Yes
Yes
Yes
Yes
No; Scientific meeting report
No; Scientific perspective
Yes
Yes
No; No EPA data

No; Data in this paper were generated by an Oregon State University student and not by EPA.
No; No primary data was generated. Secondary data from non-EPA LCA databases was used for this analysis.
No; Editorial only
No; All the data presented in the STICS entry ORD-019266 was generated by our European collaborators. EPA's contributi
Yes
No; The work was supported by a Cooperative Agreement; data was collected by participating instituions.
No; Data was generated by Duke and analyzed at HMGU. EPA authors are part of Cathgen team and guide/provide advic
No; Review article
No; Review Article
No; This is a small abstract contained within a workshop report for SETAC.
No; Data was generatred by scientists in Chile.
No; Data was generated by the author(s); EPA provided financial support for data analysis and publication only.
No; The data was collected by universities as part of a cooperative agreement 83563201 to Univ. of Virginia.
No; No data used in article
No; Article includes insights from an investigation of the primary literature. No data was generated or analyzed.
Yes
Yes
No; Used data from the Korean National Environmental Health Survey and from published articles
Yes
No; Literature review article
No; This journal article was a review product of a workshop on ionizable organic chemicals, involving no new data genera
No; Data gathering and analysis took place in China.
No; This is a workshop analysis/report that involved no generation of new data.
No; Research data consisted of secondary data only
No; We provided samples (dosed rat urine) that contained the analytes to researchers
No; This was a collaborative study. I have provided selection of chemicals with doses & provided guidance
Yes
Yes
Yes
Yes
No; It is a literature review and reflects peer reviewed literature external to EPA
Yes
No; This is a state-of-the-science literature review article.
No; This is a review article.
Yes
Yes
Yes
Yes
No; no EPA data; all the data generated by external organizations; EPA coauthors
No; This article from participation in an expert panel (no data collection or analysis)
No; review article
Yes
Yes
Yes
Yes
Yes
Yes

Yes
Yes
Yes
No; review article
Yes
No; Data generated at Stanford, used as part of a new analysis here.
Yes
Yes
No; Review paper
No; All sampling and chemical analyses published in the current paper were conducted by USGS personnel.
No; Data were generated by the USGS
No; This is a review article that contains no new EPA generated data.
No; Paper based on workshop discussions. No original data included.
Yes
Yes
Yes
Yes
Yes
No; Data were from existing external published papers.
Yes
Yes
Yes
Yes
No; It is a Letter to the Editor with no data presented.
No; Data analyses conducted by collaborator at SUNY-Binghamton. EPA contribution on interpretation and reporting.
No; This is a framework article
No; no EPA data; all the data generated by external organizations; EPA coauthors
No; Commentary
Yes
No; Work was conducted at University of Wisconsin.
No; ItÂ¿s a review and synthesis paper (only public domain data used)
Yes
Yes
No; EPA role was providing tecnical and scientific advice. All work performed in U. Georgia
Yes
Yes
Yes
No; Article is an opinion piece containing no data.
Yes
Yes
No; A Framework not research results
No; A Framework not research results
No; It uses some 2013 EPA data but they werent generated by us for the paper- we just used them
Yes
Yes
Yes
Yes

No; This is a review type of article.
No; Data were generated by the University of Idaho. I contributed to the project prior to joining EPA.
Yes
No; all coauthor data
Yes
Yes
Yes
No; Author's section is a review of current research as it relates to climate change
No; Editorial article - no data involved
No; no new data collected
No; Article presents conceptual framework resulting from multi-collaborative workshop
Yes
Yes
Yes
No; Research led and data archiving done by senior university author. ICE data is public domain
Yes
Yes
Yes
No; These data were generated by a student at the University of Delaware and have been subject to QA/QC and will b
Yes
Yes
Yes
Yes
Yes
No; Scientific meeting report
Yes
No; Research led and records maintained by non-EPA authors; data obtained from public sources and modeling tools
No; No data-Peer commentary on target article that is being published. Our article will be in the same issue.
No; This manuscript is about pre-existing publicly available protocols. No data collected, used, or analyzed.
No; Work involves modeling done at other organizations. Terry's role is overall interpretation.
No; CDC-generated data, SDP in ScienceHub outlines protocol for public access
Yes
No; Conference proceeding
Yes
No; this research was done at an acedemic institution with no EPA support
Yes
Yes
No
No; Commentary, no new data included
No; The U.S. EPA author collaborated in the experimental design and analysis data generated by the study.
No; Data was generated by USGS colleagues. Experts within EPA assisted in interpreting data and authoring.

completed_review	published_data	Sent to PMC?	
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FALSE	FALSE	Yes	
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FALSE	FALSE	Yes	
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FALSE	FALSE	Yes	

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FALSE	FALSE	Yes	

EPA Data?/Justification	(All)

Row Labels	Count of Initiator's L/C/O
Qtr1	
Jan	47
Feb	51
Mar	56
Qtr2	
Apr	48
May	64
Jun	38
Qtr3	
Jul	42
Aug	39
Sep	47
Qtr4	
Oct	51
Nov	68
Dec	53
Grand Total	**604**

published_data

Row Labels
Qtr1
Jan
Feb
Mar
Qtr2
Apr
May
Jun
Qtr3
Jul
Aug
Sep
Qtr4
Oct
Nov
Dec
Grand Total

(All)
Count of Initiator's L/C/O
47
51
56
48
64
38
42
39
47
51
68
53
604

Sent to PMC?	(All)
Row Labels	**Count of Initiator's L/C/O**
Qtr1	
Jan	47
Feb	51
Mar	56
Qtr2	
Apr	48
May	64
Jun	38
Qtr3	
Jul	42
Aug	39
Sep	47
Qtr4	
Oct	51
Nov	68
Dec	53
Grand Total	**604**

Row Labels	Count of Initiator's L/C/O
Qtr1	**154**
Jan	47
Feb	51
Mar	56
Qtr2	**150**
Apr	48
May	64
Jun	38
Qtr3	**128**
Jul	42
Aug	39
Sep	47
Qtr4	**172**
Oct	51
Nov	68
Dec	53
Grand Total	**604**

Initiator's L/C/O	Clearance Tracking Number
ord,nhsrc,wipd	ORD-006175
ord,nheerl,ephd,eb	ORD-007318
ord,nerl,ced	ORD-013209
ord,nerl,sed,eib	ORD-013297
ord,nheerl,aed,mab	ORD-013562
ord,nheerl,istd,gctb	ORD-014090
ord,nerl,emmd	ORD-014388
ord,nheerl,wed,feb	ORD-014506
ord,nheerl,ged	ORD-014749
ord,nerl,sed	ORD-015099
ord,nrmrl,lmmd,mmb	ORD-015388
ord,nerl,sed,eib	ORD-015459
ord,nheerl,aed,mab	ORD-015498
ord,nheerl,wed,eeb	ORD-016447
ord,nerl,sed,eib	ORD-016486
ord,nerl,sed,eib	ORD-016586
ord,nrmrl,lmmd,mmb	ORD-016646
ord,nheerl,ged	ORD-016853
ord,nerl,sed,ehcab	ORD-016890
ord,ncea,nceacin,crab	ORD-017113
ord,nrmrl,aemd,dsbb	ORD-017154
ord,nerl,ced	ORD-017300
ord,nerl,emmd,ieib	ORD-017584
ord,nheerl,aed,mab	ORD-017635
ord,nheerl,ephd,eb	ORD-017756
ord,nheerl,med	ORD-017864
ord,nheerl,wed,feb	ORD-018016
ord,nheerl,wed,feb	ORD-018031
ord,nheerl,wed,feb	ORD-018043
ord,nheerl,wed,eeb	ORD-018139
ord,nrmrl,aemd	ORD-018239
ord,nheerl,ged	ORD-018381
ord,nerl,sed	ORD-018382
ord,nheerl,med	ORD-018593
ord,nheerl,wed,eeb	ORD-018697
ord,nheerl,med,stb	ORD-018720
ord,nerl,sed,eib	ORD-018820
ord,nheerl,wed,pceb	ORD-018972
ord,ncea,nceacin,crab	ORD-019210
ord,nheerl,aed,heb	ORD-019279
ord,nerl,emmd,mieb	ORD-019314
ord,nheerl,wed,pceb	ORD-019387
ord,nerl,ced	ORD-019499
ord,nerl,emmd	ORD-019521
ord,nerl,sed	ORD-019571
ord,nheerl,aed,peb	ORD-019611

ord,nrmrl,lmmd,mmb	ORD-019659
ord,nheerl,aed,heb	ORD-019666
ord,nheerl,wed,pceb	ORD-019853
ord,nheerl,ephd,eb	ORD-019897
ord,nrmrl,aemd,ensb	ORD-019920
ord,nrmrl,io	ORD-019923
ord,ncea,nceacin,brab	ORD-019963
ord,nrmrl,wsd,wrrb	ORD-019987
ord,nheerl,ged	ORD-020014
ord,nheerl,ephd,crb	ORD-020127
ord,nheerl,wed,feb	ORD-020147
ord,nheerl,ephd	ORD-020192
ord,nheerl,ephd,eb	ORD-020197
ord,ncct,N/A	ORD-020198
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ord,nrmrl,aemd,ssb	ORD-020245
ord,nheerl,med,ttb	ORD-020252
ord,nheerl,wed,eeb	ORD-020266
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ord,nheerl,wed,pceb	ORD-020859
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ord,nerl,sed,ehcab	ORD-020961
ord,nheerl,istd,sbb	ORD-020969
ord,nheerl,aed	ORD-021047
ord,nerl,sed,ehcab	ORD-021102
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ord,nerl,emmd	ORD-021144
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ord,nheerl,wed,eeb	ORD-021337
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ord,nheerl,adh,rcu	ORD-021652
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ord,ncea,nceartp	ORD-021764
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ord,nheerl,ephd,eb	ORD-021835
ord,nerl,sed,eib	ORD-021863
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ord,nerl,emmd	ORD-022236
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ord,ioaa,N/A	ORD-022438
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ord,nheerl,wed,eeb	ORD-022513
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ord,nheerl,wed,feb	ORD-022589
ord,nheerl,ephd,crb	ORD-022602
ord,nerl,emmd,aqb	ORD-022629
ord,nerl,ced,amaab	ORD-022631
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ord,nheerl,med	ORD-022861
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ord,nerl,sed,eib	ORD-022914

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ord,nheerl,med,ttb	ORD-023119
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ord,nrmrl,lmmd,eceb	ORD-023353
ord,nheerl,adh,rcu	ORD-023369
ord,nheerl,med	ORD-023375
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ord,nheerl,ged,beprb	ORD-023384
ord,nheerl,ephd,crb	ORD-023462
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ord,ncct,N/A	ORD-023667
ord,ncea,nceartp,io	ORD-023674
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ord,nheerl,aed,mab	ORD-023917
ord,nheerl,med,stb	ORD-024133
ord,nerl,emmd,ieib	ORD-024201
ord,nrmrl,lmmd,rteb	ORD-024352
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ord,nerl,emmd,mieb	ORD-013843
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ord,nerl,sed	ORD-023231
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ord,nrmrl,lmmd,lcdsb	ORD-023451
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ord,nheerl,wed,eeb	ORD-013944
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ord,nheerl,aed,heb	ORD-016103
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ord,nheerl,ephd,crb	ORD-016638
ord,nheerl,ged	ORD-017137
ord,nheerl,ged	ORD-017511
ord,nheerl,ephd,cib	ORD-017572
ord,nheerl,ephd,crb	ORD-017860
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ord,nerl,ced	ORD-018294
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ord,ncct,N/A	ORD-018679
ord,nerl,sed,ehcab	ORD-018927
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ord,nerl,emmd	ORD-019814
ord,nheerl,aed,mab	ORD-019936
ord,nerl,ced,hedmb	ORD-020279
ord,nheerl,ephd,eb	ORD-020472

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ord,nerl,emmd	ORD-020756
ord,nerl,emmd	ORD-020933
ord,nrmrl,std,cpb	ORD-021041
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ord,nerl,emmd,mieb	ORD-021107
ord,nheerl,ged	ORD-021115
ord,nheerl,ephd,crb	ORD-021137
ord,nheerl,adh	ORD-021353
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ord,nerl,emmd	ORD-021579
ord,nrmrl,appcd,ecpb	ORD-021812
ord,nerl,ced,hedmb	ORD-021994
ord,nrmrl,aemd,ssb	ORD-022126
ord,nheerl,ephd,cib	ORD-022484
ord,nheerl,med,ttb	ORD-023060
ord,nheerl,med,esb	ORD-023613
ord,nheerl,ephd,crb	ORD-023921
ord,ioaa,N/A	ORD-024349
ord,nheerl,ephd,crb	ORD-024548

Title
The effect of a loss of model structural detail due to network skeletonization on contamination warning system design: c
Associations Between Residential Proximity to Traffic and Vascular Disease in a Cardiac Catheterization Cohort
Evaluation of Traffic Density Parameters as an Indicator of Vehicle Emission-Related Near-Road Air Pollution: A Case Stud
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Adaptive Management of Urban Ecosystem Restoration: Learning From Restoration Managers in Rhode Island, USA
Metabolomic effects of CeO2, SiO2 and CuO metal oxide nanomaterials on HepG2 cells
Total and Bioaccessible Soil Arsenic and Lead Levels and Plant Uptake in Three Urban Community Gardens in Puerto Rico
Disentangling the pathways of land use impacts on the functional structure of fish assemblages in Amazon streams
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Calcification continues in Caribbean reef-building corals at high pCO2 levels in a recirculating ocean acidification exposur
Energy and greenhouse gas life cycle assessment and cost analysis of aerobic and anaerobic membrane bioreactor syster
Early detection monitoring for aquatic non-indigenous species: optimizing surveillance, incorporating advanced technolo
Spatially-explicit modelling model for assessing wild dog control strategies in Western Australia
Rapid effects of the aromatase inhibitor fadrozole on steroid production and gene expression in the ovary of female fath
People and water: Exploring the social-ecological condition of watersheds of the United States
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Associations Between Disinfection By-Product Exposures and Craniofacial Birth Defects
Using diverse expertise to advance climate change fisheries science
12 Community structures of phytoplankton with emphasis of toxic cyanobacteria in an Ohio inland lake during bloom se
A mangrove creek restoration plan utilizing hydraulic modeling
Southeast Atmosphere Studies: learning from model-observation syntheses
An overview of geophysical technologies appropriate for characterization and monitoring at fractured-rock sites
Capturing microbial sources distributed in a mixed-use watershed within an integrated environmental modeling workflo
When evolution is the solution to pollution: Key principles, and lessons from rapid repeated adaptation of killifish (Fundu

Performance of Anaerobic Biotrickling Filter and Its Microbial Diversity for the Removal of Stripped Disinfection By-produ
The Role of Shellfish Aquaculture in Reduction of Eutrophication in an Urban Estuary
Effect of Green Macroalgal Blooms on the Behavior, Growth, and Survival of Cockles (Clinocardium nuttallii) in Pacific NW
Vegetated land cover near residence is associated with reduced allostatic load and improved biomarkers of neuroendocr
Chromatography related performance of the Monitor for Aerosols and Gases in Ambient Air (MARGA): laboratory and fie
A Farewell to Harms: The Audacity to Design Safer Products
Using extirpation to evaluate ionic tolerance of freshwater fish
Organism Detection in Permeable Pavement Parking Lot Infiltrates at the Edison Environmental Center, NJ
Seasonal Oxygen Dynamics in a Warm Temperate Estuary: Effects of Hydrologic Variability on Measurements of Primary
Investigating Mitochondrial Dysfunction in Human Lung Cells Exposed to Redox-Active PM Components
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Ozone exposure is associated with acute changes in inflammation, fibrinolysis, and endothelial cell function in coronary a
Extreme Precipitation and Emergency Room Visits for Influenza in Massachusetts: A Case-Crossover Analysis
(Archives of Toxicology) Predicting In Vivo Effect Levels for Repeat Dose Systemic Toxicity using Chemical, Biological, Kine
Eco-Health Linkages: Assessing the Role of Ecosystem Goods and Services on Human Health Using Causal Criteria Analysi
Characterization of Emissions from Liquid Fuel and Propane Open Burns
Testicular oocytes in smallmouth bass in Northeastern Minnesota in relation to presumed exposure to endocrine disrupt
A sprinkling experiment to quantify celerity-velocity differences at the hillslope scale
The creation, management, and use of data quality information for life cycle assessment
Impaired swim bladder inflation in early-life stage fathead minnows exposed to a deiodinase inhibitor, iopanoic acid (arti
Factors associated with NO2 and NOx concentration gradients near a highway
Summary of the development the US Environmental Protection Agency’s Medaka Extended One Generation Repr
Oxidative C-H activation of amines using protuberant lychee-like goethite
Measuring and Modeling Surface Sorption Dynamics of Organophosphate Flame Retardants in Chambers
Modeled Full-Flight Aircraft Emissions Impacts on Air Quality and Their Sensitivity to Grid Resolution
First generation annotations for the fathead minnow (Pimephales promelas) genome
Improving the simulation of convective dust storms in regional-to-global models
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Zebrafish Locomotor Responses Reveal Irritant Effects of Fine Particulate Matter Extracts and a Role for TRPA1
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Plant reproduction is altered by simulated herbicide drift toconstructed plant communities
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Subtidal Benthic Invertebrates Shifting Northward Along the U.S. Atlantic Coast
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Ultrafine Particulate Matter Exposure Impairs Vasorelaxant Response in Superoxide Dismutase 2 Deficient Murine Aortic
Representing causal knowledge in environmental policy interventions: Advantages and opportunities for qualitative influ
Novel Analyses of Long-Term Data Provide a Scientific Basis for Chlorophyll-a Thresholds in San Francisco Bay
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Heme oxygenase activity increases after exercise in healthy volunteers
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A web-based screening tool for near-port air quality assessments
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Building a Potential Wetland Restoration Indicator for the Contiguous United States.
Ultrafine Particulate Matter Increases Cardiac Ischemia/Reperfusion Injury via Mitochondrial Permeability Transition Por
Fungal Microbiomes Associated with Green and Non-Green Building Materials
In vitro bioaccessibility of copper azole following simulated dermal transfer from pressure-treated wood
Monitoring algal blooms in drinking water reservoirs using the Landsat-8 Operational Land Imager
Using exposure prediction tools to link exposure and dosimetry for risk-based decisions: A case study with phthalates
Inverse Relationship Between Urban Green Space and Childhood Autism in California Elementary School Districts

Developing qualitative ecosystem service relationships with the Driver-Pressure-State-Impact-Response framework: A ca
Risks to Fish Habitats and Populations Associated with a Transportation Corridor forProposed Mine Operations in a Salmc
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Constraints on primary and secondary particulate carbon sources using chemical tracer and 14C methods during CalNex-
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Factors associated with bat mortality at wind energy facilities in the United States
Influence of dilution water ionic composition on acute major ion toxicity to the mayfly Neocloeon triangulifer
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Accelerating the Pace of Chemical Risk Assessment
Review: Endogenously Produced Volatiles for In Vitro Toxicity Testing Using Cell Lines

PI/PO	Cleared Date	Published Date	Completed Date
Robert Janke	10/23/2017	1/4/2018	2/13/2018
Lucas Neas	2/4/2014	1/1/2018	2/9/2018
Shi Liu	1/5/2018	12/15/2017	1/17/2018
Jim Lazorchak	1/4/2017	10/27/2017	11/6/2017
Marisa Mazzotta	9/1/2015	11/1/2017	12/14/2017
Kirk Kitchin	1/13/2017	11/29/2017	12/14/2017
Karen Bradham	1/24/2018	1/26/2018	1/31/2018
Phil Kaufmann	11/25/2015	1/1/2018	1/29/2018
William Fisher	11/13/2015	4/1/2018	4/27/2018
Kiran Alapaty	12/11/2015	11/1/2017	11/3/2017
Endalkachew Sahle-Demessie	1/27/2016	1/1/2018	11/16/2017
Ken Fritz	1/27/2016	1/1/2018	12/20/2017
Nathaniel Merrill	3/4/2016	1/1/2018	12/15/2017
EHenry Lee	4/18/2016	10/1/2017	2/2/2018
Charles Lane	4/22/2016	11/1/2017	11/6/2017
Randy Bruins	5/24/2016	2/7/2018	2/7/2018
Endalkachew Sahle-Demessie	5/17/2016	12/1/2017	1/31/2018
Marcus Beck	7/22/2016	3/1/2018	2/12/2018
James Wickham	2/27/2017	11/1/2017	1/12/2018
Michael Wright	2/13/2017	11/1/2017	2/8/2018
Jonathan Steffens	9/22/2016	11/1/2017	11/2/2017
Vlad Isakov	5/9/2017	1/11/2018	2/9/2018
Eunice Varughese	8/10/2017	4/2/2018	1/11/2018
Marisa Mazzotta	11/16/2016	12/27/2017	1/3/2018
Danelle Lobdell	9/13/2016	12/1/2017	11/14/2017
Brian Hill	9/12/2016	11/1/2017	1/3/2018
Scott Leibowitz	9/22/2016	2/1/2018	2/26/2018
Scott Leibowitz	9/22/2016	12/1/2017	12/1/2017
Joe Ebersole	9/7/2016	12/22/2017	1/30/2018
EHenry Lee	9/13/2016	12/1/2017	2/2/2018
Rebecca Dodder	11/28/2016	10/2/2017	11/28/2017
Mace Barron	9/30/2016	2/1/2018	1/11/2018
Jay Garland	9/23/2016	4/2/2018	3/5/2018
Anett Trebitz	11/18/2016	11/1/2017	8/22/2017
Nathan Schumaker	10/11/2016	1/24/2018	12/13/2017
Dan Villeneuve	2/1/2017	10/1/2017	4/30/2018
Joseph Flotemersch	10/28/2016	11/9/2017	12/7/2017
Ted DeWitt	10/21/2016	10/20/2017	4/30/2018
Michael Wright	11/29/2016	2/1/2018	3/14/2018
Kate Mulvaney	12/30/2016	11/15/2017	11/3/2017
Jingrang Lu	10/16/2017	11/2/2017	11/2/2017
Darryl Marois	12/1/2016	11/1/2017	11/13/2017
Havala Pye	11/23/2016	2/22/2018	2/28/2018
D Werkema	2/21/2017	12/15/2017	11/6/2017
Gene Whelan	8/17/2017	1/1/2018	11/7/2017
Diane Nacci	2/22/2017	11/10/2017	11/21/2017

Endalkachew Sahle-Demessie	12/5/2016	11/1/2017	11/16/2017
Suzanne Ayvazian	12/22/2016	1/2/2018	1/10/2018
Ted DeWitt	12/23/2016	11/6/2017	11/14/2017
Andrey Egorov	2/7/2017	10/1/2017	7/31/2017
Johnt Walker	2/3/2017	10/24/2017	2/15/2018
Nicholas Anastas	4/10/2017	1/25/2018	3/9/2018
Michael Griffith	5/31/2017	3/1/2018	2/27/2018
Ariamalar Selvakumar	2/8/2017	1/1/2018	1/25/2018
Michael Murrell	1/10/2017	5/1/2018	4/2/2018
James Samet	2/10/2017	3/1/2018	2/27/2018
Jana Compton	1/30/2017	11/1/2017	11/3/2017
Robert Devlin	5/23/2017	11/21/2017	11/22/2017
E Hilborn	3/21/2018	10/17/2017	3/21/2018
Richard Judson	5/2/2017	2/1/2018	3/19/2018
Rebeca DeJesus-Crespo	2/7/2017	1/18/2018	1/22/2018
Brian Gullett	2/28/2017	11/7/2017	1/3/2018
Dave Mount	4/26/2017	12/1/2017	12/8/2017
Reneej Brooks	2/1/2017	11/27/2017	11/28/2017
Wesley Ingwersen	3/17/2017	4/1/2018	3/22/2018
Dan Villeneuve	3/3/2017	11/1/2017	11/20/2017
Jennifer Richmond-Bryant	3/24/2017	11/21/2017	1/22/2018
Kevin Flynn	5/16/2017	12/1/2017	12/5/2017
Rajender Varma	3/17/2017	1/31/2018	2/1/2018
Xiaoyu Liu	3/13/2017	1/3/2018	11/28/2017
Rohit Mathur	3/7/2017	1/13/2018	2/8/2018
Dan Villeneuve	3/24/2017	12/1/2017	12/7/2017
Hosein Foroutan	8/30/2017	10/21/2017	10/31/2017
Walt Nelson	2/24/2017	2/1/2018	12/4/2017
Joe Wood	5/31/2017	11/9/2017	11/28/2017
Dustin Herrmann	4/25/2017	12/1/2017	3/12/2018
Kiran Alapaty	9/19/2017	12/1/2017	1/12/2018
Nathaniel Merrill	4/13/2017	4/1/2018	11/3/2017
Jim Kaldy	3/17/2017	12/1/2017	11/3/2017
JohnM Johnston	3/23/2017	1/1/2018	1/22/2018
John Iiames	4/27/2017	1/12/2018	1/17/2018
James Wickham	11/9/2017	3/1/2018	1/12/2018
Chris Corton	4/19/2017	11/1/2017	1/25/2018
Marisa Mazzotta	5/22/2017	4/15/2018	5/4/2018
John Darling	6/16/2017	11/1/2017	11/6/2017
Jingrang Lu	1/17/2018	3/1/2018	3/1/2018
Muluken Muche	8/28/2017	1/1/2018	3/16/2018
Lukas Valin	12/11/2017	10/25/2017	12/11/2017
Richard Judson	4/14/2017	12/1/2017	1/22/2018
Rohit Mathur	8/31/2017	10/19/2017	11/6/2017
Joe Ebersole	4/24/2017	1/1/2018	1/30/2018
Jeff Szabo	5/1/2017	3/20/2018	3/20/2018
Reneej Brooks	4/26/2017	3/9/2018	3/29/2018

Brian Gullett	5/12/2017	10/20/2017	2/21/2018
Kirk Scheckel	6/13/2017	12/19/2017	3/14/2018
EHenry Lee	4/26/2017	2/1/2018	11/28/2017
DavidM Martin	5/22/2017	2/1/2018	12/18/2017
Stephen McDow	9/28/2017	12/2/2017	2/28/2018
Holly Mortensen	5/11/2017	3/15/2018	4/10/2018
Chris Nolte	11/6/2017	12/15/2017	11/6/2017
Mace Barron	5/15/2017	1/1/2018	2/8/2018
Russell Erickson	6/21/2017	11/30/2017	12/7/2017
Ihab Mikati	7/12/2017	3/7/2018	3/29/2018
Dan Campbell	6/1/2017	2/1/2018	2/2/2018
Chris Corton	9/18/2017	1/21/2018	1/22/2018
Wesley Ingwersen	6/28/2017	1/1/2018	12/19/2017
Tim Wade	6/16/2017	3/28/2018	5/1/2018
Heather Golden	6/12/2017	1/1/2018	1/5/2018
John Vandenberg	6/8/2017	11/6/2017	12/14/2017
Tom Luben	7/19/2017	11/3/2017	12/14/2017
Theodore Angradi	10/24/2017	4/1/2018	5/3/2018
Matthew Landis	1/22/2018	4/2/2018	1/29/2018
Aimen Farraj	6/12/2017	2/1/2018	5/1/2018
Stephen Edwards	6/8/2017	12/1/2017	12/28/2017
Cavin Ward-Caviness	2/28/2018	10/18/2017	5/3/2018
Mark Tapper	12/6/2017	3/1/2018	5/2/2018
Brian Gullett	6/15/2017	3/6/2018	2/13/2018
Robert Vanderpool	9/11/2017	1/1/2018	1/17/2018
Charles Lane	8/15/2017	1/18/2018	1/22/2018
Mace Barron	9/29/2017	4/20/2018	4/27/2018
Alan Hecht	6/29/2017	10/16/2017	11/30/2017
Havala Pye	8/22/2017	1/12/2018	1/22/2018
Nathan Schumaker	9/8/2017	2/1/2018	2/15/2018
Paul Mayer	9/25/2017	10/24/2017	11/3/2017
Theran Riedel	1/29/2018	4/2/2018	2/6/2018
Jim Szykman	9/14/2017	10/25/2017	10/31/2017
Michael Pennino	8/8/2017	11/21/2017	12/14/2017
James Samet	7/20/2017	2/20/2018	11/17/2017
Ivan Piletic	10/24/2017	11/2/2017	11/3/2017
Christian Hogrefe	4/10/2018	3/16/2018	4/11/2018
John Nichols	10/12/2017	2/1/2018	2/9/2018
Autumn Oczkowski	8/7/2017	3/1/2018	2/5/2018
Robert Burgess	9/15/2017	4/17/2018	4/17/2018
Mace Barron	9/18/2017	1/1/2018	1/23/2018
Sandy Raimondo	9/7/2017	5/1/2018	4/16/2018
Stephen Vesper	9/1/2017	10/1/2017	10/31/2017
Gerald Ankley	8/9/2017	3/1/2018	2/22/2018
Mehdi Hazari	8/18/2017	3/6/2018	5/7/2018
Kim Rogers	12/7/2017	4/1/2018	12/11/2017
Charles Lane	10/18/2017	1/1/2018	1/17/2018

Mark Cantwell	8/17/2017	3/1/2018	5/7/2018
Stephen Edwards	9/14/2017	1/16/2018	1/22/2018
Rick Kolanczyk	9/19/2017	2/1/2018	2/6/2018
David DeMarini	9/11/2017	2/6/2018	3/9/2018
Matthew Etterson	8/31/2017	5/1/2018	5/3/2018
D Werkema	11/22/2017	1/1/2018	12/15/2017
Raymond Smith	9/20/2017	12/6/2017	4/10/2018
Holly Mortensen	9/22/2017	2/1/2018	4/10/2018
Dan Villeneuve	9/19/2017	1/18/2018	2/9/2018
Sigmund Degitz	12/18/2017	4/3/2018	4/20/2018
Jill Awkerman	9/25/2017	3/1/2018	11/28/2017
Cavin Ward-Caviness	3/12/2018	2/6/2018	3/20/2018
Jason Weinstein	4/12/2018	4/1/2018	4/13/2018
Antony Williams	3/19/2018	11/28/2017	3/19/2018
Annie Jarabek	10/18/2017	12/22/2017	1/22/2018
Autumn Oczkowski	10/16/2017	2/14/2018	2/14/2018
Dan Campbell	11/20/2017	3/10/2018	1/10/2018
Brett Blackwell	11/2/2017	4/1/2018	5/3/2018
Armah Delacruz	1/25/2018	1/25/2018	1/25/2018
John McKernan	11/17/2017	1/1/2018	2/22/2018
Laura Jackson	11/22/2017	4/1/2018	2/12/2018
Yang Ou	12/4/2017	4/15/2018	2/26/2018
Theodore Angradi	12/14/2017	1/22/2018	2/13/2018
Cecilia Tan	2/20/2018	3/1/2018	4/9/2018
Helen Buse	1/24/2018	3/16/2018	3/26/2018
Blake Schaeffer	3/5/2018	3/14/2018	3/16/2018
Robert Burgess	5/4/2018	3/20/2018	5/4/2018
Robert Burgess	5/4/2018	5/1/2018	5/4/2018
Elin Ulrich	7/20/2017	1/1/2018	4/23/2018
Nicolle Tulve	8/17/2017	1/1/2018	1/12/2018
Souhail Al-Abed	9/10/2015	3/31/2018	4/24/2018
Marirosa Molina	10/6/2015	11/15/2017	1/31/2018
Nichole Brinkman	3/5/2018	4/3/2018	4/16/2018
Ariamalar Selvakumar	2/8/2016	11/15/2017	1/10/2018
Brian Gullett	8/11/2016	4/2/2018	4/10/2018
Marsha Morgan	5/10/2016	1/1/2018	1/12/2018
Tammy Jones-Lepp	9/21/2017	2/1/2018	3/5/2018
Timothy Barzyk	9/12/2016	11/1/2017	11/6/2017
Ellen Cooter	9/12/2016	12/26/2017	2/9/2018
John Darling	3/29/2018	3/18/2018	4/16/2018
Gerardo Ruiz-Mercado	9/27/2016	1/15/2018	4/10/2018
William Kepner	1/29/2018	4/1/2018	4/16/2018
Ken Fritz	12/13/2016	4/2/2018	4/5/2018
Hodon Ryu	1/24/2017	10/10/2017	1/11/2018
Anthony Zimmer	1/31/2017	12/15/2017	5/4/2018
William Shuster	1/30/2017	2/1/2018	4/10/2018
Blake Schaeffer	12/11/2017	4/2/2018	4/20/2018

Jake Beaulieu	2/8/2017	11/1/2017	1/26/2018
Tim Wade	2/13/2017	3/30/2018	4/23/2018
Dan Loughlin	8/24/2017	3/2/2018	4/23/2018
Brian Gullett	4/28/2017	10/11/2017	3/19/2018
Karen Bradham	9/12/2017	1/1/2018	4/16/2018
Armah Delacruz	4/10/2017	11/7/2017	4/20/2018
Richard Fulford	2/21/2017	12/1/2017	1/11/2018
Richard Zepp	11/22/2017	10/12/2017	11/30/2017
Matthew Hopton	3/17/2017	3/2/2018	4/12/2018
Michael Schock	4/14/2017	11/14/2017	1/11/2018
Mary Gilbert	8/23/2017	11/1/2017	11/20/2017
Kristin Isaacs	12/4/2017	4/2/2018	4/20/2018
Ahjond Garmestani	3/31/2017	5/1/2018	4/10/2018
Dermont Bouchard	9/13/2017	10/3/2017	10/31/2017
Matthew Landis	11/16/2017	4/1/2018	4/16/2018
Charles Lane	5/5/2017	4/2/2018	4/5/2018
Deborah Luecken	5/22/2017	12/27/2017	4/16/2018
John Offenberg	1/29/2018	2/27/2018	4/16/2018
Mitchell Kostich	8/29/2017	12/1/2017	11/3/2017
D Werkema	12/20/2017	12/1/2017	12/20/2017
Golam Sarwar	8/2/2017	1/1/2018	11/6/2017
Shaibal Mukerjee	10/31/2017	2/2/2018	2/1/2018
Jeanette VanEmon	11/20/2017	1/1/2018	11/30/2017
Kirk Scheckel	11/13/2017	5/4/2018	5/4/2018
Jonathan Mosley	5/11/2017	2/26/2018	4/16/2018
Armah Delacruz	5/25/2017	5/5/2018	4/16/2018
Matthew Landis	10/4/2017	3/1/2018	1/17/2018
Karen Bradham	4/23/2018	3/19/2018	4/23/2018
Eric Villegas	9/7/2017	11/15/2017	4/16/2018
PaulS Price	6/12/2017	3/1/2018	1/22/2018
Clay Nelson	1/23/2018	1/16/2018	2/20/2018
Seth Newton	12/8/2017	3/1/2018	12/11/2017
Matthew Landis	12/7/2017	1/27/2018	2/28/2018
Rong-Lin Wang	6/22/2017	10/19/2017	11/6/2017
Adam Biales	8/8/2017	10/1/2017	11/6/2017
Ron Williams	8/10/2017	11/1/2017	11/6/2017
Roy Martin	6/26/2017	2/1/2018	11/6/2017
Matt Heberling	8/25/2017	3/19/2018	3/13/2018
Mace Barron	7/13/2017	1/18/2018	2/6/2018
Stephen Vesper	11/20/2017	1/1/2018	1/3/2018
Susan Yee	7/7/2017	3/14/2018	3/26/2018
Todd Luxton	8/21/2017	2/1/2018	4/13/2018
Marcus Beck	8/1/2017	2/12/2018	2/13/2018
Rick Wilkin	8/3/2017	10/11/2017	3/22/2018
Mike Borst	8/11/2017	2/1/2018	1/17/2018
Tiffany Yelverton	7/26/2017	3/1/2018	4/24/2018
Orin Shanks	8/25/2017	1/1/2018	1/22/2018

Rajender Varma	8/25/2017	10/19/2017	11/28/2017
Mohamed Sallam	11/17/2017	10/16/2017	11/30/2017
Endalkachew Sahle-Demessie	4/11/2018	4/1/2018	4/11/2018
Rick Wilkin	11/28/2017	12/14/2017	5/3/2018
Cecilia Tan	11/6/2017	4/1/2018	4/20/2018
Michael Hornung	9/29/2017	4/1/2018	3/30/2018
Joachim Pleil	11/6/2017	2/6/2018	2/6/2018
Jonathan Krug	8/24/2017	3/6/2018	4/16/2018
David Heist	3/9/2018	4/2/2018	4/20/2018
Marsha Morgan	11/27/2017	3/1/2018	1/4/2018
Caroline Stevens	9/19/2017	3/1/2018	1/11/2018
Jim Jetter	9/29/2017	12/15/2017	4/3/2018
Christian Daughton	11/15/2017	4/1/2018	12/15/2017
Andrea Clements	10/16/2017	11/1/2017	10/30/2017
Ahjond Garmestani	10/2/2017	4/10/2018	4/10/2018
Gayle Hagler	11/14/2017	11/1/2017	12/15/2017
Susan Glassmeyer	1/9/2018	4/9/2018	4/16/2018
Mace Barron	10/31/2017	11/9/2017	4/2/2018
Joachim Pleil	12/4/2017	1/2/2018	1/5/2018
Blake Schaeffer	3/5/2018	3/5/2018	3/9/2018
Richard Zepp	2/21/2018	2/28/2018	2/22/2018
Russell Kreis	3/2/2018	10/17/2017	3/26/2018
Charles Lane	3/6/2018	4/9/2018	4/16/2018
E Hilborn	5/24/2017	11/28/2017	
David Olszyk	9/21/2015	10/1/2017	9/25/2017
Rajender Varma	8/17/2016	1/1/2018	9/28/2017
David Heist	4/20/2018	3/1/2018	
Stephen Hale	7/8/2016	11/1/2017	9/27/2017
Brian McMinn	7/12/2017	11/1/2017	9/7/2017
Tim Wade	6/2/2016	10/2/2017	
Haiyan Tong	5/13/2016	1/1/2018	
William Benson	7/27/2016	5/1/2018	
Jim Hagy	8/8/2016	10/15/2017	9/12/2017
Mehdi Hazari	10/11/2016	3/6/2018	
Andy Ghio	9/30/2016	2/6/2018	
Kristin Isaacs	9/7/2017	11/1/2017	9/21/2017
Vlad Isakov	8/11/2017	12/1/2017	9/25/2017
Thomas Johnson	10/31/2016	11/9/2017	
Rochelle Araujo	9/5/2017	11/1/2017	9/7/2017
Imran Shah	7/5/2017	11/20/2017	
Megan Mehaffey	8/4/2017	12/1/2017	9/28/2017
Robert Devlin	11/19/2016	10/1/2017	9/30/2017
Stephen Vesper	8/22/2017	10/25/2017	10/25/2017
Kim Rogers	12/15/2016	11/15/2017	6/9/2017
Darryl Keith	2/7/2017	1/29/2018	
Katherine Phillips	6/30/2017	10/1/2017	7/19/2017
Laura Jackson	2/17/2017	10/1/2017	8/25/2017

DavidM Martin	3/6/2017	1/1/2018	9/25/2017
Michael Kravitz	8/23/2017	10/2/2017	
Craig Barber	3/27/2017	12/15/2017	7/19/2017
Michael Lewandowski	8/14/2017	10/1/2017	9/7/2017
DavidJ Williams	9/14/2017	10/2/2017	9/18/2017
Matthew Hopton	4/14/2017	1/15/2018	9/6/2017
Christopher Gordon	3/29/2017	10/1/2017	9/11/2017
Jingrang Lu	10/10/2017	10/26/2017	10/26/2017
Marcus Beck	5/2/2017	11/10/2017	9/6/2017
Neal Fann	4/17/2017	1/1/2018	8/25/2017
Robert Devlin	5/3/2017	11/1/2017	8/11/2017
Mohammed Jaoui	9/5/2017	11/1/2017	9/25/2017
JohnH Zimmerman	6/13/2017	11/15/2017	6/27/2017
Sue Kimbrough	5/31/2017	3/5/2018	
Cecilia Tan	9/7/2017	11/1/2017	9/7/2017
Amara Holder	6/15/2017	10/17/2017	
Janice Dye	7/20/2017	2/1/2018	
Matthew Etterson	8/17/2017	11/1/2017	9/25/2017
Dave Mount	3/2/2018	4/1/2018	
Andy Ghio	11/2/2017	2/7/2018	
Maureen Gwinn	11/16/2017	3/30/2018	
Michael Madden	12/15/2017	4/27/2018	

EPA Data?/Justification
Yes
No; Data used for this manuscript was generated and owned by Duke Univ Med. Center part of CATHGEN cohort
Yes
Yes
Yes; NAGE Exempt
Yes
Yes
No; Data is generated by Generated using EPA methods
No; Article focuses on problem formulation phase of enviro prot plan & does not include quantitative data analyses
Yes
Yes
Yes
No; Data came from graduate school work.
Yes
No; commentary article
No; This is a review article
Yes
No; Article is based on secondary data from sources like satellite remote sensing and state environmntl agencies
Yes
No; Data analysis of human subjects with individual-level data that is potentially sensitive and not shareable.
Yes
Yes
Yes
No; The article is an overview of the findings of qualitative interviews with coastal managers.
No; This publication contains EPA generated data, however it was finalized and cleared for publication before the Science
Yes
Yes
Yes
No; Lead author developed and ran the model using published literature values and NOAA data.
Yes
No; This is literature review.. No original data was generated. It used data from outside sources
Yes
Yes
No; Article is a review/synthesis, presenting no EPA data or outside data whatsoever.
No; Research data consisted of secondary data only
Yes
Yes
No; Uses secondary data only, including some from EPA National Wetland Condition Assessment
No; DBP and health data came from state agencies in Massachusetts, and from individual public water utilities
No; This work was conducted prior to my employment at the EPA, and it is composed of qualitative interviews.
Yes
No; The data in this manuscript was gathered as part of my dissertation research at The Ohio State University.
Yes
No; This is a review article.
Yes
Yes; NAGE Exempt

Yes
No; This work was done by NOAA led researchers as part of a REServ Program that started in 2011.
Yes
Yes
Yes
No; I am editing a special edition of a journal
Yes
Yes
Yes; GED exempt - paper cleared before 6/30/2017
Yes
Yes
Yes
No; Human health data
Yes
Yes
Yes
No; Research was a graduate research project conducted by the Univ of MN-Duluth with funding from MN Sea Grant.
No; The data was generated by Oregon State University
No; The article proposed a methodological approach and did not require data creation.
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
No; review type-article no data
No; Data belongs to Zhejiang University
No; This was work done at URI before my hire at EPA
Yes
No; Johnston provided modeling training, guidance and oversight to MRC staff, while did modeling & GIS analyses
Yes
Yes
Yes
No; Research data consisted of secondary data only
No; This was a review article.
No; no EPA data is involved with this article
No; data from Kansas State when author was a grad student there
No; EPA coauthor, no data generated here
Yes
Yes
No; Lead author (NOAA) and other co-authors (USGS and UW) provided data.
Yes; N/A
Yes

Yes
Yes
No; This is a synthesis paper that reviews the literature.
No; Used published data set
Yes
No; This article contains only previously published EPA data and publicly available information
Yes
Yes; GED exempt - paper cleared before June 30 2017
Yes
Yes
No; All pre-exisiting data from federal, state and local agencies
No; This is a review article, not a research article.
Yes
Yes
No; This is an overview article without data
No; This is an invited opinion paper with no associated data.
No; Review article - EPA did not generate data
Yes
No; Publicly available data collected and QAÂ¿d by the Canadian Wood Buffalo Environmental Association
Yes
Yes
No; Data was generated and analyzed at the Helmholtz Institute. I have provided technial assistance and direction
Yes
Yes
Yes
No; EPA scientists provided their technical expertise in interpreting data collected and analyzed by co-authors
No; research lead and data owned by external authors
Yes
Yes
No; The article has no data.
No; Manuscript represents an introduction to special issue of journal WATER; only conceptual ideas and synthesis
Yes
Yes
Yes
No; This is a review only, no data are presented.
Yes; N/A
Yes
No; All measured values presented in article, were generated at the Univ. of WA. John Frew was a graduate student.
No; These data were generated by colleagues at Drexel University and the Nature Conservancy.
No; This article is a critical review of existing data.
Yes
No; This paper describes a methodological framework and does not use data
No; This is the result of a study conducted by the University of Cincinnati.
Yes
Yes
Yes
Yes

Yes; NAGE EXEMPT
No; We assembled a multi-species dataset based on previously published studies.
Yes
Yes
No; The data were all supplied by USGS.
No; No EPA-generated data are associated with this product.
No; All of the data presented in this journal article comes from outside references.
No; all data presented is publically available, and has already been published
No; All experimental work was done at Nanjing Univ. China group conducted the experiments/data collections.
Yes
No; Models were based on simulations using published values in literature.
No; Article uses data generated during my postdoctoral research to associate exposure to NO2 with DNA methylation
No; EPA acted as technical consultation for the paper and NCSU conducted the real-time sample collection and data
No; This manuscript is a descriptive white paper of a database website and does not contain EPA-generated data.
No; Summary of Webinars and Associated Workshop
Yes; NAGE Exempt
No; This study was performed in China.
Yes
No; PI at the University of Cincinnati
No; the product is a white paper, it reviews the state of the science.
Yes
Yes
Yes
No; This is a concept paper, so there are no data generated by EPA or any other organizations
Yes
No; there is no epa-generated data in this article
No; Inter-laboratory study - I particpated with a group located at a local university - no work performed at AED.
No; This is a review article. No new data is presented.
Yes
No; This is a literature review and does not contain any analysis of data.
Yes
No; Journal article is a review paper and no EPA data was generated for this manuscript.
Yes
Yes
Yes
Yes
Yes
Yes
Yes
No; This is a literature review article. It contains no new data or analyses, either EPA-generated or otherwise
No; Research data consisted of secondary data only.
No; Data belongs to USDA-ARS
No; This paper reviews the published literature; it contains no EPA-generated data.
Yes
No; This is a literature review and includes officially available data from EPA.
Yes
No; review

No; Data were generated by Lead Author from Central Washington University.
Yes
Yes
Yes
Yes
No; main PIs at NKU
Yes; GED exempt - paper cleared before June 30 2017
Yes
No; Commentary/Review-type paper
Yes
Yes
Yes
No; No data
Yes
Yes
No; This is a review article
Yes
No; no EPA data
No; no data used
No; no EPA data
Yes
Yes
Yes
No; Data collected collaboratively while on sabbatical in Australia (2011) at the University of South Australia
Yes
No; Data created by primary author - UC postdoc & personnel generated the data
No; N/A
No; Review Article
Yes
Yes
Yes
Yes
Yes
No; The data were generated by researchers from St Cloud State Univ
No; perspectives article
No; No data from EPA or anyone else.
Yes
No; This is an essay of EPA's perspective on benefit transfer challenges.
Yes
No; Data were generated by commercial lab.
No; This is work done by the University of Hawaii. EPA is only a co-author and did not generate any data.
Yes
No; All data were provided by the System Wide Monitoring Program of the Grand Bay National Estuarine Research Rese
No; Reg 2 RARE project QA/QC plan was prepared by Univ of Ottawa & reviewed by EPA. EPA did not provide any data.
Yes
Yes
Yes

Yes
No; Review Article
Yes
Yes
No; This is a review article that discusses some challenges in applying a tool in risk assessment
Yes
No; journal article is a commentary based on the authors' collective opinions. There are no data.
Yes
Yes
Yes
Yes
Yes
No; Presenting a new concept-no data generated
No; This paper is a review and therefore summarizes only the major lessons and conclusions of other work.
No; Secondary data
No; This is an opinion article, does not contain data.
Yes
No; letter to the editor with no data
No; no EPA generated data
No; no data used - meeting report based on workshop held at NASA Goddard
No; meeting report, no data
No; KreisÂ¿s review/consultation on work not related to any current milestones or deliverables in ORD RAPs.
Yes
No; NOAA generated data
Yes
No; no experimental data. authors analyze publication work from literature
Yes
Yes; n/a
Yes
No
No
No
No; The data were collected or compiled by non-EPA co-authors.
No
No; publicaton cleared prior to Science Hub workflow process was developed for personally identifiable information
Yes
Yes
Yes
Yes
Yes
Yes
No; PM samples collected by the EPA were sent to outside collaborators who used them to generate data
No; no EPA data was generated for this article
Yes
Yes; NAGE Exempt
Yes
No; The research involved mining and synthesizing existing health, landcover, and census data.

Yes; NAGE Exempt
No; Research data consisted of secondary data only, e.g., Nat'l Hydrogr. Dataset, AK Anadromous Waters Catalog
Yes
Yes
Yes
Yes
Yes
Yes
Yes
No; Review of existing epidemiologic data.
Yes
Yes
No; All data was generated by the lead author with no funding from EPA.
Yes
No; The survey and analysis of survey results were conducted by the lead author at JRC
Yes
Yes
No; The data were all supplied by USGS.
No; experiments performed by IL Natural History Survey; EPA only provided input on expermntl design, data,ms prep
No; This is a review article
No; Commentary from a recent workshop.
No; Review article

completed_review	published_data	Sent to PMC?	
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Row Labels	Count of Initiator's L/C/O
Qtr1	**131**
Jan	55
Feb	33
Mar	43
Qtr2	**43**
Apr	35
May	8
Qtr4	**129**
Oct	40
Nov	57
Dec	32
Grand Total	**303**

EPA Data?/Justification	(All)

Row Labels	Count of Initiator's L/C/O
Qtr1	
Jan	55
Feb	33
Mar	43
Qtr2	
Apr	35
May	8
Qtr4	
Oct	40
Nov	57
Dec	32
Grand Total	**303**

published_data (All)

Row Labels	Count of Initiator's L/C/O
Qtr1	
Jan	55
Feb	33
Mar	43
Qtr2	
Apr	35
May	8
Qtr4	
Oct	40
Nov	57
Dec	32
Grand Total	**303**

62

Sent to PMC? (All)

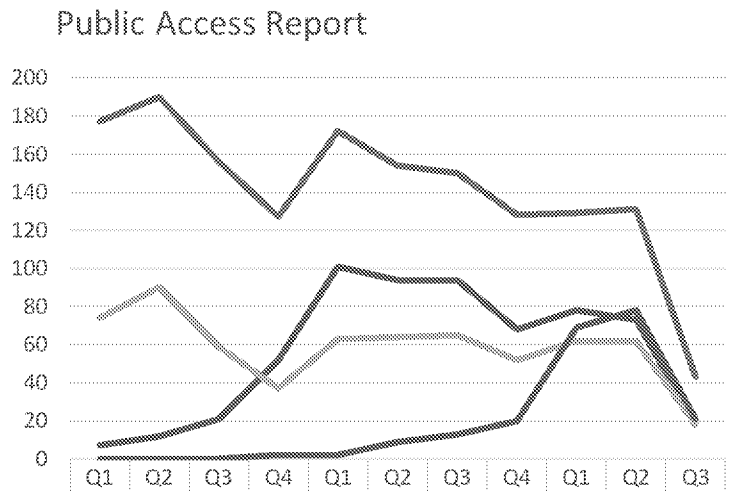
Row Labels	Count of Sent to PMC?
Qtr1	**78**
Jan	36
Feb	19
Mar	23
Qtr2	**21**
Apr	17
May	4
Qtr4	**69**
Grand Total	**168**

	FY16				FY17				FY18		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Number of Published Articles	177	190	156	127	172	154	150	128	129	131	43
Number of Articles with Associated Data	7	12	21	52	101	94	94	68	78	73	18
Number of Articles with Published Data	74	90	**59**	37	63	64	65	52	62	62	18
Number of Articles sent to PMC	0	0	0	**2**	2	9	13	20	69	78	21

*All AED articles and GED articles published before 7/1/2017 are exempt

*PMC submission process began

*STICS wasn't modified to track articles with associated EPA data until



	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
	FY16				FY17				FY18		
Number of Published Articles	177	190	156	127	172	154	150	128	129	131	43
Number of Articles with Associated Data	7	12	21	52	101	94	94	68	78	73	18
Number of Articles with Published Data	74	90	59	37	63	64	65	52	62	62	18
Number of Articles sent to PMC	0	0	0	2	2	9	13	20	69	78	21

Message

From: Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]
Sent: 1/30/2018 4:51:59 PM
To: Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]
Subject: draft doc
Attachments: ORD and HONEST Act .docx

Hi John and Jerry,

Appreciate the almost hour long call – didn't mean to keep you both from other meetings – Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Richard

Richard Yamada
Deputy Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency

Phone: Personal Matters / Ex. 6
yamada.richard@epa.gov

Message

From: Doa, Maria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99E502A905374B0B890DB9B22E18D92E-MDOA02]
Sent: 7/16/2018 3:21:48 PM
To: Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]
Subject: RE: strengthening transparency in science rulemaking

Great. Thanks, Jerry

Maria J. Doa, Ph.D.
Office of Science Policy
Office of Research and Development
Environmental Protection Agency
Tel. 202.566.0718

From: Blancato, Jerry
Sent: Monday, July 16, 2018 11:02 AM
To: Doa, Maria <Doa.Maria@epa.gov>
Subject: RE: strengthening transparency in science rulemaking

Maria,

Yes of course. Thank you for asking…

Before I give you a name let me discuss with staff on time and commitments. We have a few folks that would be good… just want to see where and on whose plate we make some room. But this important so we'll get one of our folks on it.

Let me get back to you early next week if that is not too late.

Jerry
919-541-2854

From: Doa, Maria
Sent: Monday, July 16, 2018 10:53 AM
To: Blancato, Jerry <Blancato.Jerry@epa.gov>
Subject: strengthening transparency in science rulemaking

Hi Jerry,

As I mentioned on Friday on the call on the impacts to ORD of the science transparency rule, we are pulling together an internal team to address public comments submitted in response to the science issues raised in the proposed rule. One of the areas we need support on is the infrastructure for housing and accessing the raw data for studies considered to be "pivotal regulatory science". Could we get someone from OSIM to participate on this group? It would be helpful to have someone with a broad view.

This internal team will help us identify issues and draft responses to comments. This would be a collaborative effort with us in OSP and to some extent OGC. We would ask that if needed they participate in one or more Agency workgroup meetings. We are conscious of their time and would only ask them to participate in these meetings when necessary. The participation would start in mid-August and would continue for about 7 months.

Please let me know if you have any questions or need additional information.

Maria J. Doa, Ph.D.
Office of Science Policy
Office of Research and Development
Environmental Protection Agency
Tel. 202.566.0718

August 2018

Status of ORD's OIG Audits

Start Date	Audit Title/ #	Objectives	NPD/LCO	Subject Matter Experts (SMEs)	Current Status
Gathering Data Phase					
7/2/2018	***ORD Support of and Alignment with Regional Science Programs*** / OA&E-FY18-0247	To determine whether the ORD's support of regional science programs helps accomplish the EPA's mission, and whether results of regional science initiatives impact the agency's decision-making.	OSP, NPDs, Regions 4,5,7, and 8.	Sarah Mazur, Michelle Latham, Fred Hauchman, Maggie LaVay, Kacee Deener, Valerie, Blank	OIG sent notification on 7/2/18. OSP lead efforts to respond to OIG's data request prior to kick-off meeting on 7/23; OSP, SHC, OPARM, and regions attended. Data gathering /interviews.
6/7/2018	***Review of EPA's Office of Research and Development Grants to Universities*** / OAE-FY18-0248	To determine whether (1) ORD oversees and monitors grants awarded to universities in accordance with applicable laws, regulations, policies and procedures; and (2) university grantees are completing agreed-upon work that meets the defined purpose of the grant.	ORD-OPARM, NCER	James Gentry, Lisa Doucet, John Nanartowicz	OIG sent notification letter on 6/7/18, OPARM and NCER responded to data request. The OIG kick-off meeting on June 28th. OIG requested ORD contact info of staff who oversee grants - for future interviews. OPARM provided contact list on 7/13. OIG conducting interviews with NCER, NRMRL, NHEERL, OARS, and OARM/OGD management and staff. Data gathering /interviews.
5/17/2018	***EPA's Processes for Preserving Emails and Text Messages, and Responding to Freedom of Information Act Requests*** / OAE-FY18-0217	To determine whether the EPA took action to complete OIG recommendations regarding the preservation of email and text messages, and the improvement of the agency's Freedom of Information Act (FOIA) process.	OEI & AO (lead)	ORD- Christiane Routt, Norm Adkins	OIG sent notification letter on 5/17/2018. Kick-off meeting will be w/ OEI and AO, other offices may be invited (TBD). Data gathering /interviews.

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August 2018

Status of ORD's OIG Audits

Start Date	Audit Title/ #	Objectives	NPD/LCO	Subject Matter Experts (SMEs)	Current Status
2/20/2018	***EPA's Management of Counter Terrorism and Emergency Response Equipment*** /OAE-FY18-0109	To determine whether the EPA has the needed and required counter terrorism and emergency response equipment and whether the equipment is efficiently managed, tracked and available for potential counter terrorism or emergency response incidents.	Agency-wide: OA/OHS (lead), ORD/HSRP	Greg Sayles	OIG sent notification letter on 2/20/2018. Entrance conference was held on 3/8/18. On 3/21/18, OIG held a meeting with HSRP staff. On April 12th, the OIG provided a written status update regarding the audit. **Data gathering /interviews.**
2/2/2017	***Audit of EPA File Server Security*** / OA-FY17-0138	To determine whether the EPA is implementing security controls around the agency's file servers. OEI will be the lead office for this audit, with support from program offices and the regions.	Agency-wide: OEI (lead), ORD/OSIM	Jerry Blancato, David Updike, Rebecca Clausen, Craig Hammel	OIG sent prelim analysis notification memo on 2/2/17 which includes a survey to EPA's IT offices re file server security due by 2/16/17. Kick-off meeting on 2/8/17 with OSIM and OPARM in attendance. OSIM sent completed survey to OIG on 2/16. OIG meeting on 3/28 with OSIM and OU server administrators. 11/6/17 OIG issued audit notification with updated audit objective. **Data gathering / interviews.**

If edits are necessary or there are any suggestions, please contact ORD's audit coordinator, Maureen Hingeley at hingeley.maureen@epa.gov. Also, if the OIG or GAO has contacted you or staff directly, please contact Maureen.

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August 2018

Status of ORD's OIG Audits

Tracking #	Audit/Report Title	NPD/LCO	Subject Matter Experts (SMEs)	Current Status
Initial Reporting Phase: Responding to Discussion Document / Statement of Facts				
Responding to OIG Draft Report Phase				
OPE-FY18-0002	**OIG Report:** ***EPA Needs a Vision and Strategy for Citizen Science that Aligns with Its Strategic Objectives on Public Participation***	OSA	Jay Benforado, Tom Sinks, Deb Szaro (Reg 1)	On 7/3/18, the OIG issued a draft report with 4 recommendations to address (2 ORD and 2 OA). **ORD received an extension to submit a response by 8/16/18. IOAA reviewed/concurred on response on 8/9/18. Response under review by OA. Once OA signs response, OPARM will work w/ IOAA for Jennifer's signature.**
Responding to OIG Final Report Phase				
OA-FY17-0156	**OIG Report:** ***EPA's Laboratory Fellowship Cooperative Agreements Funded Foreign Nationals***	NCER, OARS, & OPARM/RPAD, and OGD, OITA, OGC	Jayne Michaud, Gelena Constantine, Patti Palmer, Mary Sue McNeil, Eric Burman	On 5/14/18, the OIG issued a draft report with 3 recs addressed to OARM related to limiting fellowships to US citizens. ORD meeting w/ OGC and OGD on 5/29 to discuss the OIG report and recs. On 6/12, OPARM, NCER, and OARS' management provided comments and sent to IOAA for review. OIG granted an extension to submit agency response to June 27th. OARM submitted agency response, including revised ORD memo, to OIG on 6/28/18. ORD must address OARM corrective actions by 12/31/18. OIG exit meeting on 7/23/18 to discuss agency response and next steps. **Final report to follow.**

If edits are necessary or there are any suggestions, please contact ORD's audit Liaison, Maureen Hingeley, at hingeley.maureen@gao.gov. Also, if the OIG or GAO has contacted you or staff directly, please contact Maureen.

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Tracking ORD's Corrective Actions to OIG's Report Recommendation(s)			
Report Title/No	**Recommendation(s)**	**Corrective Action(s) / Due Date**	**NPD/LCO**
Management Alert: EPA Should Promptly Reassess Community Risk Screening Tool/ 17-P-0378 (OIG Hotline Complaint) **(2 of 4 recommendations)**	**Rec 1:** Review the Community-Focused Exposure and Risk Screening Tool and develop an action plan with timeframes to address issues identified, including considerations on whether to retain the tool. **a)** Develop metrics for measuring the tool's performance and establish a regular schedule for performance evaluations. **b)** Survey users to obtain feedback on tool utilization and any needed improvements. **Rec 2:** Develop policies and procedures for planning, developing, implementing and monitoring the performance of web-based research tools. Policies and procedures could build on the draft guidance for web-based tools developed by NERL, and should ensure that any new ORD research tool stems from a clear project proposal that includes ongoing monitoring metrics and outcome measures, and vetting to ensure there is a need and no overlap with other tools.	**CA#1:** ORD does intend to retain this tool, we have provided responses to the additional recommendations below. **a)** ORD agrees. ORD has already initiated the development of performance metrics for C-FERST and other tools. ORD intended to have this be the topic for discussion and review by the BOSC which is now on hold pending appointment of new BOSC members. A completion date is therefore pending when the BOSC is formed and is able to advise ORD on recommendations for appropriate metrics. **b)** ORD agrees and as was mentioned in previous discussions with OIG, is partnering with ECOS and ASTHO as part of an MOA established with EPA April 2016 to survey state agencies. This survey is targeted for FY2018. **(Sept 30, 2018). CA#2:** ORD will work with OEI and the Chief Information Officer to develop criteria to determine when a research tool should be subject to the agency's information technology requirements. ORD will use the criteria to review its new and existing major public interface research tools to determine the applicability of the agency's IT requirements. In addition, ORD will continue improving its investment portfolio review process for IT investments as required under various laws, policies, and regulations including FITARA. ORD will expand its application development roadmap and checklist to require informing OSIM before such projects are started and to report progress and expenditures on such development projects on a regular basis (at least annually or more frequent). OSIM will review and help the developers through the appropriate Life Cycle reviews throughout the project duration and ORD will regularly monitor performance of these web-based tools. This process is being developed and will be implemented starting FY 2018 and will be continuous. **(Sept 30, 2018).**	NERL, SHC, OSIM

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***Management Alert: EPA Should Promptly Reassess Community Risk Screening Tool* /** 17-P-0378 (OIG Hotline Complaint) **(4 of 4 recs)**	**Rec 3:** Review new and existing Office of Research and Development research tools to determine the applicability of the agency's information technology requirements. **Rec 4:** Work with agency offices responsible for other geospatial analysis tools to develop a decision support matrix for when to use certain tools and for what purposes.	**CA#3:** ORD agrees and as stated in the response to recommendation #2: ORD will work with OEI and the Chief Information Officer to develop criteria to determine when a research tool should be subject to the agency's information technology requirements. ORD will use the criteria to review its new and major existing public interface research tools to determine the applicability of the agency's information technology requirements. **(Sept 30, 2019). CA #4:** While ORD agrees that such a decision matrix is valuable and will work other offices, predominantly OEI, ORD will cede the lead to other parts of the Agency on this cross-agency effort. ORD does not own most of those applications and thus is not well positioned to develop such a matrix. **(Sept 30, 2019).**	NERL, SHC, OSIM
***EPA Needs to Provide Leadership and Better Guidance to Improve Fish Advisory Risk Communications* /** 17-P-0174	Conduct an assessment for methylmercury to determine whether the reference dose requires updating, as indicated by the Integrated Risk Information System, and as proposed in the system's 2012 and 2015 agendas.	Within the broader IRIS assessment development process, identification of whether a specific toxicity value (such as the reference dose) requires updating is accomplished following scoping and problem formulation. The IRIS Program will complete scoping and problem formulation for methylmercury and determine whether the reference dose needs to be updated **(12/31/2018)**.	NCEA
EPA Achieved Scientific Benefits When Using Reimbursable Research Agreements, but Better Estimating of In-Kind Costs Is Needed / 16-P-0279	Direct ORD project managers and staff to use guidance developed and issued by the OGD for estimating in-kind contributions, and provide training.	ORD will direct its project managers and staff to use this new procedure to estimate the costs for CRADAs and CAIAs. In a related action, ORD will work with OGD, OCFO, and OGC to provide training to ORD staff on the new procedure **(COMPLETED on 6/12/18). OPARM to work with OARS to prepare certification of completed corrective actions memo for AA signature.**	OARS, OPARM & OGD
EPA Has Not Met Statutory Requirements to Identify Environmental Impacts of Renewable Fuel Standard / 16-P-0275	Provide triennial reports to Congress on the impacts of biofuels as required by the Energy Independence and Security Act.	ORD agrees to provide triennial reports to Congress on the impacts of biofuels as required by the Energy Independence and Security Act. Planned completion date: 12/31/17. **(COMPLETED on 6/29/18) OPARM to work with ACE to prepare certification of completed corrective actions memo for AA signature.**	IOAA/ ACE & OAR

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August 2018 **Status of ORD's OIG Audits**

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August 2018

Status of ORD's GAO Audits

Start Date / Tracking #	*Audit Title* / Congressional Requester(s)	Objectives	NPD/LCO	Subject Matter Experts (SMEs)	Current Status
Gathering Data Phase					
7/5/18 - JC 102874	***Alternatives to Animal Research*** / Based on a congressional request by the House Subcommittee on Interior, Environment and the Senate Subcommittee on Commerce, Justice, Science.	To determine: 1) What efforts have federal agencies made to develop, validate, and promote alternatives to the use of animals in research, testing, or training? 2) What challenges do agencies face in their efforts to develop, validate, and promote alternatives to the use of animals in research, testing, or training?	NCCT, NHEERL, NERL and OCSPP	Rusty Thomas, Monica Linninbrink, Maureen Gwinn, Reeder Sams, Ron Hines, Tim Shafer	Notification memo sent on 7/5/18. GAO entrance meeting with OCSPP and ORD on 8/8/18. GAO sent discussion questions on 7/26/18. **Internal ORD prep meeting to review questions on 8/1/18; pre-briefing for IOAA on 8/8 re the discussion questions. Gathering data/interviews**
6/14/18 - JC 102689	***Agencies' Implementation of Scientific Integrity Poilcies*** / Based on a congressional request by Senator Bill Nelson of the Committee on Commerce, Science, and Transportation	To determine: (1) what are the main components of selected agencies' scientific integrity policies? (2) To what extent do selected agencies have processes in place to reasonably ensure that the objectives of their scientific integrity policies are achieved? (3) To what extent have agencies established processes for reporting and investigating allegations of misconduct of their scientific integrity policies?	IOAA, OSA, & OEI	Francesca Grifo, Vince Cogliano, Tom Sinks, and Mary Greene	Notification memo sent on 6/14/18. ORD issued Transmittal on 6/15/18 announcing audit and requesting SMEs. GAO entrance meeting on July 19th. **Follow up interview on 8/8. Gathering data/interviews**
5/17/18 - JC 102767	***Small Business R&D Venture Capital*** / Based on a congressional mandate under PL 112-81	To determine: (1) the extent to which agencies elected to include majority-owned portfolio companies in their SBIR programs from fiscal years 2015 through fiscal years 2017 and (2) the results of allowing majority-owned portfolio companies to participate in the SBIR program.	NCER	April Richards	Notification memo sent to ORD on 5/17/18. NCER and OPARM met w/ GAO for an entrance conference on 6/5/18. **Based on this meeting, it does not appear this review will be relevant to ORD.**

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Status of ORD's GAO Audits

2/27/18 - JC 102673	***EPA's Chemical Management Strategies*** / Based on GAO's own initiative pursuant to its authority under 31 U.S.C. 717.	To determine: 1) To what extent has EPA demonstrated progress assessing chemicals through the Integrated Risk Information System (IRIS) program and how have recent changes to the program addressed underlying challenges? 2) To what extent has EPA demonstrated progress implementing the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act, and ensured that EPA has the resources necessary?	NCEA and OCSPP	Tina Bahadori, Samantha Jones, Lou D'mico, Mary Ross, James Avery (lead), and Kris Thayer	On 3/27/18, GAO issued notification letter. OPARM and NCEA attended entrance conference on 4/17/18. OPARM and NCEA participated in a followup meeting on 5/9/18. Follow up meetings w/ GAO to address discussion questions on 6/12, 6/13, and 7/9. GAO to interview OW, OAR, R10, and OP. On 8/7/18, NCEA briefed IOAA on GAO's feedback regarding ORD progress to address GAO's IRIS open recommendations. **Gathering data/interviews**
2/22/18 - JC 102451	***Access to Federally Funded Research and Data*** / Based on a request by Representative Bernice Johnson of the House Committee on Science, Space and Technology and Representative Sensenbrenner; and Chairman Thune and Senator Nelson of the Senate Committee on Commerce, Science and Transportation	To determine (1) How are agencies implementing the Office of Science and Technology Policy (OSTP) memorandum directing federal agencies with over $100 million in annual research and development expenditures to develop a plan to support increased access to federally funded research results? (2) What are selected agency officials' and stakeholders' views on the extent to which implementation of agencies' plans has achieved the OSTP memorandum objectives and any challenges faced? (3) What steps have selected agencies taken to work with stakeholders to implement plans, and what options exist to improve implementation and address any challenges identified?	OSA, OSIM, NCER; OEI	Tom Sinks, Kevin Teichman, Cheryl Hawkins, Jerry Blancato, James Gentry	Notification memo sent on 2/22/18. Entrance conference has been scheduled for March 14th. ORD responded to GAO's first data call on 3/13/2018; GAO's data call included a request for a copy of EPA's public access plan, and any associated implementing guidance/documents. **GAO sent questionnaire for ORD to complete. ORD's completed questionnaire sent to GAO on 7/31/18. ORD responded to follow up questions on 8/10/18. Gathering data/interviews**
2/22/18 - JC 102601	***Asbestos in Federal Buildings*** / Based on a request by Ranking Member Donald S. Beyer Jr. of the Committee on Science, Space and Technology's Subcommittee on Oversight.	To determine: 1) What are the current government efforts to maintain an up-to-date inventory of federal buildings containing asbestos and are the data readily available to the public? 2) Are there technologies that could be deployed to ensure the rapid detection of asbestos fibers? 3) Does the government have guidelines or policies to inform federal workers if they have been exposed-or potentially exposed-to asbestos, and have those policies been followed?			Notification memo sent to EPA on 2/22/18. OPARM is still working to find out how/whether this review would impact ORD, and who from the L/C/Os may be appropriate subject matter experts. On April 5th, OPARM called into the entrance conference. Based on this meeting, it does not appear this review will be relevant to ORD.

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Status of ORD's GAO Audits

1/17/18 - JC 102517	***Potential Health and Environmental Effects of Leaks from Natural Gas Storage Sites*** / Based on request from Representative Eddie Bernice Johnson of the House Committee on Science, Space, and Technology, and Representatives Suzanne Bonamici and Donald S. Beyer	To examine issues regarding natural gas storage safety. Specifically, what is known about the extent of natural gas storage leaks? What is known about the risks to human health and the environment from natural gas storage leaks? To what extent has the federal government established human exposure limits for the components of natural gas? What progress has DOT made in implementing its safety enforcement program and what factors have affected DOT's progress?	NHEERL; OAR (lead), OLEM, and OP	Mark Higuchi	Notification memo sent on 1/17/18, GAO entrance conference on 1/30/18 at 3p. OPARM and NHEERL to attend. **Gathering data/interviews**
11/22/17 - JC 102380	***EPA Advisory Committees*** / Based on a request from request from Senators Thomas Carper and Sheldon Whitehouse of the Senate Environment and Public Works Committee, as well as Senators Edward Markey, Brian Schatz, Bernard Sanders, Jeanne Shaheen, Mazie Hirono, Gary Peters, Michael Bennet, Sherrod Brown, and Al Franken.	To determine 1) what are the legal requirements and policies for ensuring the balance and independence of EPA advisory committee members? 2. To what extent is EPA following these requirements and policies? 3. How, if at all, has the composition of EPA's advisory committees changed over time?	OARM (lead), OSA and OSP, agency-wide	Tom Tracey, Tom O'Farrell	Notification memo sent on 11/22/17. GAO sent data request for FACA membership documents. OSP prepared docs and sent to GAO by March 16, 2018. **Gathering data/interviews**

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Status of ORD's GAO Audits

10/11/17 - JC 102349	***Federal Efforts to Address Marine Debris /*** Based on a request from Sen. Gary C. Peters of the Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard; Committee on Commerce, Science, and Transportation; and other Senators	To determine: 1) what have been achievements and shortcomings of the Marine Debris Research, Prevention, and Reduction Act (the Act)? 2) What tools and mechanisms are available to the fed gov't under the act and what other relevant authorities are available for the US to coordinate internationally to prevent, reduce, and mitigate marine debris? 3) What is the effectiveness of these tools and mechanisms, and what are challenges with their use? 4) To what extent are there other fed env programs that could provide useful parallels that could be applied to federal efforts to address marine debris? 5) How does the fed gov't consider international trade agreements, particularly in countries with limited infrastructure, in dealing with practices that may contribute to marine debris?	NHEERL	Kay Ho, Robert Burgess	Notification memo sent on 10/11/17, entrance conference on 11/9/17. OW to be agency lead. **Gathering data/interviews**
06/27/2017 - JC 102103	***Assessing technologies that can help reduce the agricultural sector's impact on water supplies/*** Request by Ranking Member Raul Grijalva of the House Committee on Natural Resources, and Sen Edward Markey	To determine: 1) What technologies can reduce agriculture's demand on water supplies? 2) What technologies reduce the negative impact of agricultural runoff into water supplies? 3) What impact does adopting these technologies have in areas experiencing water scarcity?	SSWR & OW	Suzanne van Drunick, Joe Williams, Rachel Matney	Notification memo sent on 6/27/17, entrance conference 7/13/17. Followup meeting w/ SSWR on 9/14/17, GAO sent discussion questions in advance of meeting. **Gathering data/interviews**
2/7/17 - JC 101407	***Audit of EPA and states' use of effluent limitations in the National Pollutant Discharge Elimination System (NPDES) /*** Request from Senator Sheldon Whitehouse of the Senate Subcommittee on Fisheries, Water, and Wildlife	To determine: 1) What are the trends in point source pollutant loads and the reasons for these trends? 2) To what extent does EPA monitor state implementation of effluent limits in NPDES permits, and what do the results of this monitoring show? 3) To what extent do states use effluent guidelines, water quality-based guidelines, or best professional judgment when issuing NPDES permits?	SSWR, OW, OECA, regions	Suzanne vanDrunick	Notification memo sent on 2/7/17. Entrance conference on 2/23/17. **Gathering data/interviews.**

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Status of ORD's GAO Audits

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Status of ORD's GAO Audits

Product Received Date	*Audit Title* / Report No	NPD/LCO	Subject Matter Experts (SMEs)	Findings / Current Status
Initial Reporting Phase: Responding to Statement of Facts				
7/30/2018 - JC 102207	***Offshore Oil Spill Prevention, Response, and Restoration Efforts***	NHEERL, NCER, NRMRL (co lead), RPAD & OLEM (co lead), OW	Bill Fisher, Robyn Conmy, Lisa Docuet, James Gentry, Mitch Lasat	**On 7/30/18, GAO issued a statement of facts for agency review with no recommendations. On 8/3/18, ORD subject experts reviewed and reported no comment. Draft report to follow.**
Responding to GAO Draft Report Phase				
8/2/2018 - JC 101189	***Science and Technology: Considerations for Maintaining U.S. Competitiveness in Quantum Computing, Synthetic Biology, and Other Potentially Transformational Research Areas***	CSS, NHEERL, NCER, and NCCT	Jeff Frithsen, Joe Tietge, Jay Reichman, Jay, Jim Carleton, Barbara Klieforth, Tom Knudsen, Ron Hines, Rusty Thomas	**On Aug 2nd, GAO issued a draft report for the audit on Federal Research for Transformational Technological Advances. The report contains 5 recommendations addressed to OSTP, Commerce, DOE, and NSF to fully implement leading collaboration practices. No recommendations for EPA. Subject experts from CSS, NCCT, NCER, and NHEERL are reviewing the report for technical accuracy by Aug 22nd. Any comments will be sent to the IOAA for review/concurrence. OCSPP and OEI are also reviewing the report.**
Responding to GAO Final Report Phase				

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Tracking ORD's Corrective Actions to GAO's Report Recommendation(s)		
Report Title/No	**Recommendation(s)**	**Corrective Actions**
2017 High-Risk Report - IRIS (3 GAO Reports, 7 open recommendations) GAO-08-440; GAO-12-42; GAO-13-369	GAO published the 2017 High Risk Report on 2/15/17 (biennial report) **ORD provided GAO status updates on the (7) open IRIS recommendations on June 5, 2018.	

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GAO-08-440, Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System - 1 open recommendation	GAO-08-440, report rec #5: To develop timely chemical risk information that EPA needs to effectively conduct its mission, the Administrator, EPA, should require ORD to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in this report and ensure that any revised process periodically assesses the level of resources that should be dedicated to this significant program to meet user needs and maintain a viable IRIS database.	**GAO-08-440 Report status: June 2018 Update:** In light of the release of the EPA's Strategic Plan (https://www.epa.gov/sites/production/files/2018-02/documents/fy-2018-2022-epa-strategic-plan.pdf), the IRIS Program further enhanced and augmented its engagement strategy with program and regional offices. This included engaging these offices to affirmatively evaluate their continued need for and interest in existing assessment products in the IRIS pipeline, their priority or urgency, and additional considerations for the development of the assessment, including the specific form or focus of the product (portfolio approach), and its timeline. New priority areas of interest were also identified. Results of this evaluation were summarized through a Program Management effort in IRIS which was used to calibrate resource commitments for the next 12 months. To ensure that the work in IRIS remains tethered to the needs of the program/region, during monthly EPA-wide calls, the offices are provided routine updates. This provides real-time information on EPA program priorities and allows the IRIS Program management to be aware of changes in priorities that occur as a result of high priority regulatory developments, such as under TSCA implementation or addressing OAR's court-mandated Risk Technology Review regulations. Additionally, NCEA's Assistant Center Director for Scientific Support works with the IRIS Program to provide frequent chemical-specific micro-updates to the offices around critical milestones in assessment development. The EPA Science Advisory Board met on August 29-30, 2017 to review the progress of the IRIS program. In their letter following that meeting (https://yosemite.epa.gov/sab/sabproduct.nsf/A9A9ACCE42B6AA0E8525818E004CC597/$File/EPA-SAB-17-008.pdf) the SAB recognized the great progress made by the IRIS program: "The Board was particularly impressed and pleased with the rapid progress that the Agency has made in responding to recommendations from the National Research Council of the National Academies of Sciences (NAS) and the SAB, with particularly notable improvements in the program over the past year." April 2017 Update - As indicated in the preamble, in addition to the Multi-Year Agenda, we will ground-truth program and regional office priority needs annually, evaluate the continued responsiveness of the Agenda for that fiscal year, and realign resources and priorities as needed. We started this ground-truthing informally in 2017, and depending on feedback from the offices and the SAB-CAAC, we will formalize this process starting in 2018.

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GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (1 of 5 open recommendations)	GAO-12-42, report rec #1: To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require ORD to assess the feasibility and appropriateness of the established time frames for each step in the IRIS assessment process and determine whether different time frames should be established, based on complexity or other criteria, for different types of IRIS assessments.	**GAO-12-42, Rec #1 status: June 2018 Update:** As part of an IRIS program and project management initiative and broader Agency commitment to LEAN management, the IRIS Program has been evaluating resources and priorities throughout 2017 and into 2018. These activities include the implementation of project and program management to optimize resource utilization and establish assessment timelines, reaffirming Agency stakeholder interest in assessments under development, and sharing new assessment plans and protocols to provide stakeholders and the public greater transparency. Management practices include frequent engagement with EPA partners per chemical assessment to monitor any changes in priority status. IRIS staff allocation is monitored multiple times a month at standing meetings of the IRIS Management Council. See update on recommendation [2008 Rec #5] for additional information. April 2017 Update: In 2017, we furthered this concept. NCEA assessments that support policy and regulatory decisions are being consolidated into a 'portfolio' of Chemical Evaluation products that optimize the application of best available science and technology. The workflow will be reoriented and timelines and resources will be tailored to flexibly fit the intended purpose of the assessment as described in the Assessment Plan (see preamble). Examples of other products incorporated in the portfolio may derive from the Updated Health Assessments pilot described in the preamble. This approach will be presented to the EPA's Science and Technology Policy Council in June and the SAB CAAC in Sept 2017 for their consideration and evaluation. In FY 2017, NCEA has also deployed program and project management (PM) for the assessments. These include working with chemical managers to develop timelines and a system that tracks the portfolio of products in development, allowing the IRIS Program to more effectively and efficiently utilize human resources across assessment projects and ensure timely delivery of products. NCEA has developed tools for tracking decisions and actions taken, and has ongoing training for staff and managers in the use of PM tools and systems.

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GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (2 of 5 open recommendations)	GAO-12-42, report rec #2: To better ensure the credibility of IRIS assessments by enhancing their timeliness and certainty, the EPA Administrator should require ORD, should different time frames be necessary, to establish a written policy that clearly describes the applicability of the time frames for each type of IRIS assessment and ensures that the time frames are realistic and provide greater predictability to stakeholders.	**GAO-12-42, Rec #2 status: June 2018 Update:** In the last year, IRIS has moved away from one-size-fits-all assessments to a mixed portfolio of chemical evaluation products, with the following objectives: Targeted assessments with laser-sharp focus on the science specific to decision needs; Optimize the application of best practices and automation tools to promote greater throughput and higher productivity overall; Increase opportunities for public engagement, thereby mitigating later stage controversies; Develop a nimble, flexible and efficient way to draw on new data streams and create a continuum of risk assessment products to better meet the needs of stakeholders and decision makers; When possible, build on existing assessments developed by other authoritative government agencies; Significantly increase the speed, transparency, and access to assessment products and democratize the process for all stakeholders impacted by decisions. This portfolio approach is a fundamental departure from the previous approach to assessment development within the IRIS Program, which had generated the GAO recommendation. The portfolio approach will allow IRIS to remain flexible and responsive to customers within EPA, as well as the diverse stakeholders beyond EPA, including states, tribal nations, and other Federal agencies. The 2018 report of National Academy of Sciences (NAS), Progress Toward Transforming the Integrated Risk Information System (IRIS) Program, indicated: "The move toward a portfolio approach appears to add need-based and context-based flexibility to the IRIS program. . . Overall, the portfolio approach is expected to conserve agency resources, and it is consistent with the recommendations of the National Academies report, Science and Decisions: Advancing Risk Assessment (NRC 2009)." See update for recommendation [2008 Rec #5] for additional information. April 2017 Update: After receiving feedback from the EPA SAB CAAC (expected, September 2017), such a public statement will be developed. We expect the statement to emphasize the portfolio approach to chemical evaluation and reflect that the timelines and milestones will be commensurate to the scale and type of assessment product. This will also provide an opportunity to evaluate whether the program and project management training has provided the consistency in planning and delivery that was expected.

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GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (3 of 5 open recommendations)	GAO-12-42, report rec #4: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct ORD to annually publish the IRIS agenda in the Federal Register each fiscal year.	**GAO-12-42, Rec #4 status: June 2018 Update:** In 2017, the IRIS Program reconfirmed with Agency stakeholders that information in the multi-year Agenda was consistent with broad Agency needs. Additionally, new priorities such as perfluorinated compounds emerged with some urgency, and were assigned the highest priority by the EPA Administrator. As described in the update for [2008 Rec #4] to reflect this reconfirmation and accommodate the urgent need for assessment of perfluorinated compounds, the IRIS Program recalibrated resources. The IRIS website will be updated shortly to summarize this workflow and resource commitment as planned for the next 12 months. This process will be formalized in 2018. Updates to the Agenda will be published on the IRIS website and disseminated appropriately. In addition, as part of full implantation of systematic review, there will be increased opportunity for early engagement with stakeholders. April 2017 Update: As described in the preamble, starting in 2017, the IRIS Program will ground-truth the information in the Multi-Year Agenda annually to ensure that it remains responsive. An informal process implemented in 2017, will be formalized starting in 2018. Updates to the Agenda will be published on the IRIS website and disseminated appropriately.
GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (4 of 5 open recommendations)	GAO-12-42, report rec #5: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct ORD to indicate in published IRIS agendas which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals.	**GAO-12-42, Rec #5 status: June 2018 Update**: The update to the IRIS Program agenda described for [2011 Rec #4] includes information on current assessments underway and on the assessment products that are planned for the future. **April 2017 Update:** As described in the preamble, starting in 2017, the IRIS Program will ground-truth the information in the Multi-Year Agenda annually to ensure that it remains responsive. An informal process implemented in 2017, will be formalized starting in 2018. Updates to the Agenda will be published on the IRIS website and disseminated appropriately. The Program and Project Management tools deployed in FY 2017 are expected to facilitate estimation and adherence to the projected timelines. Following SAB-CAAC evaluation of proposed approaches to ground-truth and update the Multi-Year Agenda (expected, September 2017), an updated agenda will be published that will list which chemicals EPA is actively assessing and when EPA plans to start assessments of the other listed chemicals.

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GAO-12-42, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (5 of 5 open recommendations)	GAO-12-42, report rec #6: To ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users--including stakeholders such as EPA program and regional offices, other federal agencies, and the public--the EPA Administrator should direct ORD to update the IRIS Substance Assessment Tracking System (IRISTrack) to display all current information on the status of assessments of chemicals on the IRIS agenda, including projected and actual start dates, and projected and actual dates for completion of steps in the IRIS process, and keep this information current.	**GAO-12-42, Rec #6 status: June 2018 Update:** As stated in our responses on Recs 2011 #4 and #5, the IRIS Program has begun to update the IRIS Program agenda on an annual basis, and is providing information on current and planned assessments on the website. The IRIS Program is also implementing program and project management to effectively plan, track and maintain resources and timelines for assessments. April 2017 Update: Following SAB-CAAC evaluation of proposed approaches to ground-truth and update the Multi-Year Agenda (expected, September 2017), the IRIS website will be updated with this information.

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GAO-13-369, Chemical Assessments: An Agency wide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments - 1 open recommendation	GAO-13-369 report rec #3: To ensure that EPA maximizes its limited resources and addresses the statutory, regulatory, and programmatic needs of EPA program offices and regions when IRIS toxicity assessments are not available, and once demand for the IRIS Program is determined, the EPA Administrator should direct the Deputy Administrator, in coordination with EPA's Science Advisor, to develop an agency-wide strategy to address the unmet needs of EPA program offices and regions that includes, at a minimum: (1) coordination across EPA offices and with other federal research agencies to help identify and fill data gaps that preclude the agency from conducting IRIS toxicity assessments, and (2) guidance that describes alternative sources of toxicity information and when it would be appropriate to use them when IRIS values are not available, applicable, or current.	**GAO-13-369 Report status: June 2018 Update:** The IRIS Program has moved away from one-size-fits all assessments to a mixed portfolio of chemical evaluation products. Targeted assessments bring laser-sharp focus on the science specific to decision needs. These products are being shaped for use by several partners, including the states, tribes, other federal agencies, and EPA's national and regional program offices. During FY18, the IRIS Program has posted assessment plans for Uranium and Ammonia that provide examples of targeted assessments underway. IRIS Program portfolio development has been recognized in two recent reviews. In the SAB letter regarding their review of the IRIS program, the SAB recognized the progress made in implementing a portfolio approach in the IRIS program: "The changes are so extensive and positive that they constitute a virtual reinvention of IRIS. . . Finally, the IRIS documents are now more modular and structured to enhance transparency and readability." In addition, NAS met in February 2018 to review the progress made by the IRIS Program in addressing previous NAS report recommendations. In their report, Progress Toward Transforming IRIS, the NAS stated: "The move toward a portfolio approach appears to add need-based and context-based flexibility to the IRIS program. . . . Overall, the portfolio approach is expected to conserve agency resources, and it is consistent with the recommendations of the National Academies report, Science and Decisions: Advancing Risk Assessment (NRC 2009)."While this recommendation highlights the need for Agency level coordination, steps taken by the IRIS Program should significantly to addressing this recommendation. For example: The new portfolio of chemical evaluation products is being developed with input from EPA program and regional offices to ensure the scope of an assessment is appropriate for user needs. The goal will be to produce more assessments in a timely fashion. Additional discussions are being held with EPA partners and others in the federal community to ensure that the products developed with the portfolio approach meet their statutory needs or decisional requirements. Collaboration between the NCEA and NCCT is ongoing to evaluate how the emerging data, models, and tools will inform assessment development and fill gaps in assessments, especially for data poor chemicals. IRIS has increased its coordination with other Federal agencies and states with an aim of reducing duplication of effort and collaborating on assessments of mutual interest (when feasible) to promote the development of more toxicity values. The increasing embrace of systematic review practices across agencies helps create clear and transparent venues for data and knowledge exchange. These activities were presented to the NAS at their

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GAO-17-453, Small Business Research Programs: Most Agencies Met Spending Requirements, but DOD and EPA Need to Improve Data Reporting - 1 recommendation	**GAO-17-453, report rec #2:** To ensure full compliance with SBIR and STTR spending and reporting requirements, the Secretary of Defense and the EPA Administrator should establish procedures to collect and submit obligations data or--through SBA, independently, or through a working group of agencies participating in the SBIR and STTR programs--propose to Congress an alternative methodology for calculating spending requirements for their agencies.	**GAO Comments:** In its comments on the draft report, EPA concurred with the recommendation and stated that EPA will work with SBA to develop an alternative methodology for calculating spending requirements. **June 2018 Update:** EPA has initiated discussion with SBA and held a meeting on 1/23/18. **Nov 2017 Update:** EPA will start discussions with the SBA in Nov 2017, so there is no update at this time.
GAO-18-207, Small Business Research Programs: Agencies Need to Take Steps to Assess Progress Toward Commercializing Technologies - 1 recommendation	**GAO-18-207, report rec #10:** The Small Business Innovation Research (SBIR) Program Manager within the EPA should update the agency's SBIR project solicitation to accurately reflect how the consequences of not meeting the benchmarks are to be implemented.	**June 2018 Update:** EPA has drafted its 2019 solicitation which is scheduled to open in June 2018 and has included the updated language on the transition benchmarks. **EPA Response (Feb 2018):** EPA concurs with this recommendation. EPA will update the next SBIR solicitation (which will be released in 2018) to provide information to small businesses on the consequences of not meeting the benchmarks (i.e., from ineligibility to receive certain awards to ineligibility to submit certain proposals). EPA will also plan on referencing the SBA website on performance benchmarks (https://www.sbir.gov/performance-benchmarks) to ensure consistency with SBA guidance.

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<clause id="H602624FFFA2C469999C80DDCFED1D512"><enum>(i)</enum><text>materials, data, and associated protocols necessary to understand, assess, and extend conclusions;</text></clause>
<clause id="H95B04EB15BB34235BDFEA3A7A9317E9C"><enum>(ii)</enum><text>computer codes and models involved in the creation and analysis of such information;</text></clause>
<clause id="H6FE9773FD9F54A25A5BD29E12DFE02ED"><enum>(iii)</enum><text>recorded factual materials; and</text></clause>
<clause id="HF922E3AA332B4222822946A47E62BB8A"><enum>(iv)</enum><text>detailed

descriptions of how to access and use such
information.</text></clause></subparagraph></paragraph>
<paragraph id="H0B827704041B41848AC98CF5D14A834E" indent="up1"><enum>(5)</enum><text
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in a manner that does not exceed $1,000,000 per fiscal year, to be derived from amounts
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January 26, 2018

Friday

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FRIDAY

26

7 AM

RTP

8

Daily Check-in w/Megan; 41209 RRB; Orme-Zavaleta, Jennifer

9

Discuss State Dept SES CDP Orientation; Bernice can call Personal Matters / Ex. 6 Orme-Zavaleta, Jennifer

10

CONFIRMED: CALL WITH SEN KAMALA HARRIS' STAFF RE: SCIENTIFIC INTEGRITY COMMITTEE
Conference Call
Moody, Christina

11

12 PM

HOLD

1

Monthly Discussion Hauchman/Jennifer; via video to Jennifer in her RTP office; Orme-Zavaleta, Jennifer

2

CONFIRMED: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
DIAL IN: Personal Matters / Ex. 6 CONFERENCE ID: Personal Matters / Ex. 6
Gomez, Laura

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Private appt

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January 26, 2018

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FRIDAY

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Daily Check-in w/ MER; RR 41226 ; Robbins, Chris

8

CDO

HOLD - Reading Time
Robbins, Chris

Daily - McPherson/Ifediora; Robbins, Chris

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January 26, 2018

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CONFIRMED: CALL WITH SEN KAMALA HARRIS' STAFF RE: SCIENTIFIC INTEGRITY COMMITTEE
Conference Call
Moody, Christina

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12 PM

General Discussion Rodan/Shaw; 41226 RRB; Rodan, Bruce

1

Biweekly General Rodan/Vette; Alan to video Bruce (back up: Alan can call 202-564-6620); Rodan, Bruce

2

CONFIRMED: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
DIAL IN: Personal Matters / Ex. 6 CONFERENCE ID: Personal Matters / Ex. 6
Gomez, Laura

3

Biweekly Discussion Rodan/Hubbell; Bryan to Skype Video Bruce (back up: Bryan to call 202-564-3331); Rodan, Bruce

4

Daily Check in Rodan/Sjogren/Fleming; RRB 41226; Rodan, Bruce

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January 26, 2018

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FRIDAY

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CONFIRMED: CALL WITH SEN KAMALA HARRIS' STAFF RE: SCIENTIFIC INTEGRITY COMMITTEE
Conference Call
Moody, Christina

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CONFIRMED: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
DIAL IN: Personal Matters / Ex. 6 ONFERENCE ID: Personal Matters / Ex. 6
Gomez, Laura

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January 26, 2018

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	Daily Check-in w/ MER; RR 41226 ; Robbins, Chris
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9	**Daily Check-In Radzikowski/Branch;** Mary Ellen's Office; Radzikowski, Mary Ellen
	Canceled: Daily Check-in 41209 RRB Orme-Zavaleta, Jennifer
10	**general;** Liz office; Radzikowski, Mary Ellen
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January 26, 2018

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FRIDAY

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general; Liz office; Radzikowski, Mary Ellen

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General; Liz's Office; Blackburn, Elizabeth

12 PM

Private Appointment

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Records
Megan's Office
Christian, Megan

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PLOS | MEDICINE

EDITORIAL

All science should inform policy and regulation

John P. A. Ioannidis[1,2,3]*

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Provenance: Commissioned; not externally peer reviewed.

Not all scientific information is created equal. Large differences exist across topics on how much is known, and with what degree of certainty. Some questions are more difficult to answer, and some research tools are more reliable than others. Not all methods can be applied to answer every question. Credibility depends [1] on how large and rigorous studies are, how well researchers have contained conflicts of interest (financial or other), and how successfully the study design and analysis have limited bias, properly accounting for the complexity inherent in each scientific question. Coordinated efforts among scientists instead of furtive competition help improve the odds of success. Transparency with full sharing of data, protocols and computer codes improves trust in research findings. Re-analysis of data by independent teams adds to that trust and replication in new studies further enhances it.

Scientific findings vary in their credibility. Some findings are beyond reasonable doubt. For example, we have extremely strong evidence that the tobacco pandemic is devastating; that the MMR vaccine is generally safe; that climate change is happening; and that air pollution is a major health hazard. Conversely, our evidence base is notoriously weak on most dietary advice one might hope to give about specific nutrients [2]. Within a given discipline, evidence may be strong for some findings but weak for others. E.g., we have strong evidence for some medical interventions, modest evidence for others, and dismally biased evidence for many.

Our society will benefit from using the best available science for governmental regulation and policy. One can only applaud when governments want to support the best possible science, invest in it, find ways to reduce biases, and provide incentives that bolster transparency, reproducibility, and the application of best methods to address questions that matter. However, perceived perfection is not a characteristic of science, but of dogma. Even the strongest science may have imperfections. In using scientific information for decision-making, it is essential to examine evidence in its totality, recognize its relative strengths and weaknesses, and make the best judgment based on what is available.

Making scientific data, methods, protocols, software, and scripts widely available is an exciting, worthy aspiration [3–5]. Government-based regulatory and funding incentives can be instrumental in making this happen at large scale. However, we should recognize that most of the raw data from past studies are not publicly available. In a random sample of the biomedical literature (2000–2014) [6], none of 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand. The number of studies that have been exactly replicated in new investigations is quite larger, but still a minority in most fields. A new

standard currently proposed for the Environmental Protection Agency [7] aims to ban the use of scientific studies for regulatory purposes unless all their raw data are widely available in public and can be reproduced. If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim.

Past collected and analyzed information can and should still be used for decision-making, taking into account any relevant imperfections. While fully transparent and reproducible information should certainly be valued more highly, studies with weaknesses can still offer insights. Some deficiencies may be unavoidable. For example, researchers cannot ethically randomize people to harmful exposures in order to tackle confounding, nor violate informed consent agreements that prohibit open sharing of private data from past studies. Instead of violating ethics, we should focus more on future efforts, informed by what we have learned in the past. When avoidable weaknesses are identified, we can improve rigor, transparency and reproducibility (and, eventually, credibility) for future studies.

Successful examples of rigorous, reproducible research can be used as templates for other fields that are struggling with suboptimal research practices. For example, the pivotal research on the health effects of air pollution is particularly strong. The Six Cities [8] and American Cancer Society [9] studies are exemplary large-scale investigations, with careful application of methods, detailed scrutiny of measurements, replication of findings, and, importantly, detailed re-analysis of results and assessment of their robustness by entirely independent investigators [10]. The re-analysis and sensitivity analyses were conducted by the Health Effects Institute that was funded by stakeholders some of whom may have desired to see opposite conclusions. It would be wonderful, if in the future the same rigorous re-analysis and replication standards could become the standard for all important areas of research that can inform policy.

In the USA and elsewhere, governments are major funders of research and their regulatory mandates provide powerful incentives for best science. Making widely applicable, reproducible research practices and sharing the default option for research (with sparse exceptions, when appropriately justified) will strengthen scientific investigation and maximize its benefits to society at large. Governments can bolster their legacy through such initiatives and scientists would be broadly supportive of such a transformative vision to promote a standard of openness in science.

The opposite scenario, of simply ignoring science that has not yet attained such standards, is a nightmare. On the one hand, we would see governments discarding science at massive scale because of perceived imperfections and impurities. Perhaps worse, we would see scientists respond by becoming politically entrenched dogmatic advocates, falsely believing that they defend science. Even well-intentioned academics, perceiving an attack on science, may be tempted to take an unproductive, hand-waving defensive position: "we have no problem with reproducibility", "everything is fine", "science is making progress". Certainly, science is making progress; with 20 million smart people working in and co-authoring scientific work and with major funding investment, it would be horrible if no progress were made. The issue is how we can accelerate progress. To do this, instead of hiding trash under the carpet, we should make the best use of past work and materialize bigger and better plans for the future. Science is facing a major transformation nowadays, with exponentially more data and far more scientists working on them than ever. Financial and other conflicts are major threats. Many analyses are becoming black boxes and reproducibility problems are widely documented across many fields. Most of the effects pursued by current investigations are of modest size, nowhere close to the huge harms of tobacco or the huge benefits of childhood vaccinations. Many fields lack the high reproducibility standards that are already used in fields such as air pollution and climate change. The scientific enterprise faces great challenges and great opportunities and we need the best research practices in order to succeed [11].

While scientists can work to improve science, governments and regulators can also do better. Most governments around the world have largely neglected the need to support reproducible research practices. Moreover, they have not used science as much as they should. This is particularly worrisome when the evidence is strong, yet governments have not acted forcefully enough. It is a scandal that we continue to allow companies to make money from selling tobacco products, despite expecting about 1 billion tobacco-related deaths in the next 100 years, a Holocaust equivalent of lost lives repeated every year. It is a scandal that the response of governments to climate change and pollution has not been more decisive. It is a scandal that we don't have higher standards for drugs, biologics, and devices. It is a scandal that people die from measles in the 21st century. Current governments have plenty of room to improve over the mediocre performance of their predecessors. They can do this by using, not discarding, science.

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August 7, 2018

By Electronic Submission to www.regulations.gov

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Docket ID No. EPA-HQ-OA-2018-0259

Re: COMMENTS ON PROPOSED RULE, STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, 83 FED. REG. 18,768 (Apr. 30, 2018)

Dear Acting Administrator Wheeler:

The Emmett Environmental Law & Policy Clinic at Harvard Law School submits this letter on behalf of a distinguished group of experts committed to the advancement of research to improve the health and safety of Americans and people around the world. The signatories include the President of Harvard University, the Presidents and a number of Department Chairs and Chiefs of four of the world's foremost research and teaching hospitals (Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Massachusetts Eye and Ear, and Massachusetts General Hospital), the Deans of Harvard's T.H. Chan School of Public Health and Harvard Medical School, preeminent faculty at the Harvard T.H. Chan School of Public Health, the Harvard Medical School, and the Harvard School of Engineering and Applied Sciences, and numerous esteemed research and clinical doctors affiliated with Harvard and its research hospitals. Work done by the signatories and/or their institutions addresses a broad spectrum of health impacts on infants, children, and adults from exposures to chemicals and activities that are regulated by the U.S. Environmental Protection Agency ("EPA") under various statutes including the Safe Drinking Water Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation, and Liability Act, the Resource Conservation and Recovery Act, the Clean Water Act, and the Clean Air Act, collectively referred to herein as "the Statutes."

Specifically, signatories of this letter have conducted research to determine whether and how exposures to chemical substances such as lead and mercury in food, water, soil, and air affects the development of fetuses, infant mortality, children's development, and children's educational performance. They have also studied the health effects of indoor and outdoor chemical exposures on adult health and safety, including worker productivity and well-being.

Some of the signatories' research is used to develop vaccines and cures for cancer, improve the medical care of infants, children and adults, improve public and private building design, and plan responses to emergencies. The results are also used to demonstrate the benefits of proposed regulatory actions in accordance with statutory and regulatory requirements.[1]

Their research is routinely relied upon by international, federal, and state agencies—including EPA—when they set standards and establish rules and best practices for the protection of human health, safety, and the environment. As explained below, the proposed rule would—for no rational reason—prevent EPA from relying on much of the research that the signatories, their institutions, and other public health and environmental exposure researchers have conducted and continue to conduct. The rule will cripple EPA's ability to implement the aforementioned Statutes and will jeopardize the health and safety of infants, children, and adults in the United States and beyond.[2]

Without the ability to protect and respect patient/human subject privacy and confidentiality, signatories and other researchers would not be able to conduct the studies that are pivotal to their work and to EPA's ability to fulfill its statutory duty to protect public health. The proposed rule ignores a host of existing methods and best practices already established—and adhered to—by the research community to ensure the transparency, reproducibility, replicability, objectivity, and validity of studies, analyses, models, and reports.[3] The proposed rule thus does not serve its stated purpose to ensure that regulatory decisions are based on "valid" science.[4]

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[1] Signatories' research—which analyzes the human health and environmental impacts of the presence of chemicals in air, soil, drinking water, food, and consumer products—is relevant to EPA's required determinations under the Statutes that its regulations provide societal benefits by reducing harm to human health and the environment. Such research is also critically important to identifying the benefits of EPA regulations when the agency is required by the Statutes or Executive Order to conduct a formal cost-benefit analysis. *See* Exec. Order No. 13783, 82 Fed. Reg. 16,093, §1(e) (Mar. 31, 2017) ("It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.").

[2] David Cutler & Francesca Dominici, *A Breath of Bad Air: Cost of the Trump Environmental Agenda May Lead to 80 000 Extra Deaths per Decade*, JAMA NETWORK (June 12, 2018), https://jamanetwork.com/journals/jama/fullarticle/2684596 (copy attached for inclusion in the administrative record, Attachment 1).

[3] *See* Section IV, below, for a discussion of best practices. EPA already has detailed policy and procedural guidance for ensuring and maximizing the quality of information the agency disseminates. *See* EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf. Note further that the proposed rule incorrectly uses the terms "reproducibility" and "replicability" as though they are interchangeable. In fact, they have different meanings. Typically, in the scientific community, "*reproducibility* refers to the ability of a researcher to duplicate the results of a prior study using the same materials as were used by the original investigator." Steven N. Goodman, et al., *What does research reproducibility mean?*, 8 SCIENCE TRANSLATIONAL MEDICINE 341ps12 (2016). By contrast, "replicability" refers to the ability of a researcher to duplicate the results of a prior study following the same procedures but collecting new data. *Id.*

[4] *See* 83 Fed. Reg. 18,768, 18,773 (Apr. 30, 2018) (stated purpose "to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation"); *see also id.* at 18,770 ("It is the charge of regulators to ensure that key findings [of science that informs regulatory actions] are valid and credible.").

Signatories teach graduate and undergraduate students and doctors-in-training about best practices in the conduct of public health, medical, and scientific research. They publish their research results in the most reliable, highest-quality, peer-reviewed medical and scientific journals, including Lancet, Nature, Science, New England Journal of Medicine, Journal of the American Medical Association, Cell, and Environmental Health Perspectives. They conduct peer reviews of the work of other researchers. The approach advocated in the proposed rule is inconsistent with professional best practices in their respective disciplines for conducting, reviewing, and confirming the results/findings of studies, especially those based on confidential personal health data of study participants. As will be shown below, the proposed rule will wreak havoc on public health, medical, and scientific research and undermine the protection of public health and safety.

Accordingly, the signatories strenuously object to the proposed rule and urge EPA to withdraw it.

I. THE PROPOSED RULE WOULD PREVENT EPA FROM RELYING ON THE BEST AVAILABLE INFORMATION AND SCIENCE

In the proposed rule, EPA acknowledges that it must use the "best available science" in all of its regulatory actions.[5] The signatories agree that is the correct starting point for EPA. They disagree, however, with EPA's new position in this proposed rule that science is not the "best" unless the associated raw data are released to the public.[6] As an initial matter, releasing raw data will not improve the quality of the resulting report/study/analysis, and therefore will do nothing to render any individual study "better." EPA itself affirmed this point as recently as 2016.[7] Moreover, while it might be helpful in some situations to make raw data publicly available, it is neither practical nor desirable to impose this requirement as a one-size-fits-all approach.

Instead, there are a variety of other best practices that already exist to test and ensure the rigor, quality, and validity of research. These include the peer review process, which evaluates whether the work is based on the best available scientific understanding, and scientists' detailed description of their research methods, code and non-confidential data in their published articles. That detail allows other researchers not only to challenge the study results, but also to reproduce or validate them using the original data, and/or replicate them via other studies using different data sets. The scientific community considers results valid if they are or can be replicated by other researchers conducting studies using new data, but the same method.[8]

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[5] 83 Fed. Reg. at 18,769 (citing Exec. Order No. 13563, 76 Fed. Reg. 8,321 (Jan. 21, 2011)).

[6] *See* 83 Fed. Reg. at 18,772 (rule would require that "dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.").

[7] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf ("Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications.").

[8] *See, e.g.*, Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons, *Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory*

Contrary to EPA's stated goal of improving the basis for its regulatory decisions, requiring the public availability of all raw data will instead undermine EPA's ability to make reasonable decisions. This requirement will effectively prohibit EPA from considering studies that by design are based on data that *cannot* be made publicly available due to laws and contracts designed to protect patient and human subject privacy and ensure willingness of people to participate in research by sharing their private information with researchers. The proposed rule precludes consideration of studies based on confidential data, even when those results have been confirmed by other studies.[9] Hence, the proposal would in many instances *prohibit* EPA from relying on the best available science relevant to many of the regulatory issues that the agency faces.

Moreover, this proposed requirement contravenes five decades of EPA practice. EPA has repeatedly affirmed that its mission requires it to rely on the best available scientific evidence, without ever asserting that it should exclude from consideration studies for which the underlying data were not publicly available. For example, in its 1997 strategic plan, EPA declared one of its seven overall purposes was to ensure that "efforts to reduce environmental risk are based on the best available scientific information."[10] In 2002, EPA issued Information Quality Guidelines in which it took the position that the standard set forth in the Safe Drinking Water Act — "the best available, peer-reviewed science"[11] — should apply to all of the agency's risk assessments.[12]

Science RIN (2080-AA14) 4 (May 12, 2018), https://perma.cc/MM3J-CHEA [hereinafter "SAB Memo"]; Bernard Goldstein, Op-Ed., *This is Why EPA's "Secret Science" Proposal Alarms Public Health Experts*, THE CONVERSATION (May 18, 2018), https://theconversation.com/why-the-epas-secret-science-proposal-alarms-public-health-experts-96000.

[9] One example is the Six Cities Study, Douglas W. Dockery, et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND J. MED. 1753 (1993), whose results were subsequently confirmed by independent reanalysis, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality* (2000), https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf. Indeed, both the Six Cities Study and the American Cancer Study of Particulate Air Pollution and Mortality have each been reproduced and replicated. The findings are consistent with the original studies. *See, e.g.*, Qian Di, Francesca Dominici, Joel D. Schwartz, et al., *Air Pollution and Mortality in the Medicare Population*, 376 NEW ENGLAND J. MED. 2513-2522 (2017) (copy attached for inclusion in the administrative record, Attachment 2).

[10] EPA, EPA/190-R-97-002, *EPA Strategic Plan*, at 16 (1997), https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=40000 9JX.PDF. Earlier, in a March 1992 report titled *Safeguarding the Future: Credible Science, Credible Decisions*, an independent committee convened by EPA declared that "science is one of the soundest investments the nation can make for the future. Strong science provides the foundation for credible environmental decision making. With a better understanding of environmental risks to people and ecosystems, EPA can target the hazards that pose the greatest risks, anticipate environmental problems before they reach a critical level, and develop strategies that use the nation's, and the world's, environmental protection dollars wisely." EPA, *Safeguarding the Future: Credible Science, Credible Decisions*, at 15 (Mar. 1992), https://nepis.epa.gov/Exe/ZyPDF.cgi/30001ZWJ.PDF?Dockey=30001ZWJ.PDF.

[11] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[12] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, at 21-23 (2005), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.

EPA's historic position is consistent with the Statutes. For example, one of EPA's core duties under the Clean Air Act is to set and periodically review the National Ambient Air Quality Standards ("NAAQS") for six common air pollutants. In carrying out this responsibility, Congress commanded EPA to use "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects [of air pollution] on public health or welfare."[13] Similarly, the Safe Drinking Water Act commands EPA in general to use "the best available, peer-reviewed science" and when deciding whether to regulate a particular contaminant to consider the "best available public health information."[14] The Toxic Substances Control Act requires that regulation of chemical substances be "consistent with the best available science" and that EPA make decisions "based on the weight of the scientific evidence."[15] The water quality criteria that EPA develops under the Clean Water Act must "accurately reflect[] the latest scientific knowledge" on a variety of factors.[16]

Furthermore, because EPA is required under the Statutes to assess the public health benefits of its regulations, it must take into account all relevant science and cannot arbitrarily exclude certain studies demonstrating those benefits. Under the Clean Air Act, EPA must set the NAAQS at a level "requisite to protect the public health."[17] Under the Safe Drinking Water Act, EPA must determine whether a contaminant "may have an adverse effect on the health of persons" before deciding to regulate it.[18]

Many of the fundamental public health studies on which EPA has based key rules and standards under the Statutes are studies for which the raw data were not or could not have been released. Attachment 3 to this letter contains a partial list of studies that likely contain confidential data; these are all studies on which EPA has relied and cited as the basis for its actions under some of the Statutes. Until now, release of the underlying raw data was not an EPA criterion for determining the "best available" reports, studies, analyses, or models. Indeed, none of the Statutes invoked by EPA as support for the proposed rule limits EPA in this fashion; none of the Statutes requires EPA to make raw data publicly available.[19]

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[13] 42 U.S.C. § 7408(a)(2).

[14] 42 U.S.C. §§ 300g-1(b)(3)(A)(i), 300g-1(b)(1)(B)(ii)(II).

[15] 15 U.S.C. § 2625(h), (i).

[16] 33 U.S.C. § 1314(a)(1).

[17] 42 U.S.C. § 7409(b).

[18] 42 U.S.C. § 300g-1(b)(1)(A)(i).

[19] When litigants in the past argued that EPA could not rely on studies for which the raw data had not been publicly available, the D.C. Circuit soundly rejected their argument. As the court explained in one case:

> Claiming neither that they were unable to obtain the studies, nor that the studies were improperly published or peer reviewed, Petitioners instead urge us to impose a general requirement that EPA obtain and publicize the data underlying published studies on which the Agency relies. The Clean Air Act imposes no such obligation. . . . More generally, we agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely "would be impractical and unnecessary."
>
> [...]

EPA's proposed new approach, which conflicts with the agency's obligations and curtails its authority, is irrational at best and detrimental to public health and safety at worst.

II. THE PROPOSED RULE WOULD EXCLUDE CRITICAL STUDIES FROM CONSIDERATION IN FUTURE EPA RULEMAKING

There are at least two categories of critically-important, health-based studies for which it will be impractical or illegal to make the underlying data publicly available. Within each category are studies that have already formed the basis for decades of EPA regulatory actions producing enormous public health and safety benefits. The proposal would require that EPA stop relying on these studies and prohibit automatic consideration of, or reliance on, others like them in the future for no other reason than that the raw data cannot be released to the public.[20] This result would be extremely harmful to human health, safety, and the environment.

A. THE PROPOSAL WOULD PREVENT EPA FROM RELYING ON STUDIES BASED ON CONFIDENTIAL HUMAN HEALTH DATA

For many studies, disclosure of the raw data would violate researchers' statutory or contractual duties to protect patient or human research participant confidentiality. Many types of crucial health impact studies cannot be conducted without human participants. For any research carried out by healthcare providers that involves the handling of individually identifiable health information, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

As EPA persuasively stated in denying Petitioners' original request for information:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment. . . . Such data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].

Am. Trucking Associations, Inc. v. E.P.A., 283 F.3d 355, 372 (D.C. Cir. 2002) (quoting Particulate Matter NAAQS, 62 Fed. Reg. 38,652, 38,689 (July 18, 1997)). The court reiterated this holding six years later in a challenge to the 2008 lead NAAQS. *Coal. of Battery Recyclers Ass'n v. E.P.A.*, 604 F.3d 613, 622 (D.C. Cir. 2010). In that case, the litigants had sought access to the raw data underlying Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSP. 894 (2005).

[20] The proposal allows EPA to decide to consider such studies on a case-by-case basis. *See* 83 Fed. Reg. at 18,772. The factors EPA identifies for providing individual exemptions—that such disclosure cannot be done "in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security"—merely reiterates the main reasons that data are not currently made publicly available. *Id.* at 18,773. If EPA always allows data to be withheld for those reasons, the rule is meaningless and has no effect. On the other hand, if EPA instead picks and chooses when to allow data to be withheld for those reasons, it will be doing so based on no meaningful standards. *Cf. Pearson v. Shalala*, 164 F.3d 650, 660 (D.C. Cir. 1999) ("It simply will not do for a government agency to declare—without explanation—that a proposed course of private action is not approved. To refuse to define the criteria it is applying is equivalent to simply saying no without explanation.").

Privacy Rule imposes strict confidentiality requirements.[21] Federally-funded research involving human subjects is governed by the Federal Policy for the Protection of Human Subjects, also known as the Common Rule.[22] The Common Rule requires that researchers obtain Institutional Review Board ("IRB") approval and informed consent of research subjects, during which process the researcher will typically need to make promises regarding confidentiality.[23] Most institutions have committed to comply with the Common Rule for all of their research,[24] even when it is not federally-funded.[25]

EPA's suggestion in the proposed rule that "simple data masking, coding, and de-identification," 83 Fed. Reg. at 18,771, will be able to overcome these confidentiality concerns is incorrect. As explained by the EPA's own Science Advisory Board ("SAB"), "[i]n some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential."[26] Researchers cannot violate those promises after the fact, particularly if they want to be able to continue to find participants for their studies. In addition, "[i]n the case of clinical trials, there are studies in which removal of all identifying data negates its scientific value."[27]

The understanding of what counts as identifying data is continually expanding: true de-identification of the data may not be possible for some studies, such as those in which the participants come from a small geographical area and/or a specific profession. One study found that the researchers could re-identify approximately one-quarter of the records in a subset of a

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[21] 45 C.F.R. Part 160 and Subparts A and E of Part 164.

[22] 45 C.F.R. 46 subpart A is the U.S. Department of Health and Human Services ("HHS") citation for the Common Rule. A total of 18 federal agencies have adopted it; each agency has its own separate entry in the Code of Federal Regulations. This federal rule governs ethical constraints that federally funded studies must follow, including academic research, responding to earlier concerns of ethical lapses in medical research. *See, e.g.*, Jerry Menikoff, *Could Tuskegee Happen Today?*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 311, 312-16 (2008) (describing the Congressional response to public outcry when the details of the Tuskegee experiment were brought to light). The thrust of the Common Rule is to address such matters of research ethics as informed consent, informational risk, and institutional oversight when research involves human subjects. *See* 82 Fed. Reg. 7,149-7,274.

[23] For example, under its "Basic elements of informed consent" provisions, the Common Rule provides that "in seeking informed consent the following information shall be provided to each subject: . . . A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." 45 C.F.R. § 46.116(b)(5). The Common Rule also requires that the IRB ensure that the researchers make "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." 45 C.F.R. § 46.111(a)(7).

[24] *See Federalwide Assurance (FWA) for the Protection of Human Subjects*, HHS, https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html (describing Common Rule policy for institutions performing government-funded human subject research) (last visited August 3, 2018).

[25] Harvard University, for example, has established policies for all university research that go beyond the requirements of the Common Rule. *Statement of Policies and Procedures Governing the Use of Human Subjects in Research at Harvard University*, HARVARD UNIVERSITY, https://provost.harvard.edu/use-human-subjects-research (last visited August 3, 2018).

[26] SAB Memo, *supra* note 8, at 4.

[27] Lynn R. Goldman & Ellen K. Silbergeld, *Assuring Access to Data for Chemical Evaluations*, 121 ENVTL. HEALTH PERSPECTIVES 149, 150 (2013).

HIPAA-compliant environmental health data set.[28] For some studies, it may not be possible to de-identify the data set while still protecting patient or research subject confidentiality.

The proposed rule would prohibit the continued and future use of these studies by EPA thereby obstructing EPA's statutory duty to consider the "best," "reasonably" available information in its decision-making processes. The resulting information vacuum would occur for no other reason than that the underlying human subject data is private and cannot be publicly disseminated.[29]

The proposed rule would also impede EPA's ability to address new and emerging public health risks in future rulemakings. For example, former Administrator Pruitt announced on May 22, 2018, that EPA will begin to develop maximum contaminant levels under the Safe Drinking Water Act for two fluorochemicals, perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS").[30] EPA also plans to designate PFOA and PFOS as hazardous chemicals, potentially under the Comprehensive Environmental Response, Compensation, and Liability Act.[31] If finalized, however, the proposed rule would prevent these EPA actions.[32]

When EPA issued health advisories for these two chemicals in 2016, the Health Effects Support Documents relied extensively on epidemiological studies generated by the C8 Health Project.[33] A key component of the evidence for the harmfulness of these chemicals consists of epidemiological studies based on data that are not publicly available. Researchers published more than three dozen papers based on these data, identifying probable links between PFOA

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[28] Latanya Sweeney, et al., *Re-identification Risks in HIPAA Safe Harbor Data: A Study of Data from One Environmental Health Study*, TECH. SCI., 2017082801 (Aug. 28, 2017), https://techscience.org/a/2017082801.

[29] Note that some of the Statutes require EPA to use the "best" available information and others have a lower standard. For example, the Toxic Substances Control Act compels EPA to take "reasonably" available information into account. 15 U.S.C. § 2625(k).

[30] Amena H. Saiyid, *Pruitt Plans to Declare Two Fluorochemicals Hazardous*, BLOOMBERG BNA (May 22, 2018), https://news.bloombergenvironment.com/environment-and-energy/pruitt-plans-to-declare-two-fluorochemicals-hazardous.

[31] Press Release, EPA, *Administrator Pruitt Kicks Off National Leadership Summit on PFAS* (May 22, 2018), https://www.epa.gov/newsreleases/administrator-pruitt-kicks-national-leadership-summit-pfas.

[32] Epidemiological studies, which were essential to discovering the immunotoxicity of perfluorinated alkylate substances, including PFOA and PFOS, were based on confidential human health data. *See* Philippe Grandjean, *Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances*, 17:62 ENVTL. HEALTH 1 (2018) (copy attached for inclusion in the administrative record, Attachment 4).

[33] EPA, EPA 822-R-16-003, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, at 3-1 to 3-60 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final-plain.pdf; EPA, EPA 822-R-16-002, *Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)*, at 3-1 to 3-49 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfos_hesd_final_508.pdf. The C8 Health Project was funded through the settlement agreement in a lawsuit brought over drinking water contaminated by PFOA from the DuPont Washington Works facility near Parkersburg, West Virginia. The study involved close to 70,000 participants, for each of whom "demographic data, medical diagnoses (both self-report and medical records review), clinical laboratory testing, and determination of serum concentrations of 10 perfluorocarbons (PFCs)" were collected. Stephanie J. Frisbee et al., *The C8 Health Project: Design, Methods, and Participants*, 117 ENVTL. HEALTH PERSP. 1873, 1876 (2009) ("To protect participant privacy, the presiding judge subsequently sealed the data set.").

(also known as C8) exposure and "diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension."[34]

This situation underlines the arbitrariness and irrationality of the proposed rule. On the one hand, EPA is proposing to take regulatory action to protect the American people from emerging health threats. On the other—through the proposed rule—it is simultaneously undermining its own ability to follow through on those proposals.

B. THE PROPOSAL WOULD PREVENT EPA FROM RELYING ON STUDIES CONDUCTED MANY YEARS AGO FOR WHICH DATA ARE NO LONGER AVAILABLE

Many key EPA regulatory decisions in effect today were based on studies conducted decades ago. Due to the passage of time, the raw data from these studies may no longer be available. Records may have been lost; researchers may have retired or passed away. Or, the data may have been stored in electronic media such as tapes that are no longer compatible with existing systems or otherwise difficult to access.[35] As noted by John Ioannidis, who is a strong advocate of data transparency,[36] "we should recognize that most of the raw data from past studies are not publicly available. . . . If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim."[37]

C. STUDIES THAT EPA WILL BE PROHIBITED FROM CONSIDERING UNDER THE PROPOSAL HAVE SERVED AS THE BASIS FOR MULTIPLE RULEMAKINGS BY EPA AND OTHER AGENCIES

Studies that would be excluded from EPA consideration under the proposal form the basis for multiple regulatory actions that EPA and other agencies have taken over the course of many years. Consider, for example, early studies on the neurological effects of low-dose exposure to lead such as Herbert Needleman's 1979 paper finding a negative relationship between the level of lead in children's teeth and IQ scores.[38] EPA relied on this study in its 1986 Air Quality

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[34] *The Science Panel Website*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/index.html (last updated Jan. 4, 2017). Even the scientists selected to lead the research were provided with access only to de-identified data from the participants, except in the case of some participants who consented to provide additional data for follow-up studies.

[35] Goldman & Silbergeld, *supra* note 27, at 150.

[36] Ioannidis was one of the authors of Marcus R. Munafò et al., *A Manifesto for Reproducible Science*, 1 NATURE HUMAN BEHAVIOUR 1 (2017), DOI: 10.1038/s41562-016-0021, http://www.nature.com/articles/s41562-016-0021.pdf.

[37] John P.A. Ioannidis, *All Science Should Inform Policy and Regulation*, 15(5) PLOS MEDICINE 1, 1-2 (May 3, 2018), https://doi.org/10.1371/journal.pmed.1002576.

[38] Herbert L. Needleman, et al., *Deficits in Psychologic and Classroom Performance of Children with Elevated Dentine Lead Levels*, 300 NEW ENGLAND J. MEDICINE 689 (1979).

Criteria document for lead.[39] EPA's Lead and Copper Rule, which established the federal regulations for lead under the Safe Drinking Water Act, in turn relied on that Air Quality Criteria document to identify blood lead levels of concern.[40] EPA relied on both the 1986 Air Quality Criteria and on Needleman's research directly in establishing standards for lead-based paint hazards under the Toxic Substances Control Act.[41] Needleman's work, and subsequent studies building upon it, also supported EPA's decision to revise the NAAQS for lead in 2008.[42] The D.C. Circuit specifically ruled that the underlying data from one of the studies on which EPA relied in this rulemaking did not need to be publicly available for EPA to rely on the study.[43]

After 40 years, and with the principal investigator no longer alive, it is not clear that the raw data from the Needleman study is available. Even if the data were, they could not be made publicly available without invading the privacy of the study participants. Importantly, it would not be possible to conduct that same study at this time, because children no longer have blood or dental lead levels as high as they did in the 1970s as a result of EPA's implementation of the Statutes.

EPA's drinking water standard for arsenic under the Safe Drinking Water Act is similarly dependent on studies that the agency would now be compelled to ignore under the proposed rule. EPA established a drinking water standard of 10 ppb for arsenic in 2001.[44] The Food and Drug Administration ("FDA") then relied on EPA's determination.[45] In setting this standard, EPA relied on a National Research Council review of the scientific evidence, which "concluded that [certain epidemiological] studies from Taiwan provided the current best available data for the risk assessment of inorganic arsenic-induced cancer."[46] The Taiwanese papers looked at rates of skin cancer and blackfoot disease in villagers from southwestern Taiwan who were exposed to

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[39] EPA, AIR QUALITY CRITERIA FOR LEAD, VOL. IV, 12-86 to 12-88, 12-95 (1986), https://nepis.epa.gov/Exe/ZyPDF.cgi/9101HLA1.PDF?Dockey=9101HLA1.PDF.

[40] Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper, 56 Fed. Reg. 26,460, 26,468–26,469 (June 7, 1991).

[41] Lead; Identification of Dangerous Levels of Lead, 63 Fed. Reg. 30,302, 30,316–30,317 (proposed June 3, 1998). The final rule was published at 66 Fed. Reg. 1,206 (Jan. 5, 2001).

[42] National Ambient Air Quality Standards for Lead, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

[43] *Coal. of Battery Recyclers Ass'n v. E.P.A.*, 604 F.3d 613, 622-624 (D.C. Cir. 2010) (rejecting need to make raw data publicly available from Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113 ENVTL. HEALTH PERSPECTIVES 894 (2005)).

[44] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6,976, 7,036 (Jan. 22, 2001).

[45] The FDA subsequently relied on EPA's drinking water standard, as well as the research underlying it, when it proposed an action level for arsenic for apple juice in 2013. *See* Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic Arsenic in Apple Juice; Availability, 78 Fed. Reg. 42,086 (July 15, 2013); *see also* Clark D. Carrington et al., FDA, *A Quantitative Assessment of Inorganic Arsenic in Apple Juice* (2013), https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM360016.pdf.

[46] National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 65 Fed. Reg. 38,888, 38,902 (proposed June 22, 2000).

high levels of arsenic in their drinking water.[47] These studies were based on data from clinical examinations of the research subjects and therefore included confidential patient data that likely cannot be released to the public. In addition, given that the first data were collected more than 50 years ago, the studies are based on data that may no longer be available.

Even though the proposed rule "is intended to apply prospectively," it will also have a retroactive impact. Some of the Statutes require EPA to periodically review its prior regulatory decisions. For example, EPA must reconsider the lead NAAQS every five years.[48] EPA is also in the process of reconsidering the Lead and Copper Rule under the Safe Drinking Water Act.[49] The proposed rule would prohibit EPA from continuing to rely on Needleman's critically-important study in future reconsiderations of the lead NAAQS and revisions to the Lead and Copper Rule.

Other future rulemakings would also be undermined by the proposed rule. In 2011, EPA decided to regulate perchlorate as a contaminant under the Safe Drinking Water Act.[50] "Perchlorate is commonly used as an oxidizer in rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches, and signal flares" and is also present in some fertilizers.[51] It is known to disrupt thyroid function by competitively inhibiting the uptake of iodide by the thyroid, and EPA in 2011 concluded "that there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern."[52] Late in 2017, EPA issued a draft report identifying potential approaches to deriving a maximum contaminant level goal for perchlorate.[53] To develop these approaches, EPA focused on five epidemiological studies.[54] All five studies relied on confidential patient data. In addition, all five studies were

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[47] The original papers were W.P. Tseng et al., *Prevalence of Skin Cancer in an Endemic Area of Chronic Arsenicism in Taiwan*, 40 J. NAT'L CANCER INST. 453 (1968) and Wen-Ping Tseng, *Effects and Dose Response Relationships of Skin Cancer and Blackfoot Disease with Arsenic*, 19 ENVTL. HEALTH PERSP. 109 (1978). Subsequent articles discussed longer-term health effects among the study cohort.

[48] 42 U.S.C. § 7409(d)(1).

[49] *See Lead and Copper Rule Long-Term Revisions*, EPA, https://perma.cc/U5GV-B93M.

[50] Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7,762 (Feb. 11, 2011).

[51] *Perchlorate in Drinking Water*, EPA, https://www.epa.gov/dwstandardsregulations/perchlorate-drinking-water (last visited August 3, 2018).

[52] 76 Fed. Reg. at 7,763.

[53] EPA, *Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (2017), https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0438-0019.

[54] *Id.* at 6-1 to 6-19 (citing Tim I. M. Korevaar et al., *Association of Maternal Thyroid Function during Early Pregnancy with Offspring IQ and Brain Morphology in Childhood: A Population-based Prospective Cohort Study*, 4 THE LANCET DIABETES & ENDOCRINOLOGY 35 (2016); Martijn J. J. Finken et al. *Maternal Hypothyroxinemia in Early Pregnancy Predicts Reduced Performance in Reaction Time Tests in 5- to 6-Year-Old Offspring*, 98 J. CLINICAL ENDOCRINOLOGY & METABOLISM 1417 (2013); F. Vermiglio et al., *Attention Deficit and Hyperactivity Disorders in the Offspring of Mothers Exposed to Mild-Moderate Iodine Deficiency: A Possible Novel Iodine Deficiency Disorder in Developed Countries*, 89 J. CLINICAL ENDOCRINOLOGY & METABOLISM 6054 (2004); Victor J. Pop et al., *Maternal Hypothyroxinemia during Early Pregnancy and Subsequent Child Development: A 3-year Follow-up Study*, 59 CLINICAL ENDOCRINOLOGY 282 (2003); Victor J. Pop et al., *Low Maternal Free Thyroxine Concentrations during Early Pregnancy Are Associated with Impaired Psychomotor Development in Infancy*, 50 CLINICAL ENDOCRINOLOGY 149 (1999)).

carried out in Europe, where scientists may be subject to different data confidentiality requirements than in the United States. As a result, the proposed rule risks undermining the scientific basis for this EPA action as well.

Many other EPA rulemakings and decisions have relied on studies that cannot be replicated and whose data likely could not be made publicly available. For example:

- **PCBs**: EPA's regulations establishing water quality standards for polychlorinated biphenyls ("PCBs") under the Clean Water Act were based in part on long-term epidemiological studies of cancer rates in workers exposed to PCBs.[55]

- **Radionuclides**: EPA's Safe Drinking Water Act regulation for radionuclides relied on epidemiological studies of survivors from the Hiroshima and Nagasaki atomic bomb attacks.[56]

- **Particulate matter**: EPA's 1997, 2006, and 2012 NAAQS for fine particulate matter all relied on studies using confidential data, such as the Six Cities Study.[57]

- **Methylmercury**: EPA's reference dose for methylmercury in fish that will be consumed by humans relied on data from human exposures in the Faroe Islands.[58]

Precluding reliance on these and other studies for the sole reason that the underlying raw data has not been or cannot be released to the public is arbitrary, capricious, contrary to professional best practices, and antithetical to protection of public health and safety as required by the Statutes. The proposed rule will prevent EPA from relying on the "best available science."

III. "TRANSPARENCY" IN SCIENCE DOES NOT REQUIRE RELEASE OF PRIVATE INFORMATION; IT REQUIRES A CLEAR STATEMENT AND DETAILED DESCRIPTION OF THE METHODOLOGY USED BY THE RESEARCHER

Transparency is valuable and important. As used in the draft rule, however, transparency is a guise for excluding large bodies of valid—and best available—science. The concept of

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[55] Thomas Sinks et al., *Mortality among Workers Exposed to Polychlorinated Biphenyls*, 136 AM. J. EPIDEMIOLOGY 389 (1992); Pier Alberto Bertazzi et al., *Cancer Mortality of Capacitor Manufacturing Workers*, 11 AM. J. INDUS. MED. 165 (1987).

[56] *See* Environmental Data and Governance Initiative ("EDGI"), *Public Protections Under Threat at the EPA: Examining Safeguards and Programs That Would Have Been Blocked by H.R. 1430* 9-10 (2017), https://perma.cc/3NUU-MDHM.

[57] Douglas W. Dockery, et al., *An Association between Air Pollution and Mortality in Six U.S. Cities*, 329 NEW ENGLAND J. MED. 1753 (1993).

[58] P. Grandjean, et al., *Cognitive Deficit in 7-Year-Old Children with Prenatal Exposure to Methylmercury*, 19(6) NEUROTOXICOL TERATOL 417 (1997).

transparency promoted by the draft rule is harmful to good decision-making, to implementation of the Statutes, and, most of all, to protection of public health and safety.

In the professional scientific and medical research community, "transparency" means clear and detailed disclosure of all methods, data, assumptions, and uncertainties. Studies are considered "transparent" when the study design and methodology are clear enough to allow other scientists to challenge assumptions, test hypotheses, and either reproduce or replicate the study to determine whether the results obtained are consistent with the original study. Having the raw data associated with the original study is not usually necessary to validate a study.[59]

Transparency does *not* mean violating the confidentiality of study participants or making all raw data publicly available. The proposed rule does not comport with the fundamental approach to conducting scientific and medical research that is the standard practice for experienced, advanced scholars and researchers.

Nor is it necessary to reproduce[60] a study to validate it. The proposal provides that "[i]nformation is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and *replicate* [sic] findings."[61] Neither reproducing nor replicating studies is always possible. Indeed in some circumstances it would be inhumane, immoral, or physically impossible to do so. Some studies involve natural disasters, other one-time events, or exposures and conditions that no longer exist and cannot be reproduced or replicated. Those studies are valid but would be excluded by the proposed rule. Examples include:

- Studies of Hiroshima and Nagasaki survivors that underlie Safe Drinking Water Act radionuclides regulation;
- Studies of the effects of lead from 1970s, when blood lead levels were higher than they are now;
- Studies of worker exposure to polychlorinated biphenyls before PCBs were banned; these studies formed the basis of water quality standards for PCBs under the Clean Water Act;
- Long-term cohort studies of benzene exposure in workers which formed the basis of EPA's 2007 Clean Air Act regulation for emissions of hazardous air pollutants from mobile sources; and

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[59] *See supra* notes 3, 7, 8. In the rare instance when the raw data is needed to validate a study, EPA already has the ability to request it. This should be the exception, not the default as it has become in the proposed rule. If, ultimately, EPA is unable to obtain the raw data to verify the study results, it is within the agency's discretion to categorize such data as "qualitative," and taking into consideration inherent uncertainties, weigh the study relative to other evidence. *See* EPA, *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessments* 9 (Aug. 28, 2012), https://www.epa.gov/sites/production/files/2015-07/documents/lit-studies.pdf.

[60] In the proposed rule, EPA incorrectly uses the term "replicate." *See* note 3, above.

[61] 83 Fed. Reg. at 18,773–18,774.

- Studies based on the massive oil leak at Deepwater Horizon.

IV. THE PROPOSED RULE IGNORES MECHANISMS THAT ALREADY EXIST TO DEAL WITH CONCERNS ABOUT ACCESS TO RAW DATA

The proposed rule fails to acknowledge numerous federal laws, regulations, and guidance that regulate the quality of and access to raw data. These include: the Information Quality Act, Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("OMB Uniform Guidance"),[62] and EPA's own Information Quality Guidelines. These already address the data access concerns that EPA raises in the proposed rule. Moreover, the proposed rule is inconsistent with some aspects of these other requirements. For example, OMB Uniform Guidance exempts from its definition of "research data" subject to disclosure any "medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."[63] In contrast, the proposed rule would generally prohibit EPA from relying on studies based on data not disclosed to the public, even when disclosure would be a clearly unwarranted invasion of personal privacy. Any decision to consider the study while allowing the data to remain confidential is left to the whim of the EPA Administrator. This standardless, case-by-case approach is inconsistent with OMB's uniform privacy protections.

In the proposed rule, EPA ignores a variety of commonly-used mechanisms for assessing and ensuring the validity of studies without requiring public disclosure of the raw data. These mechanisms include peer reviews, pre-registration of study methodology, corroboration of results by subsequent studies, and in some instances special agreements that enable an independent third party, such as the Health Effects Institute ("HEI"), to re-analyze the raw data. As explained by the Science Advisory Board, the HEI's reanalysis of the Six Cities Study, through "an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods."[64]

For these reasons, the public health, medical, and scientific research community does not regard the public disclosure of all raw data as necessary. For example, the Committee on Publication Ethics ("COPE"), which has over 12,100 member journals and editors covering all areas of scholarly inquiry, has established 10 core practices. COPE's core practice #5 on data and reproducibility provides that "[j]ournals should include policies on data availability and encourage the use of reporting guidelines and registration of clinical trials and other study

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[62] *See* OMB, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 78 Fed. Reg. 78,590, at 78,631, 2 C.F.R. § 200.315(e)(3) (Dec. 26, 2013) (guidance incorporated from OMB, *OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations* § 36(d) (as amended Sept. 30,1999)) [hereinafter "OMB, *Uniform Guidance*"].

[63] OMB, *Uniform Guidance*, 2 C.F.R. § 200.315(e)(3)(ii).

[64] SAB Memo, *supra* note 8, at 4.

designs according to standard practice in their discipline."[65] The simplicity and generality of this core practice statement signals that the question of standards for data transparency, data access, data sharing, data peer review, and replication and reproducibility practices are far from settled. There is no one-size-fits-all approach to the critical questions of data transparency, data sharing, and reproducibility.

The proposed rule was announced by EPA without any meaningful consultation with the broad research community despite the fact that it addresses a complex and contentious issue that is not yet ripe for regulatory action. There are ample and adequate safeguards in place at the leading journals to ensure "transparency" – the ability of other researchers to question, challenge, and validate the results of published studies. This would include the journals' policies on treatment of data from research published years and even decades ago. It is contrary to good scientific study and practice and the advancement of knowledge for EPA to arrogate to itself the determination of what constitutes useable research and data, and to grant sweeping discretion to the Administrator—who may not even be a scientist—to make those determinations.

In a rare joint statement, the editors of the journals *Science*, *Nature*, *PLOS One*, *Proceedings of the National Academy of Sciences*, and *Cell* explained:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[66]

As has long been recognized by the professional public health, medical, and scientific research community—and by EPA itself until now[67] —whether or not the raw data underlying a study is released does not determine the quality of the study. Rather, it is the scientific method that is determinative. The proposed rule fails to take into account the fact that studies are reliable and constitute the best available science when they comply with professionally-established best practices for describing the methodology, sampling size, sampling procedure and assumptions utilized and the results are consistent with those of other studies.

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[65] *Core Practices*, COPE, https://publicationethics.org/core-practices (last visited August 3, 2018) (copy attached for inclusion in the administrative record, Attachment 5).

[66] Jeremy Berg et al., *Joint Statement on EPA Proposed Rule and Public Availability of Data*, SCIENCE (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116 (copy attached for inclusion in the administrative record, Attachment 6).

[67] *See supra* note 7.

V. THE PROPOSAL WOULD IMPOSE AN IMMENSE AND UNNECESSARY COST AND PAPERWORK BURDEN ON EPA, OTHER FEDERAL AGENCIES, AND THE RESEARCH COMMUNITY

EPA has not established a legitimate need for the proposed rule. EPA has made thousands of regulatory decisions over the last 50 years. The Congressional Budget Office estimates that EPA "relies on about 50,000 scientific studies annually to perform its mission."[68] The proposed rule fails to identify a single regulatory action based on faulty science.[69] The rule is not needed or warranted. It will do far more harm than good.

Although OMB did not have a meaningful opportunity to review the proposed rule before former Administrator Pruitt signed and released it (OMB had a mere five days) and presumably did not intend to allow EPA's new definitions to modify OMB's Uniform Guidance, one might argue that that is an effect of the proposed rule. If so, its radical and erroneous "transparency" requirements would extend to all federal agencies, wreaking chaos.

The CBO estimates that it will cost between $10,000 and $30,000 per study to make the raw data available.[70] If EPA continues to rely on roughly the same number of studies, it could cost hundreds of millions of dollars a year to implement the proposal. Imposing these costs on all federal agencies would be a staggering burden. Given the cost and the impracticality of releasing all raw data to the public, EPA will have effectively but wrongly undermined public health and safety.[71]

Even if EPA or the researchers do spend this money and considerable time to de-identify data to comply with the proposed rule, that effort will not necessarily protect patient or research subject confidentiality. As mentioned above, it is frequently possible to re-identify individuals from supposedly de-identified datasets. For example, one study found that the researchers could re-

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[68] Congressional Budget Office ("CBO"), *Cost Estimate: H.R. 1030, Secret Science Reform Act of 2015* 2 (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

[69] Importantly, this proposed rule shifts the presumption of validity away from non-biased, peer-reviewed studies conducted by professional and academic researchers to non-peer reviewed studies conducted by the interested, regulated enterprises. In fact, if there is a problem anywhere in the science on which EPA relies, it is in the industry studies submitted for licensing and permitting—yet these actions are excluded from the coverage of the rule by the definition of "regulatory decisions." *See* Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 559-63 (2002) (detailing incidents in which data required to be submitted by manufacturers or their contractors under the Federal Fungicide, Insecticide, and Rodenticide Act ("FIFRA") and the Food, Drug, and Cosmetic Act ("FDCA") were either withheld or were misleading or fraudulent); *cf.* SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTURE OF BIOMEDICAL RESEARCH? (2003) (discussing this problem throughout the book and providing considerable support).

[70] CBO, *supra* note 68, at 2.

[71] In the proposal, EPA cites a paper prepared by Randall Lutter and David Zorn for the Mercatus Center, which arrives at a lower cost estimate than the CBO, to support its conclusion that "the benefits of this proposed rule justify the costs." 83 Fed. Reg. at 18,772 & n.24. EPA cannot abdicate its responsibility to conduct its own analysis of the costs and benefits of this regulation by relying on this paper.

identify approximately one-quarter of the records in a subset of a HIPAA-compliant environmental health dataset.[72]

Relatedly, for some studies (e.g. prospective cohort studies that include extensive personal data; environmental health effects studies), it is impossible to de-identify the data without negating its scientific value. To protect against re-identification, it would be necessary to remove so much demographic information from the dataset that other scientists would not be able to perform meaningful re-analyses of the data.

VI. THE PROPOSED RULE WOULD CREATE CONFUSION AND CHAOS DETRIMENTAL TO THE PROTECTION OF PUBLIC HEALTH

The proposal, as drafted, contains significant ambiguities. As a result, it is entirely unclear what the effect of the proposed rule will be on studies that have already formed the basis of existing rules but as to which the underlying raw data has not been and cannot be made available for various reasons. These studies are considered by professionals to be the "best" available science.

The following crucial questions are not addressed by the proposed rule:

1. Will EPA continue to rely on those studies or will they now arbitrarily be excluded from consideration?

2. Will EPA implement the new rule by ensuring that raw data are made available (very costly) or simply by ignoring existing, valid studies as to which the data cannot be made available or would be extremely expensive to de-identify?

3. How will EPA implement its exemption authority? What are the governing standards for when the Administrator will exercise this authority?

4. Will the proposed rule apply to old studies or only new ones and to past regulatory decisions or only new ones? The latter point is especially a concern under statutes that require EPA to revise standards periodically. Will previously-established standards be abandoned because the data from the studies underlying those decisions (in many cases decades old) is no longer available?

5. How will the proposal affect the actions of other agencies that rely on EPA's findings or decisions or that provide information to EPA? For example, what will the effect be on Agency for Toxic Substances and Disease Registry ("ATSDR") analyses that EPA is required to consider pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act?

6. How will EPA's re-interpretation of OMB's Uniform Guidance and other rules that apply uniformly to the entire federal government be administered? For example, how will the Food and Drug Administration's review of applications for new drugs be affected?

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[72] Sweeney, et al., *supra* note 28.

In addition, EPA has not included any analysis of the impact of the proposed rule on its existing or future regulations.

Many of the signatories conduct studies, reports, analyses, and models that are used to support the work of numerous state and federal agencies. The proposed rule will interfere with the ability of these agencies to work together as required by some statutes to develop joint approaches to protection of public health and safety due to the restrictions in the proposed rule. Specifically, the rule will impede EPA's ability to work effectively with the Food and Drug Administration, ATSDR, the Department of Agriculture, and other agencies whose mission is to protect public health.

VII. THE PROPOSED NEW APPROACH TO DOSE-RESPONSE MODELING IS ANTITHETICAL TO PROPER SCIENTIFIC METHODOLOGY AND CONTRAVENES THE ADVICE OF EXPERTS IN THE FIELD, INCLUDING THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

EPA proposes to use "default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis....When available, EPA shall give explicit consideration to high quality studies that explore: a broad class of parametric dose-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity."[73] This proposed new approach allows for assuming a safe threshold below which humans can be exposed to chemicals in circumstances where data may be sparse. This approach runs counter to EPA's own historic practice and to the best practice employed by the scientific community when conducting risk assessments. Specifically, the National Research Council has recommended that linear and conceptual models be used "unless data is sufficient to reject low-dose linearity."[74] The scientific research and risk assessment community have also reached a consensus that cancer and non-cancer risk assessment should be unified so that all compounds, not just carcinogens, should be subjected to benchmark dose modeling.[75] This means that researchers should not assume a safe threshold of exposure even for non-carcinogens such as lead and mercury.[76]

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[73] 83 Fed. Reg. at 18,774.

[74] This has also been the position of the federal government since 1983. Eileen Abt, et al. *Science and Decisions: Advancing Risk Assessment*, 30 RISK ANALYSIS 1028 (2010); Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences and National Research Center, *Risk Assessment in the Federal Government: Managing the Process* (1983), http://www.nap.edu/catalog/366/risk-assessment-in-the-federal-government-managing-the-process.

[75] EPA, Risk Assessment Forum, *Benchmark Dose Technical Guidance* (June 2012), https://www.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf; Eileen Abt, et al. *Science and Decisions: Advancing Risk Assessment*, 30 RISK ANALYSIS 1028 (2010).

[76] EPA, *supra* note 75; Eileen Abt, et al., *supra* note 75.

The approach EPA proposes also conflicts with the advice of EPA's own Science Advisory Board as well as the advice of the National Academies of Sciences, Engineering, and Medicine.[77] And, EPA's proposed new approach directly conflicts with the statutory mandates that it must protect develop rules that protect human health "with an adequate margin of safety."[78]

EPA's assertion in the proposed rule that there is "growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects" is dangerous and unsupported by scientific evidence.[79] In recent years, several toxicants such as lead and particulate matter air pollution have been shown to have either superlinear responses at low dose or no threshold.[80] The consensus of the academic scientific community has been for over a decade that threshold effects should not be presumed in the absence of robust concentration-response data.[81] Accordingly, this comment letter endorses and incorporates by reference the comments on this point that have been submitted by: The National Academies of Sciences, Engineering, and Medicine dated July 16, 2018, and the Center for Science in the Public Interest dated July 17, 2018.

VIII. THE RULE SHOULD BE WITHDRAWN

The proposed rule will undermine EPA's ability to fulfill its mission to protect human health, safety, and the environment by using the best available information and science. First, the proposed rule would exclude from EPA's consideration any reports, studies, analyses, and models that rely on confidential, inaccessible, or unavailable data but that historically have been considered the best available science and therefore used to support regulations and standards designed to protect public health and safety. Second, in so doing, the rule also eliminates EPA's access to fundamental information necessary for identifying and calculating the "health benefits" of rules and standards needed to protect public health. Finally, it threatens to impose significant costs on both the federal government and independent scientists. Worst of all, the proposed rule creates these multiple problems without providing any significant countervailing benefits.

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[77] EPA, *supra* note 75; Eileen Abt, et al., *supra* note 75.

[78] For example, the Clean Air Act, 42 U.S.C. § 7409(b)(1) (setting NAAQS); the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(4)(A) (setting Maximum Contaminant Level Goals ("MCLG's")).

[79] 83 Fed. Reg. at 18,770.

[80] Bruce P. Lanphear, et al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis,* 113 ENVTL. HEALTH PERSP. 894 (July 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1257652/; Joel Schwartz, *Assessing Confounding, Effect Modification, and Thresholds in the Association between Ambient Particles and Daily Deaths*, 108 ENVTL. HEALTH PERSP. 563 (June 2000), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1638159/pdf/envhper00307-0129.pdf; Qian Di, et al., *Association of Short-term Exposure to Air Pollution With Mortality in Older Adults*, JAMA NETWORK (Dec. 26, 2017), https://jamanetwork.com/journals/jama/fullarticle/2667069.

[81] Eileen Abt, et al., *supra* note 75.

For these and all of the reasons explicated above, the proposed rule should be withdrawn.

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The JAMA Forum

A Breath of Bad Air: Cost of the Trump Environmental Agenda May Lead to 80 000 Extra Deaths per Decade

David Cutler, PhD; Francesca Dominici, PhD

President Donald Trump and Environmental Protection Agency (EPA) Administrator Scott Pruitt have pledged to reexamine landmark environmental policies and to repeal regulations. In their view, excessive regulations are harming US industry, and thus reducing regulation will be good for business. As Donald Trump has said, seemingly without irony, "We are going to get rid of the regulations that are just destroying us. You can't breathe—you cannot breathe."

Stockbyte/Thinkstock

As has become apparent, however, it is the changes Trump is proposing that are likely to make breathing more difficult. A central feature of his agenda is environmental damage: making the air dirtier and exposing people to more toxic chemicals. The beneficiaries, in contrast, will be a relatively few well-connected companies.

The Trump Agenda

In pursuit of its wide-ranging environmental agenda, the administration has already reversed or proposed to reverse more than 60 environmental rules. The full extent of the effects on health has not been tabulated and is hard to quantify, but guesses can be made for some of the larger ones (see the Table).

The largest health consequences are likely to come through changes in air quality. The Trump administration has announced its intention to repeal the Clean Power Plan rule, President Barack Obama's signature policy on climate change. The rule provides for the EPA to assign each state a goal for limiting emissions from existing power plants and gives the states latitude in meeting those goals, such as switching from coal to natural gas or building new wind or solar farms. Based on the regulatory impact analysis done by the EPA when the rule was implemented (as well as other analyses), repealing the rule would lead to an estimated 36 000 deaths each decade and nearly 630 000 cases of respiratory infection in children alone.

The administration is also targeting the control of air pollution from motor vehicles, indicating a desire to weaken greenhouse gas and fuel economy targets for automobiles. Nothing formal has been proposed, but Trump has spoken about rolling back new rules put in place by the Obama administration. Based on the regulatory impact analysis performed when those rules were proposed, it was estimated that they would lead to a reduction of 5500 deaths and 140 000 cases of respiratory ailments in children over a decade—benefits that would be lost if the rules are rolled back. Repealing these rules will also have negative effects on certain types of jobs, the environment (global warming pollution), and consumer savings. The administration is also planning to repeal the emission requirements for glider vehicles—rebuilt trucks that do not meet current environmental standards—a loophole that could lead to as many as 41 000 premature deaths per decade and 900 000 cases of respiratory tract symptoms.

Other elements of the administration's environmental agenda will also affect health, though it is hard to know by how much. Withdrawing from the Paris agreement on global warming, imposing tariffs on solar panels, and rolling back the "once in, always in" rule for industrial plants will all lead to increases in fine particulate matter and additional exposure to pollutants such as sulfur dioxide, nitrogen oxides, mercury, and others that adversely affect respiratory and cardiovascular health.

Water quality is also being targeted. The Trump EPA has proposed to rescind the Waters of the United States rule published in 2015, which brought more US streams and wetlands areas under the Clean Water Act. Rivers and streams are sources of drinking water for more than 130 million people and if polluted, might pose major health risks. The rule itself does not mandate any specific changes in water cleanliness, so we do not estimate a specific health consequence of repealing this rule.

Finally, the administration is proposing to withdraw or not implement regulatory actions affecting particular chemicals shown to be harmful to health, including lead, agricultural pesticides, and coal ash waste. Exposure to these hazardous substances will affect fewer people than the number of individuals affected by air pollution, but each will affect a concentrated number. As Christine Todd Whitman, head of the EPA under President George W. Bush, said: "You stop enforcing those regulations and [deaths] will go way up."

Overall, an extremely conservative estimate is that the Trump environmental agenda is likely to cost the lives of over 80 000 US residents per decade and lead to respiratory problems for many more than 1 million people. This sobering statistic captures only a small fraction of the cumulative public health damages associated with the full range of rollbacks and systemic actions proposed by the Trump administration.

An Attack on Science

One might imagine that the science that supported enactment of these rules would make repealing them difficult. But that is not the case. Even as it is targeting environmental rules, the Trump administration is taking aim at the use of science that supports public policy.

Scott Pruitt recently signed a controversial rule stipulating that policy can be based only on research for which the underlying data have been made accessible to the general public. The idea is to

Proposed Changes in Environmental Protections and Possible Effects

Area	Actions	Projected Effects
Air Quality	Repeal of Clean Power Plan	• Increases exposure to small atmospheric particulate matter • An estimated 36 000 deaths over a decade • An estimated 630 000 cases of respiratory ailments in children over a decade
	Rollback of CAFE[a] standards for automobiles	• Increases exposure to small atmospheric particulate matter and ozone • An estimated 5500 deaths over a decade • An estimated 140 000 cases of respiratory ailments in children over a decade
	Repeal of emission requirements for glider vehicles	• Allows noncompliant diesel trucks on the roads • An estimated 41 000 premature deaths over a decade • An estimated 900 000 cases of respiratory ailments over a decade
	Loosening of other air pollution rules (eg, power plants, solar power tariffs)	• Potential for industrial plants to increase emissions by 4 times • Endangering those living near power plants (areas of high poverty)
Water Quality	Repeal of Waters of the United States rule	• Exposes water sources for approximately 117 million US residents • At least 1 million people in each of 21 different states depend on small streams for their drinking water
Chemicals	Scale back of lead-risk reduction program	• Leaves an estimated 4 million households with children at risk of exposure to high levels of lead • Approximately 500 000 children currently have elevated blood lead levels
	Delay or reduction of chemical bans	• Exposes toddlers and older children to 11 to 15 times the recommended levels of chlorpyrifos (because of denial of ban on use in agriculture) • Exposes public to 3 carcinogens (methylene chloride, trichloroethylene, and N-Methylpyrrolidone) used in furniture stripping, grease removal, and dry cleaning (action delayed)
	Weakening of rules on coal ash waste	• More than 100 million tons of coal ash are produced annually, resulting in more than 100 documented cases of coal ash poison contamination in the drinking water, wetlands, creeks, and rivers between 1948 and 2008

[a] There is substantial uncertainty with respect to the extent of the rollback of the Corporate Average Fuel Economy (CAFE) rules. Projected health effects are calculated based on the assumption of full achievement of CAFE standards vs rollback of those standards.

remove most observational studies of health effects of air pollution exposure from being considered in regulatory settings, unless the individual health records are made publicly available. This is a nearly impossible task because the health data are collected under the agreement to maintain patient confidentiality. With no evidence of harms (because of constraints on presenting the available evidence), regulations cannot be sustained. On April 23, 985 scientists sent him a letter urging him to abandon the proposal.

Fortunately for those interested in public health, the regulatory process will take many years. Whoever is sworn in as President in January 2021 will have a large effect on whether the Trump administration's full environmental agenda goes into effect.

Implications for Physicians and Policy

For physicians, the manifestation of these changes is likely to be an increase in disease and number of deaths. Respiratory and cardiovascular problems are most likely, but a wide variety of conditions are likely to be seen. Poor, black, or elderly populations are likely to be affected the most. People working with chemicals in industrial settings will also be affected, as will people who live in areas with high concentrations of power plants such as the Ohio River Valley from Indiana to Pennsylvania, and in the southeast from Alabama and Georgia to Maryland.

One could debate the merits of these tradeoffs if there were a large number of people who would benefit economically from these changes. In practice, however, any economic benefits are not likely to accrue to those most in need. Employment is down in many fossil fuel industries because technology has made workers less necessary for production, not because of environmental regulations. And even if a large number of coal jobs were restored, it would come at the expense of employment in new industries such as wind and solar, which are already being hurt by the Trump administration policies. Not having to comply with environmental rules will increase corporate profits, but not worker bank accounts.

Overall, the ultimate effects of the Trump administration's policies seem clear, even through the haze they will create. ■

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Air Pollution and Mortality in the Medicare Population

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ABSTRACT

BACKGROUND

Studies have shown that long-term exposure to air pollution increases mortality. However, evidence is limited for air-pollution levels below the most recent National Ambient Air Quality Standards. Previous studies involved predominantly urban populations and did not have the statistical power to estimate the health effects in underrepresented groups.

METHODS

We constructed an open cohort of all Medicare beneficiaries (60,925,443 persons) in the continental United States from the years 2000 through 2012, with 460,310,521 person-years of follow-up. Annual averages of fine particulate matter (particles with a mass median aerodynamic diameter of less than 2.5 μm [$PM_{2.5}$]) and ozone were estimated according to the ZIP Code of residence for each enrollee with the use of previously validated prediction models. We estimated the risk of death associated with exposure to increases of 10 μg per cubic meter for $PM_{2.5}$ and 10 parts per billion (ppb) for ozone using a two-pollutant Cox proportional-hazards model that controlled for demographic characteristics, Medicaid eligibility, and area-level covariates.

RESULTS

Increases of 10 μg per cubic meter in $PM_{2.5}$ and of 10 ppb in ozone were associated with increases in all-cause mortality of 7.3% (95% confidence interval [CI], 7.1 to 7.5) and 1.1% (95% CI, 1.0 to 1.2), respectively. When the analysis was restricted to person-years with exposure to $PM_{2.5}$ of less than 12 μg per cubic meter and ozone of less than 50 ppb, the same increases in $PM_{2.5}$ and ozone were associated with increases in the risk of death of 13.6% (95% CI, 13.1 to 14.1) and 1.0% (95% CI, 0.9 to 1.1), respectively. For $PM_{2.5}$, the risk of death among men, blacks, and people with Medicaid eligibility was higher than that in the rest of the population.

CONCLUSIONS

In the entire Medicare population, there was significant evidence of adverse effects related to exposure to $PM_{2.5}$ and ozone at concentrations below current national standards. This effect was most pronounced among self-identified racial minorities and people with low income. (Supported by the Health Effects Institute and others.)

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A Quick Take is available at NEJM.org

The adverse health effects associated with long-term exposure to air pollution are well documented.[1,2] Studies suggest that fine particles (particles with a mass median aerodynamic diameter of less than 2.5 μm [$PM_{2.5}$]) are a public health concern,[3] with exposure linked to decreased life expectancy.[4-6] Long-term exposure to ozone has also been associated with reduced survival in several recent studies, although evidence is sparse.[4,7-9]

Studies with large cohorts have investigated the relationship between long-term exposures to $PM_{2.5}$ and ozone and mortality[4,9-13]; others have estimated the health effects of fine particles at low concentrations (e.g., below 12 μg per cubic meter for $PM_{2.5}$).[14-18] However, most of these studies have included populations whose socioeconomic status is higher than the national average and who reside in well-monitored urban areas. Consequently, these studies provide limited information on the health effects of long-term exposure to low levels of air pollution in smaller cities and rural areas or among minorities or persons with low socioeconomic status.

To address these gaps in knowledge, we conducted a nationwide cohort study involving all Medicare beneficiaries from 2000 through 2012, a population of 61 million, with 460 million person-years of follow-up. We used a survival analysis to estimate the risk of death from any cause associated with long-term exposure (yearly average) to $PM_{2.5}$ concentrations lower than the current annual National Ambient Air Quality Standard (NAAQS) of 12 μg per cubic meter and to ozone concentrations below 50 parts per billion (ppb). Subgroup analyses were conducted to identify populations with a higher or lower level of pollution-associated risk of death from any cause.

METHODS

MORTALITY DATA

We obtained the Medicare beneficiary denominator file from the Centers for Medicare and Medicaid Services, which contains information on all persons in the United States covered by Medicare and more than 96% of the population 65 years of age or older. We constructed an open cohort consisting of all beneficiaries in this age group in the continental United States from 2000 through 2012, with all-cause mortality as the outcome. For each beneficiary, we extracted the date of death (up to December 31, 2012), age at year of Medicare entry, year of entry, sex, race, ZIP Code of residence, and Medicaid eligibility (a proxy for low socioeconomic status). Persons who were alive on January 1 of the year following their enrollment in Medicare were entered into the open cohort for the survival analysis. Follow-up periods were defined according to calendar years.

ASSESSMENT OF EXPOSURE TO AIR POLLUTION

Ambient levels of ozone and $PM_{2.5}$ were estimated and validated on the basis of previously published prediction models.[19,20] Briefly, we used an artificial neural network that incorporated satellite-based measurements, simulation outputs from a chemical transport model, land-use terms, meteorologic data, and other data to predict daily concentrations of $PM_{2.5}$ and ozone at unmonitored locations. We fit the neural network with monitoring data from the Environmental Protection Agency (EPA) Air Quality System (AQS) (in which there are 1928 monitoring stations for $PM_{2.5}$ and 1877 monitoring stations for ozone). We then predicted daily $PM_{2.5}$ and ozone concentrations for nationwide grids that were 1 km by 1 km. Cross-validation indicated that predictions were good across the entire study area. The coefficients of determination (R^2) for $PM_{2.5}$ and ozone were 0.83 and 0.80, respectively; the mean square errors between the target and forecasting values for $PM_{2.5}$ and ozone were 1.29 μg per cubic meter and 2.91 ppb, respectively. Data on daily air temperature and relative humidity were retrieved from North American Regional Reanalysis with grids that were approximately 32 km by 32 km; data were averaged annually.[21]

For each calendar year during which a person was at risk of death, we assigned to that person a value for the annual average $PM_{2.5}$ concentration, a value for average ozone level during the warm season (April 1 through September 30), and values for annual average temperature and humidity according to the ZIP Code of the person's residence. The warm-season ozone concentration was used to compare our results with those of previous studies.[10] In this study, "ozone concentration" refers to the average concentration during the warm season, unless specified otherwise.

As part of a sensitivity analysis, we also obtained data on $PM_{2.5}$ and ozone concentrations from the EPA AQS and matched that data with

each person in our study on the basis of the nearest monitoring site within a distance of 50 km. (Details are provided in Section 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org.)

STATISTICAL ANALYSIS

We fit a two-pollutant Cox proportional-hazards model with a generalized estimating equation to account for the correlation between ZIP Codes.[22] In this way, the risk of death from any cause associated with long-term exposure to $PM_{2.5}$ was always adjusted for long-term exposure to ozone, and the risk of death from any cause associated with long-term exposure to ozone was always adjusted for long-term exposure to $PM_{2.5}$, unless noted otherwise. We also conducted single-pollutant analyses for comparability. We allowed baseline mortality rates to differ according to sex, race, Medicaid eligibility, and 5-year categories of age at study entry. To adjust for potential confounding, we also obtained 15 ZIP-Code or county-level variables from various sources and a regional dummy variable to account for compositional differences in $PM_{2.5}$ across the United States (Table 1, and Section 1 in the Supplementary Appendix). We conducted this same statistical analysis but restricted it to person-years with $PM_{2.5}$ exposures lower than 12 μg per cubic meter and ozone exposures lower than 50 ppb (low-exposure analysis) (Table 1, and Section 1 in the Supplementary Appendix).

To identify populations at a higher or lower pollution-associated risk of death from any cause, we refit the same two-pollutant Cox model for some subgroups (e.g., male vs. female, white vs. black, and Medicaid eligible vs. Medicaid ineligible). To estimate the concentration-response function of air pollution and mortality, we fit a log-linear model with a thin-plate spline of both $PM_{2.5}$ and ozone and controlled for all the individual and ecologic variables used in our main analysis model (Section 7 in the Supplementary Appendix). To examine the robustness of our results, we conducted sensitivity analyses and compared the extent to which estimates of risk changed with respect to differences in confounding adjustment and estimation approaches (Sections S2 through S4 in the Supplementary Appendix).

Data on some important individual-level covariates were not available for the Medicare cohort, including data on smoking status, body-mass index (BMI), and income. We obtained data from the Medicare Current Beneficiary Survey (MCBS), a representative subsample of Medicare enrollees (133,964 records and 57,154 enrollees for the period 2000 through 2012), with individual-level data on smoking, BMI, income, and many other variables collected by means of telephone survey. Using MCBS data, we investigated how the lack of adjustment for these risk factors could have affected our calculated risk estimates in the Medicare cohort (Section 5 in the Supplementary Appendix). The computations in this article were run on the Odyssey cluster, which is supported by the FAS Division of Science, Research Computing Group, and on the Research Computing Environment, which is supported by the Institute for Quantitative Social Science in the Faculty of Arts and Sciences, both at Harvard University. We used R software, version 3.3.2 (R Project for Statistical Computing), and SAS software, version 9.4 (SAS Institute).

RESULTS

COHORT ANALYSES

The full cohort included 60,925,443 persons living in 39,716 different ZIP Codes with 460,310,521 person-years of follow-up. The median follow-up was 7 years. The total number of deaths was 22,567,924. There were 11,908,888 deaths and 247,682,367 person-years of follow-up when the $PM_{2.5}$ concentration was below 12 μg per cubic meter and 17,470,128 deaths and 353,831,836 person-years of follow-up when the ozone concentration was below 50 ppb. These data provided excellent power to estimate the risk of death at air-pollution levels below the current annual NAAQS for $PM_{2.5}$ and at low concentrations for ozone (Table 1).

Annual average $PM_{2.5}$ concentrations across the continental United States during the study period ranged from 6.21 to 15.64 μg per cubic meter (5th and 95th percentiles, respectively), and the warm-season average ozone concentrations ranged from 36.27 to 55.86 ppb (5th and 95th percentiles, respectively). The highest $PM_{2.5}$ concentrations were in California and the eastern and southeastern United States. The Mountain region and California had the highest ozone concentrations; the eastern states had lower ozone concentrations (Fig. 1).

Table 1. **Cohort Characteristics and Ecologic and Meteorologic Variables.**

Characteristic or Variable	Entire Cohort	Ozone Concentration		$PM_{2.5}$ Concentration	
		≥50 ppb*	<50 ppb	≥12 $\mu g/m^3$	<12 $\mu g/m^3$
Population					
Persons (no.)	60,925,443	14,405,094	46,520,349	28,145,493	32,779,950
Deaths (no.)	22,567,924	5,097,796	17,470,128	10,659,036	11,908,888
Total person-yr†	460,310,521	106,478,685	353,831,836	212,628,154	247,682,367
Median yr of follow-up	7	7	7	7	7
Average air-pollutant concentrations‡					
Ozone (ppb)	46.3	52.8	44.4	48.0	45.3
$PM_{2.5}$ ($\mu g/m^3$)	11.0	10.9	11.0	13.3	9.6
Individual covariates‡					
Male sex (%)	44.0	44.3	43.8	43.1	44.7
Race or ethnic group (%)§					
White	85.4	86.6	85.1	82.0	88.4
Black	8.7	7.2	9.2	12.0	5.9
Asian	1.8	1.8	1.8	2.1	1.6
Hispanic	1.9	2.0	1.9	1.9	1.9
Native American	0.3	0.6	0.3	0.1	0.6
Eligible for Medicaid (%)	16.5	15.3	16.8	17.8	15.3
Average age at study entry (yr)	70.1	69.7	70.2	70.1	70.0
Ecologic variables‡					
BMI	28.2	27.9	28.4	28.0	28.4
Ever smoked (%)	46.0	44.9	46.2	45.8	46.0
Population including all people 65 yr of age or older (%)					
Hispanic	9.5	13.4	8.4	8.4	10.0
Black	8.8	7.2	9.3	13.3	6.3
Median household income (1000s of $)	47.4	51.0	46.4	47.3	47.4
Median value of housing (1000s of $)	160.5	175.8	156.3	161.7	159.8
Below poverty level (%)	12.2	11.4	12.4	12.5	12.0
Did not complete high school (%)	32.3	30.7	32.7	35.3	30.6
Owner-occupied housing (%)	71.5	71.3	71.6	68.6	73.2
Population density (persons/km^2)	3.2	0.7	3.8	4.8	2.2
Low-density lipoprotein level measured (%)	92.2	92.0	92.2	92.2	92.2
Glycated hemoglobin level measured (%)	94.8	94.6	94.8	94.8	94.8
≥1 Ambulatory visits (%)¶	91.7	92.2	91.6	91.7	91.7
Meteorologic variables‡					
Average temperature (°C)	14.0	14.9	13.8	14.5	13.7
Relative humidity (%)	71.1	60.8	73.9	73.7	69.6

* Summary statistics were calculated separately for persons residing in ZIP Codes where average ozone levels were below or above 50 ppb and where $PM_{2.5}$ levels were below or above 12 μg per cubic meter. The value 12 μg per cubic meter was chosen as the current annual National Ambient Air Quality Standard (NAAQS) (e.g., the "safe" level) for $PM_{2.5}$. BMI denotes body-mass index (the weight in kilograms divided by the square of the height in meters) and ppb parts per billion.

† The number for total person-years of follow-up indicates the sum of individual units of time that the persons in the study population were at risk of death from 2000 through 2012.

‡ The average values for air pollution levels and for ecologic and meteorologic variables were computed by averaging values over all ZIP Codes from 2000 through 2012.

§ Data on race and ethnic group were obtained from Medicare beneficiary files.

¶ The variable for ambulatory visits refers to the average annual percentage of Medicare enrollees who had at least one ambulatory visit to a primary care physician.

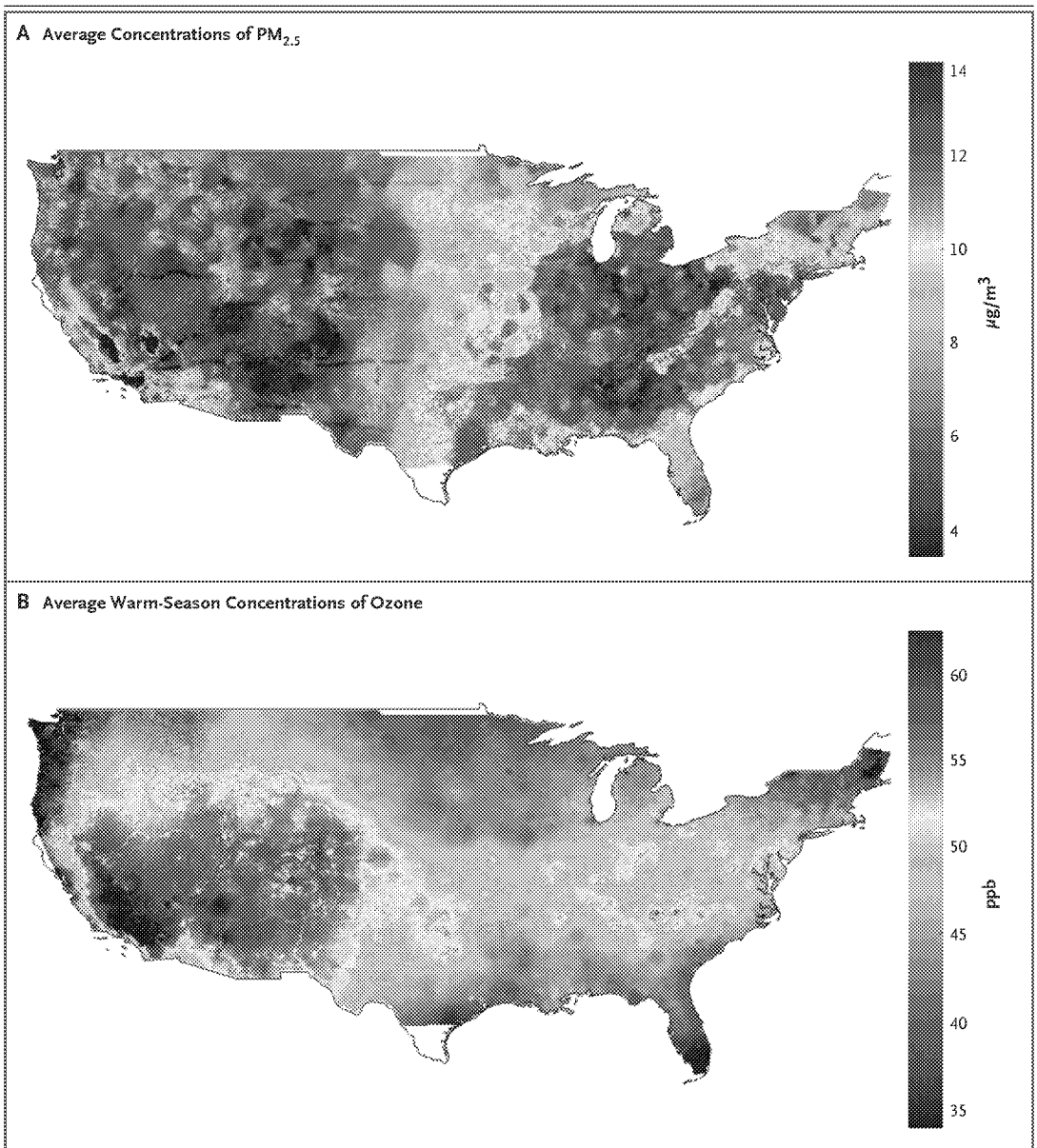

Figure 1. **Average $PM_{2.5}$ and Ozone Concentrations in the Continental United States, 2000 through 2012.**
Panel A shows the average concentrations of fine particulate matter (particles with a mass median aerodynamic diameter of less than 2.5 μm [$PM_{2.5}$]) in micrograms per cubic meter, as estimated on the basis of all daily predictions during the study period. Panel B shows the concentration of ozone levels in parts per billion as averaged from April 1 through September 30 throughout the study period.

In a two-pollutant analysis, each increase of 10 μg per cubic meter in annual exposure to $PM_{2.5}$ (estimated independently of ozone) and each increase of 10 ppb in warm-season exposure to ozone (estimated independently of $PM_{2.5}$) was associated with an increase in all-cause mortality of 7.3% (95% confidence interval [CI], 7.1 to 7.5) and 1.1% (95% CI, 1.0 to 1.2), respectively. Estimates of risk based on predictive, ZIP-Code–specific assessments of exposure were slightly higher than those provided by the nearest data-monitoring site (Table 2). When we restricted the $PM_{2.5}$ and ozone analyses to location-years with low concentrations, we continued to see significant associations between exposure and mortality (Table 2). Analysis of the MCBS

Table 2. **Risk of Death Associated with an Increase of 10 μg per Cubic Meter in $PM_{2.5}$ or an Increase of 10 ppb in Ozone Concentration.***

Model	$PM_{2.5}$	Ozone
	hazard ratio (95% CI)	
Two-pollutant analysis		
Main analysis	1.073 (1.071–1.075)	1.011 (1.010–1.012)
Low-exposure analysis	1.136 (1.131–1.141)	1.010 (1.009–1.011)
Analysis based on data from nearest monitoring site (nearest-monitor analysis)†	1.061 (1.059–1.063)	1.001 (1.000–1.002)
Single-pollutant analysis‡	1.084 (1.081–1.086)	1.023 (1.022–1.024)

* Hazard ratios and 95% confidence intervals were calculated on the basis of an increase of 10 μg per cubic meter in exposure to $PM_{2.5}$ and an increase of 10 ppb in exposure to ozone.

† Daily average monitoring data on $PM_{2.5}$ and ozone were obtained from the Environmental Protection Agency Air Quality System. Daily ozone concentrations were averaged from April 1 through September 30 for the computation of warm-season averages. Data on $PM_{2.5}$ and ozone levels were obtained from the nearest monitoring site within 50 km. If there was more than one monitoring site within 50 km, the nearest site was chosen. Persons who lived more than 50 km from a monitoring site were excluded.

‡ For the single-pollutant analysis, model specifications were the same as those used in the main analysis, except that ozone was not included in the model when the main effect of $PM_{2.5}$ was estimated and $PM_{2.5}$ was not included in the model when the main effect of ozone was estimated.

subsample provided strong evidence that smoking and income are not likely to be confounders because they do not have a significant association with $PM_{2.5}$ or ozone (Section 5 in the Supplementary Appendix).

SUBGROUP ANALYSES

Subgroup analyses revealed that men; black, Asian, and Hispanic persons; and persons who were eligible for Medicaid (i.e., those who had low socioeconomic status) had a higher estimated risk of death from any cause in association with $PM_{2.5}$ exposure than the general population. The risk of death associated with ozone exposure was higher among white, Medicaid-eligible persons and was significantly below 1 in some racial subgroups (Fig. 2). Among black persons, the effect estimate for $PM_{2.5}$ was three times as high as that for the overall population (Table S3 in the Supplementary Appendix). Overall, the risk of death associated with ozone exposure was smaller and somewhat less robust than that associated with $PM_{2.5}$ exposure. We also detected a small but significant interaction between ozone exposure and $PM_{2.5}$ exposure (Table S8 in the Supplementary Appendix). Our thin-plate–spline fit indicated a relationship between $PM_{2.5}$, ozone, and all-cause mortality that was almost linear, with no signal of threshold down to 5 μg per cubic meter and 30 ppb, respectively (Fig. 3, and Fig. S8 in the Supplementary Appendix).

DISCUSSION

This study involving an open cohort of all persons receiving Medicare, including those from small cities and rural areas, showed that long-term exposures to $PM_{2.5}$ and ozone were associated with an increased risk of death, even at levels below the current annual NAAQS for $PM_{2.5}$. Furthermore, the study showed that black men and persons eligible to receive Medicaid had a much higher risk of death associated with exposure to air pollution than other subgroups. These findings suggest that lowering the annual NAAQS may produce important public health benefits overall, especially among self-identified racial minorities and people with low income.

The strengths of this study include the assessment of exposure with high spatial and temporal resolution, the use of a cohort of almost 61 million Medicare beneficiaries across the entire continental United States followed for up to 13 consecutive years, and the ability to perform subgroup analyses of the health effects of air pollution on groups of disadvantaged persons. However, Medicare claims do not include extensive individual-level data on behavioral risk fac-

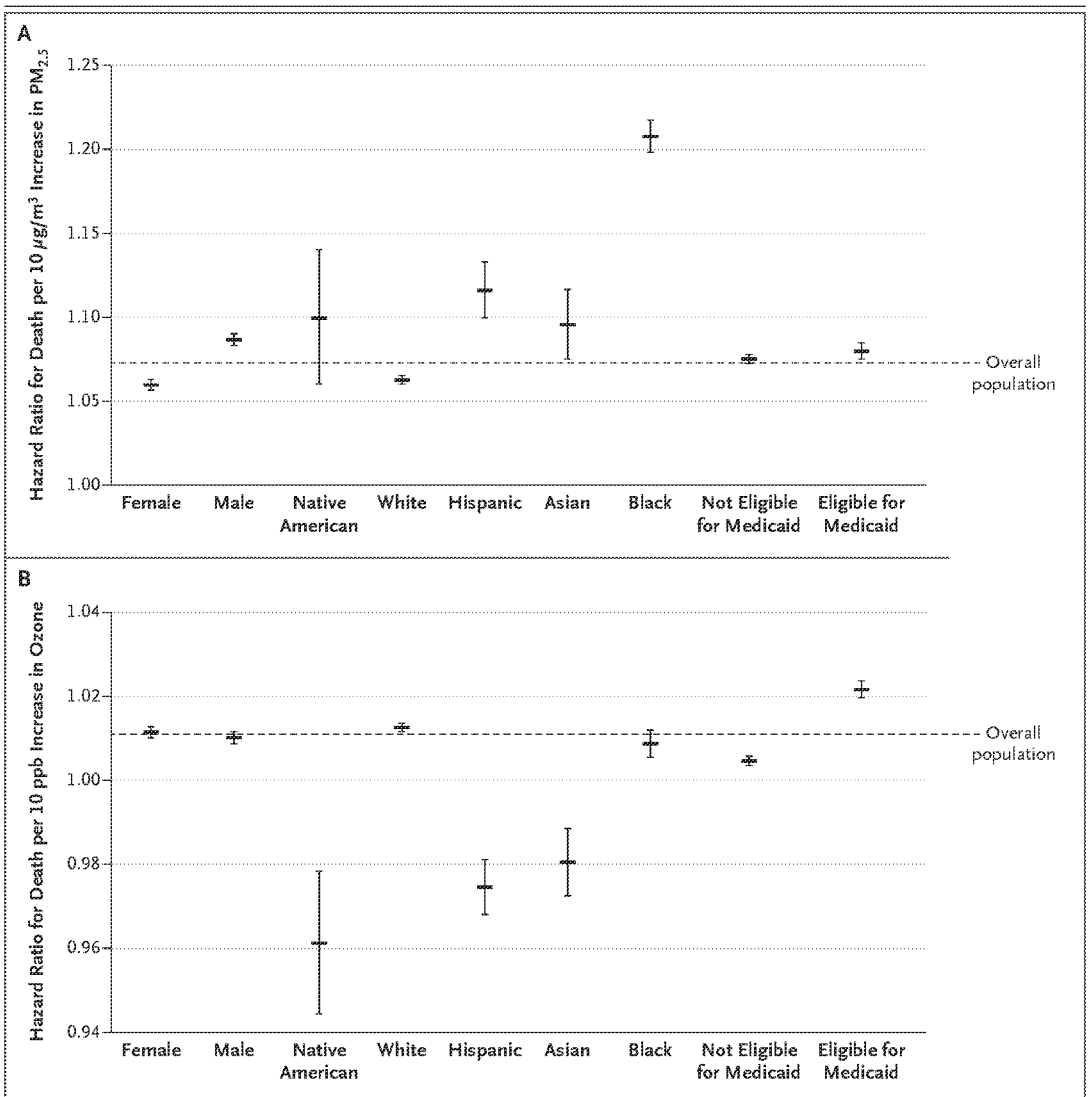

Figure 2. Risk of Death Associated with an Increase of 10 μg per Cubic Meter in $PM_{2.5}$ Concentrations and an Increase of 10 ppb in Ozone Exposure, According to Study Subgroups.

Hazard ratios and 95% confidence intervals are shown for an increase of 10 μg per cubic meter in $PM_{2.5}$ and an increase of 10 parts per billion (ppb) in ozone. Subgroup analyses were conducted by first restricting the population (e.g., considering only male enrollees). The same two-pollutant analysis (the main analysis) was then applied to each subgroup. Numeric results are presented in Tables S3 and S4 in the Supplementary Appendix. Dashed lines indicate the estimated hazard ratio for the overall population.

tors, such as smoking and income, which could be important confounders. Still, our analysis of the MCBS subsample (Table S6 in the Supplementary Appendix) increased our level of confidence that the inability to adjust for these individual-level risk factors in the Medicare cohort did not lead to biased results (Section 5 in the Supplementary Appendix). In another study, we analyzed a similar Medicare subsample with detailed individual-level data on smoking, BMI, and many other potential confounders linked to Medicare claims.[23] In that analysis, we found that for mortality and hospitalization, the risks of exposure to $PM_{2.5}$ were not sensitive to the additional control of individual-level variables that were not available in the whole Medicare population.

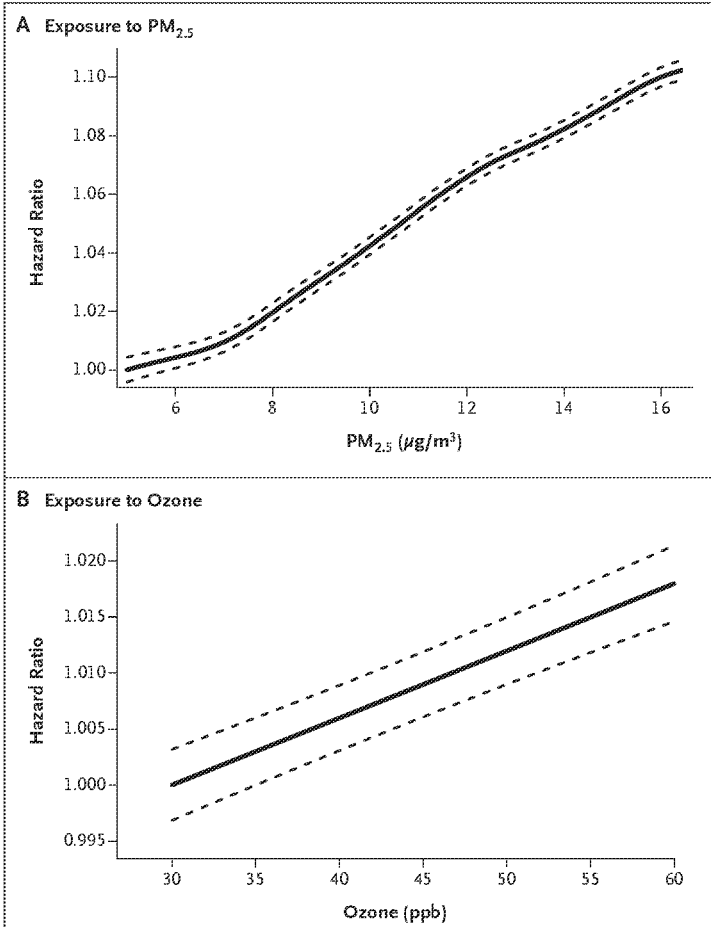

Figure 3. Concentration–Response Function of the Joint Effects of Exposure to $PM_{2.5}$ and Ozone on All-Cause Mortality.

A log-linear model with a thin-plate spline was fit for both $PM_{2.5}$ and ozone, and the shape of the concentration-response surface was estimated (Fig. S8 in the Supplementary Appendix). The concentration–response curve in Panel A was plotted for an ozone concentration equal to 45 ppb. The concentration–response curve in Panel B was plotted for a $PM_{2.5}$ concentration equal to 10 μg per cubic meter. These estimated curves were plotted at the 5th and 95th percentiles of the concentrations of $PM_{2.5}$ and ozone, respectively. The complete concentration–response three-dimensional surface is plotted in Fig. S8 in the Supplementary Appendix.

We also found that our results were robust when we excluded individual and ecologic covariates from the main analysis (Fig. S2 and Table S2 in the Supplementary Appendix), when we stratified age at entry into 3-year and 4-year categories rather than the 5 years used in the main analysis (Fig. S3 in the Supplementary Appendix), when we varied the estimation procedure (by means of a generalized estimating equation as opposed to mixed effects) (Tables S3 and S4 in the Supplementary Appendix), and when we used different types of statistical software (R, version 3.3.2, vs. SAS, version 9.4). Finally, we found that our results were consistent with others published in the literature (Section 6 in the Supplementary Appendix).[5,17,24-28]

There was a significant association between $PM_{2.5}$ exposure and mortality when the analysis was restricted to concentrations below 12 μg per cubic meter, with a steeper slope below that level. This association indicated that the health-benefit-per-unit decrease in the concentration of $PM_{2.5}$ is larger for $PM_{2.5}$ concentrations that are below the current annual NAAQS than the health benefit of decreases in $PM_{2.5}$ concentrations that are above that level. Similar, steeper concentration-response curves at low concentrations have been observed in previous studies.[29] Moreover, we found no evidence of a threshold value — the concentration at which $PM_{2.5}$ exposure does not affect mortality — at concentrations as low as approximately 5 μg per cubic meter (Fig. 3); this finding is similar to those of other studies.[18,30]

The current ozone standard for daily exposure is 70 ppb; there is no annual or seasonal standard. Our results strengthen the argument for establishing seasonal or annual standards. Moreover, whereas time-series studies have shown the short-term effects of ozone exposure, our results indicate that there are larger effect sizes for longer-term ozone exposure, including in locations where ozone concentrations never exceed 70 ppb. Unlike the American Cancer Society Cancer Prevention Study II,[9,10] our study reported a linear connection between ozone concentration and mortality. This finding is probably the result of the interaction between $PM_{2.5}$ and ozone (Section 7 in the Supplementary Appendix). The significant, linear relationship between seasonal ozone levels and all-cause mortality indicates that current risk assessments,[31-33] which incorporate only the acute effects of ozone exposure on deaths each day from respiratory mortality, may be substantially underestimating the contribution of ozone exposure to the total burden of disease.

The enormous sample size in this study, which includes the entire Medicare cohort, allowed for unprecedented accuracy in the estimation of risks among racial minorities and disadvantaged subgroups. The estimate of effect size for $PM_{2.5}$ expo-

sure was greatest among male, black, and Medicaid-eligible persons. We also estimated risks in subgroups of persons who were eligible for Medicaid and in whites and blacks alone to ascertain whether the effect modifications according to race and Medicaid status were independent. We found that black persons who were not eligible for Medicaid (e.g., because of higher income) continued to have an increased risk of death from exposure to $PM_{2.5}$ (Fig. S4 in the Supplementary Appendix). In addition, we found that there was a difference in the health effects of $PM_{2.5}$ exposure between urban and rural populations, a finding that may be due to compositional differences in the particulates (Table S3 Supplementary Appendix).

Although the Medicare cohort includes only the population of persons 65 years of age or older, two thirds of all deaths in the United States occur in people in that age group. Although our exposure models had excellent out-of-sample predictive power on held-out monitors, they do have limitations. Error in exposure assessment remains an issue in this type of analysis and could attenuate effect estimates for air pollution.[34]

The overall association between air pollution and human health has been well documented since the publication of the landmark Harvard Six Cities Study in 1993.[25] With air pollution declining, it is critical to estimate the health effects of low levels of air pollution — below the current NAAQS — to determine whether these levels are adequate to minimize the risk of death. Since the Clean Air Act requires the EPA to set air-quality standards that protect sensitive populations, it is also important to focus more effort on estimating effect sizes in potentially sensitive populations in order to inform regulatory policy going forward.

The views expressed in this article are those of the authors and do not necessarily represent the official views of the funding agencies. Furthermore, these agencies do not endorse the purchase of any commercial products or services related to this publication.

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ATTACHMENT 3

Partial List of Studies That May Contain Protected Health Information and That Have Been Relied on by the Environmental Protection Agency (EPA) and Cited in EPA Documents

The following studies were cited in supporting or decision making EPA documents.

Safe Drinking Water Act (SDWA)

Six Year Review #1 Health Effects Technical Support Document

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Additional Documents

Public Health Implications of PCBs **(2015)**

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Environmental Health

EDITORIAL Open Access

Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances

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Abstract

Identification and characterization of environmental hazards that impact human health must rely on the best possible science to inform and inspire appropriate public health intervention. The perfluorinated alkylate substances (PFASs) are persistent emerging pollutants that are now being recognized as important human health hazards. Although the PFASs have been produced for over 60 years, academic research on environmental health aspects has appeared only in the most recent 10 years or so. In the meantime, these persistent chemicals accumulated in the global environment. Some early studies e.g., on population exposures and toxicity, were not released to the public until after year 2000. Still, the first PFAS risk assessments ignored these reports and relied on scant journal publications. The first guidelines and legal limits for PFAS exposure, e.g., from drinking water, were proposed 10 years ago. They have decreased substantially since then, but remain higher than suggested by data on human adverse effects, especially on the immune system, that occur at background exposure levels. By now, the best-known PFASs are being phased out, and related PFASs are being introduced as substitutes. Given the substantial delays in discovery of PFAS toxicity, in dissemination of findings, and in regulatory decisions, PFAS substitutes and other persistent industrial chemicals should be subjected to prior scrutiny before widespread usage.

Late emergence of early evidence

Industrial chemicals are often regarded inert or safe, unless proven otherwise, i.e., the so-called "untested chemicals assumption," although this belief is of course not logical [1, 2]. A high-priority group of environmental chemicals, the perfluorinated alkylate substances (PFASs), constitute a clear example how narrow reliance on published toxicity studies can be misleading and result in insufficient and delayed protection of public health [3]. New insight on PFAS immunotoxicity shows that the path from discovery of toxicity to decisions on intervention can be stalled for decades (Table 1).

After the beginning of commercial PFAS production in the 1950s, a brief review article from 1980 [4] for the first time mentioned industry-sponsored studies, some of which were carried out in monkeys. Perfluorooctanoic acid (PFOA) showed specific toxicity to the reticuloendothelial system (i.e. immune system) [5]. In this 90-day study, compound-related microscopic lesions were seen in bone marrow, spleen and lymph nodes, thus clearly suggesting immunotoxicity, although functional tests were not carried out. A parallel study on perfluorooctanoic sulfonic acid (PFOS), also from 1978, was aborted due to mortality of the monkeys at all doses (the lowest being 10 mg/kg/day) [6]. These two internal reports were eventually shared with the U.S. Environmental Protection Agency (EPA) in 2000 [7] and then became accessible to the public.

A medical thesis from 1992 mentioned the evidence from the monkey study and noted: "No follow-up studies of these observations have been reported" [8]. The thesis analyzed clinical examination data from PFOA production workers and found clear associations between increased PFAS concentrations in the blood and decreased

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Table 1 Time course of important developments regarding PFAS exposure and health risks [5, 6, 8, 10, 11, 13, 15, 16, 28, 31, 32, 44, 50]

Year	Exposure evidence	Reference
1968	Organic fluoride compounds discovered in human blood	[11]
1976	Organofluorines determined in blood from production workers	[10]
1981	PFOA found in umbilical cord blood when female worker gives birth	[13]
1993	Transfer of PFOS into milk observed in goats	[10]
1998	PFOS found in blood from the general population	[10]
2003	PFAS in blood from Red Cross blood donors	[16]
2004	PFAS detected in human milk	[15]
2014	Breastfeeding shown to be major source of PFAS exposure in infants	[31]
	Immunotoxicity	
1978	Immunotoxicity and other adverse effects in monkeys exposed to PFOA, and mortality in monkeys exposed to PFOS	[5, 6]
1992	Leukocyte cell count changes in PFOA production workers	[8]
2008	Mouse study shows immunotoxicity at serum PFAS concentrations similar to elevated human exposures	[50]
2012	Immunotoxicity reported in PFAS-exposed children	[28]
2013	Benchmark Dose calculations suggest that guidelines are far from protective	[44]
2017	PFAS exposure during infancy associated with subsequent immune deficiency	[32]

Unpublished information is shaded

leukocyte counts. The results were not reported in a scientific journal. However, in connection with a recent law suit, a draft manuscript on this study has been released ("Peripheral blood lymphocyte count in men occupationally exposed to perfluorooctanoic acid" [9]). The draft concluded: "PFOA is associated with alterations in peripheral blood lymphocyte numbers in PFOA production workers, suggesting that cell-mediated immunity may be affected by PFOA". Other company materials outlined in an expert report include the comment "We're working with [the author] regarding some of the wording" [10]. Evidently, an agreement was not reached, and the findings were not published.

Human exposure to organofluorine compounds was discovered as early as 1968 [11] and was later confirmed in a more extensive study [12]. However, the exact identity and the sources were unknown at the time. Soon thereafter, PFASs were identified in blood from production workers, and in 1981 also in umbilical cord blood at a female worker's childbirth [13]. Although the latter finding signified placental passage and prenatal PFAS exposure, this observation was not revealed until 20 years later, after which it was soon confirmed in a larger study [14]. Of additional public health significance, an unpublished study on goats from 1993 showed that PFOS was transferred into milk [10], and this pathway was verified in humans, again many years later [15].

New insight into a hidden hazard

By about 2000, the widespread occurrence and persistence of PFASs in the environment became known [7], as reflected also by the presence of PFASs in serum samples from blood banks [16]. Only after this time, and especially during the most recent 10 years, did the scientific literature on PFASs expand (Fig. 1) [17]. Immune system deficits in PFOA-exposed mice were at first observed in studies of peroxisome proliferator activation [18]. Later, experimental studies of PFOS showed reductions in lymphoid cell numbers and de novo antibody synthesis [19], and a study in mice from 2009 demonstrated that PFOS exposure reduced the survival after influenza A infection [20]. Then followed in vitro evidence of adverse effects in human white blood cells [21]. Although the 1978 monkey study [5] could have been obtained from the U.S. EPA, none of these studies referred to these original findings.

Important evidence emerged after the discovery of PFAS contamination in the Mid-Ohio River Valley and

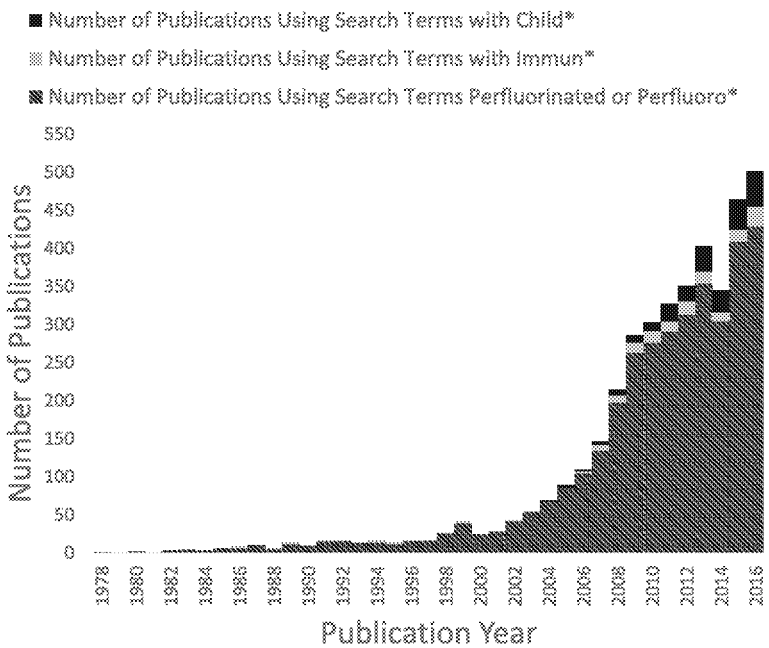

Fig. 1 Number of publications on PFASs over time, according to the Web of Science database (between 1978 and 2017), using the search terms "perfluorinated or perfluoro"* and restricting to environmental sciences, toxicology, or public, environmental, and occupational health categories. This search was further refined using the search terms "immun*" and "child*"

the court-mandated health examinations [22]. In regard to immunotoxicity, an interim report showed that increased PFOA exposure was associated with changes in serum concentrations of immunoglobulins [23]. A more focused study determined antibody responses to flu vaccination [24]. Elevated serum-PFOA concentrations were associated with a reduced antibody titer rise, particularly to an A influenza virus strain, with an increased risk of not attaining the antibody level needed to provide long-term protection. A later study on 12 adult volunteers with background exposures showed that two of the subjects failed to respond to a tetanus-diphtheria booster and that the steepness of the antibody responses was negatively associated with the serum-PFAS concentrations [25]. Cross-sectional data have also suggested lower vaccination antibody concentrations at elevated background PFAS exposures [26].

The first prospective study assessing children's antibody responses to routine childhood immunizations reported in 2012 that a doubling in exposure to PFOS and PFOA was associated with an overall decrease by up to 50% in the specific vaccine antibody concentration [27, 28]. When mutually adjusted, the regression coefficients for PFOA and PFOS changed only little [27]. Booster vaccine responses in children at age 5 years were lower at elevated serum-PFAS concentrations [28, 29]. A smaller Norwegian study of about 50 children aged 3 years also showed tendencies toward lower vaccination antibody concentrations at higher exposures during pregnancy [30]. As PFASs are now known to be transferred to the infant via human milk [31], it seems likely that PFAS exposures in early infancy represent a particular hazard to the adaptive immune system [32]. If true, the routine modeling of lifetime exposures for risk assessment is inappropriate, as it ignores the presence of vulnerable time windows.

PFAS exposure can also impact the body's ability to fight off common infections, such as colds and gastroenteritis, as seen in the Norwegian study [30]. A larger, prospective study in Denmark found that increased maternal serum concentrations of PFOA and PFOS were significantly associated with a higher frequency of fever and symptoms in the children [33], in agreement with a subsequent study from Japan that relied on retrospective assessment of the disease incidence [34]. In contrast, a substudy from the Danish National Birth Cohort examined the hospitalization rates for a variety of infections, such as airway infection, middle ear infection, and appendicitis, through to age 11 years and showed no association with PFOS and PFOA in early pregnancy serum from the mother [35]. However, a recent report from the project team raised doubt about the validity of the PFAS analyses [36].

Delayed interventions

Despite the support from both experimental and epidemiological data [37], most regulatory risk assessments of PFASs have focused on other target organs and have

emphasized toxicity testing in rodents [4]. The first opinion from the European Food Safety Authority (EFSA) in 2009 [38] listed a single report on immunotoxicity under "Other endpoints". That same year, the EPA issued provisional health advisories and concluded that "epidemiological studies of exposure to PFOA and adverse health outcomes in humans are inconclusive at present" [39]. Neither report referred to the 1978 monkey study that had become available in 2000. Early and more recent guidelines and recommended limits for PFOS and PFOA are shown in Table 2.

The EPA prepared more detailed risk assessment reports for PFOA and PFOS in 2014 [40, 41]. These drafts conclude that the two major PFASs exhibit immunotoxicity in experimental models and that the epidemiological evidence is additive, although mixed exposures complicate the attribution of effects to specific PFASs. A similar conclusion was reached by an ATSDR ToxProfile on the perfluoroalkyls in 2015 [42]. The coverage of human immunotoxicity was very brief, and no mention of this potential was made in the sections on public health implications. Although the monkey studies were cited, the risk assessment reports did not refer to the 1992 study of exposure-associated immune cell abnormalities in workers.

More recently, the National Toxicology Program (NTP) in 2016 reviewed the immunotoxicity information on PFOS and PFOA and concluded that both are "presumed" to constitute immune hazards to humans [37]. The term "presumed" is the strongest below "known" in the NTP vernacular. Both PFASs suppress the antibody response in animal studies, while the evidence in humans is "moderate", as all studies are observational (not experimental) and refer to mixed PFAS exposures. The revised ATSDR ToxProfile [43] just released concluded that decreased antibody response to vaccines is a potential outcome from exposure to all five PFASs commonly found in human blood samples. However, ATSDR stopped short of using epidemiology evidence for derivation of exposure limits.

Table 2 Guideline values expressed in terms of acceptable concentrations of PFOS and PFOA in drinking water (ng/L),[a] as compared with the estimated limit based on benchmark dose calculations for immunotoxicity in children [44]

Authority	Year	PFOS	PFOA
Australia			
	2016	70	560
Canada	2016	600	200
U.S. EPA	2009	200	400
	2016	70	70
ATSDR	2015	70	100
	2018	11	7
Minnesota	2008	300	300
	2017	27	35
New Jersey	2007	-	40
	2017	13	14
EFSA	2009	70	700
	2018	6.5	3
BMDL-based	2013	< 1	< 1

[a]Estimated from total intake limits, assuming 20% exposure contribution from water (rounded values)

Regulatory agencies frequently use benchmark dose calculations as a basis for generating exposure limits [38]. This approach relies on fitting a dose-response function to the data, and the benchmark dose (BMD) is defined as the dose that leads to a specific loss (or degree of abnormality) known as the benchmark response (BMR) in the outcome variable. The lower one-sided 95% confidence limit of the BMD is the benchmark dose level (BMDL), which is used as the point of departure for calculation of exposure limits. Relying on the vaccine antibody responses, BMDLs for PFOS and PFOA were calculated in 2013 to be about 1 μg/L serum [44], i.e., levels that are exceeded by a majority of the general population [45]. However, at first, these results were disregarded because of the absence of an unexposed control group [42], a condition that would be impossible to meet. Another concern was the high correlation between exposure components, such as PFOA and PFOS [40, 41, 43]. Still, mutual adjustment is possible and shows clear negative impacts of both of these major PFASs on immune system responses [27], and other calculations show virtually unchanged BMDLs for PFOA and PFOS after such adjustment [46].

In an updated opinion on PFOS and PFOA [47], EFSA used separate BMD calculations for several outcomes in humans, including immunotoxicity, relying on summary data in deciles or quartiles. For the vaccine response data [28], EFSA assumed that all subjects in the lowest decile exposure group had the same exposure, and the BMDs were similar to the average serum concentration in that group. For this reason, EFSA's calculated BMDs are several fold higher than the ones obtained from the continuous dose-effect relationship [44]. Still, the new tolerable intake limits are substantially lower than other published guidelines (Table 2), though quite similar to the Minimal Risk Levels developed by ATSDR [43].

The "untested chemicals assumption", as highlighted by the National Research Council [1] has clearly been inappropriately relied upon in past risk assessments of PFASs, and these substances must now be added to the list of environmental hazards [48] where standard risk assessment has failed. As a major reason, early evidence on PFAS toxicity was kept secret for 20 years or more, and even after its release, it was apparently overlooked.

A related reason is the absence of academic PFAS research on the immune system and other sensitive target organs until about 10 years ago. Further, regulatory agencies relied on experimental toxicity studies and disregarded emerging epidemiological evidence. As a result, even some of the current guidelines are orders of magnitude above exposure levels at which associations with adverse effects have been reported.

The PFASs therefore constitute an unfortunate example that risk assessment may be inappropriate to assess human health risks from chemical exposures when crucial documentation has not yet been published. Recognizing the weaknesses of conventional risk assessment, scientists from the U.S. EPA recently recommended to consider the full range of available data and to include health endpoints that reflect the range of subtle effects and morbidities in humans [48]. The present summary of delayed discovery, dissemination and decision-making on the PFASs indicates that a more comprehensive assessment of adverse health risks is urgently needed and that PFAS substitutes, as well as other persistent industrial chemicals, should not be considered innocuous in the absence of relevant documentation [49].

Conclusions

Early research on environmental PFAS exposures and their health implications became available at a substantial delay and was not taken into account in initial regulatory decisions on exposure abatement. Only in the last 10 years or so has environmental health research focused on the PFASs and revealed important human health risks, e.g., to the immune system. Although guideline values for PFASs in drinking water have decreased over time, they remain too high to protect against such toxicity. While the most commonly used PFASs will remain in the environment for many years, new PFAS substitutes are being introduced, although little information on adverse health risks is available. Given the serious delays in the discovery of PFAS toxicity, their persistence in the environment, and their public health impact, PFAS substitutes and other persistent industrial chemicals should be subjected to prior research scrutiny before widespread usage.

Abbreviations

BMD: Benchmark dose; BMDL: Benchmark dose level; BMR: Benchmark response; EFSA: European Food Safety Authority; EPA: Environmental Protection Agency; NTP: National Toxicology Program; PFAS: Perfluorinated alkylate substance; PFOA: Perfluorooctanoic acid; PFOS: Perfluorooctanoic sulfonic acid

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Authors' Contributions

The author read and approved the final manuscript.

Competing interests

The author is an editor-in-chief of Environmental Health. The author recently served as a health expert for the State of Minnesota in a lawsuit against a PFAS-producing company.

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OUR CORE PRACTICES

COPE

Core practices are the policies and practices journals and publishers need to reach the highest standards in publication ethics. We include cases with advice, guidance for day-to-day practice, education modules and events on topical issues, to support journals and publishers fulfil their policies.

1. ALLEGATIONS OF MISCONDUCT

Journals should have a clearly described process for handling allegations, however they are brought to the journal's or publisher's attention. Journals must take seriously allegations of misconduct pre-publication and post-publication. Policies should include how to handle allegations from whistleblowers.

FIND OUT MORE publicationethics.org/misconduct

2. AUTHORSHIP AND CONTRIBUTORSHIP

Clear policies (that allow for transparency around who contributed to the work and in what capacity) should be in place for requirements for authorship and contributorship as well as processes for managing potential disputes.

FIND OUT MORE publicationethics.org/authorship

3. COMPLAINTS AND APPEALS

Journals should have a clearly described process for handling complaints against the journal, its staff, editorial board or publisher.

FIND OUT MORE publicationethics.org/appeals

4. CONFLICTS OF INTEREST/COMPETING INTERESTS

There must be clear definitions of conflicts of interest and processes for handling conflicts of interest of authors, reviewers, editors, journals and publishers, whether identified before or after publication.

FIND OUT MORE publicationethics.org/competinginterests

5. DATA AND REPRODUCIBILITY

Journals should include policies on data availability and encourage the use of reporting guidelines and registration of clinical trials and other study designs according to standard practice in their discipline.

FIND OUT MORE publicationethics.org/data

6. ETHICAL OVERSIGHT

Ethical oversight should include, but is not limited to, policies on consent to publication, publication on vulnerable populations, ethical conduct of research using animals, ethical conduct of research using human subjects, handling confidential data and of business/marketing practices.

FIND OUT MORE publicationethics.org/oversight

7. INTELLECTUAL PROPERTY

All policies on intellectual property, including copyright and publishing licenses, should be clearly described. In addition, any costs associated with publishing should be obvious to authors and readers. Policies should be clear on what counts as prepublication that will preclude consideration. What constitutes plagiarism and redundant/overlapping publication should be specified.

FIND OUT MORE publicationethics.org/intellectualproperty

8. JOURNAL MANAGEMENT

A well-described and implemented infrastructure is essential, including the business model, policies, processes and software for efficient running of an editorially independent journal, as well as the efficient management and training of editorial boards and editorial and publishing staff.

FIND OUT MORE publicationethics.org/management

9. PEER REVIEW PROCESSES

All peer review processes must be transparently described and well managed. Journals should provide training for editors and reviewers and have policies on diverse aspects of peer review, especially with respect to adoption of appropriate models of review and processes for handling conflicts of interest, appeals and disputes that may arise in peer review.

FIND OUT MORE publicationethics.org/peerreview

10. POST-PUBLICATION DISCUSSIONS AND CORRECTIONS

Journals must allow debate post publication either on their site, through letters to the editor, or on an external moderated site, such as PubMed Commons or PubPeer. They must have mechanisms for correcting, revising or retracting articles after publication.

FIND OUT MORE publicationethics.org/postpublication

Core practices

COPE's role is to assist editors of scholarly journals and publishers/owners - as well as other parties, such as institutions and funders, albeit less directly - in their endeavour to preserve and promote the integrity of the scholarly record through policies and practices that reflect the current best principles of transparency and integrity. COPE's new recommendations are intended to reflect these aims, in a practical way. COPE have therefore reviewed the Code of Conduct and Best Practice Guidelines for Editors and Code of Conduct for Journal Publishers and have consolidated them into one, much shorter, document entitled "Core Practices". [Available to download as an A4 poster.] Connected to each of these core practices will be hyperlinks to the detailed documents and resources COPE already publish, which are arrived at through extensive consultation, and which we will be building into a comprehensive, yet responsive library. The full range of COPE resources can be found here. .The Core Practices are applicable to all involved in publishing the scholarly literature: editors and their journals, publishers (and institutions).

COPE's Core Practices should be considered alongside specific national and international codes of conduct for research and is not intended to replace them.

Background to why the Code of Conduct for Journal Editors has been replaced with the Core Practices.

Journals and Publishers should have robust and well-described, publicly documented practices in all the following areas for their journals:

1. Allegations of misconduct

Journals should have a clearly described process for handling allegations, however they are brought to the journal's or publisher's attention. Journals must take seriously allegations of misconduct pre-publication and post-publication. Policies should include how to handle allegations from whistleblowers.

Latest resources

- Association of Research Integrity Officers 2018 (Event)
- In the News: July Digest (News)
- In the news: May 2018 Digest (News)

View all Allegations of misconduct resources

2. Authorship and contributorship

Clear policies (that allow for transparency around who contributed to the work and in what capacity) should be in place for requirements for authorship and contributorship as well as processes for managing potential disputes

Latest resources

- Association of Research Integrity Officers 2018 (Event)
- In the News: July Digest (News)
- ISMTE North American Conference (Event)

View all Authorship and contributorship resources

3. Complaints and appeals

Journals should have a clearly described process for handling complaints against the journal, its staff, editorial board or publisher

Latest resources

- In the news: April 2018 Digest (News)
- Complaints and appeals (News)
- COPE Education Subcommittee focus: Complaints and Appeals (News)

View all Complaints and appeals resources

4. Conflicts of interest / Competing interests

There must be clear definitions of conflicts of interest and processes for handling conflicts of interest of authors, reviewers, editors, journals and publishers, whether identified before or after publication

Latest resources

- Letter from the COPE co-Chairs: July 2018 (News)
- In the news: May 2018 Digest (News)
- COPE Education Subcommittee focus: Conflicts of Interest (News)

View all Conflicts of interest / Competing interests resources

5. Data and reproducibility

Journals should include policies on data availability and encourage the use of reporting guidelines and registration of clinical trials and other study designs according to standard practice in their discipline

Latest resources

- Letter from the COPE co-Chairs: July 2018 (News)
- In the News: July Digest (News)
- Creating and implementing data research policies: COPE webinar report (News)

View all Data and reproducibility resources

6. Ethical oversight

Ethical oversight should include, but is not limited to, policies on consent to publication, publication on vulnerable populations, ethical conduct of research using animals, ethical conduct of research using human subjects, handling confidential data and of business/marketing practices

Latest resources

- In the News: July Digest (News)
- In the news: June 2018 Digest (News)
- COPE Forum discussion: Preprints: continuing the conversation (News)

View all Ethical oversight resources

7. Intellectual property

All policies on intellectual property, including copyright and publishing licenses, should be clearly described. In addition, any costs associated with publishing should be obvious to authors and readers. Policies should be clear on what counts as prepublication that will preclude consideration. What constitutes plagiarism and redundant/overlapping publication should be specified

View all Intellectual property resources

Latest resources

- Association of Research Integrity Officers 2018 (Event)
- In the News: July Digest (News)
- COPE Education Subcommittee focus: Intellectual Property (News)

8. Journal management

A well-described and implemented infrastructure is essential, including the business model, policies, processes and software for efficient running of an editorially independent journal, as well as the efficient management and training of editorial boards and editorial and publishing staff

View all Journal management resources

Latest resources

- In the News: July Digest (News)
- COPE Forum 30 April 2018: Preprints: continuing the conversation (Resource)
- COPE Forum discussion: Preprints: continuing the conversation (News)

9. Peer review processes

All peer review processes must be transparently described and well managed. Journals should provide training for editors and reviewers and have policies on diverse aspects of peer review, especially with respect to adoption of appropriate models of review and processes for handling conflicts of interest, appeals and disputes that may arise in peer review

View all Peer review processes resources

Latest resources

- Letter from the COPE co-Chairs: July 2018 (News)
- In the News: July Digest (News)
- ISMTE North American Conference (Event)

10. Post-publication discussions and corrections

Journals must allow debate post publication either on their site, through letters to the editor, or on an external moderated site, such as PubPeer. They must have mechanisms for correcting, revising or retracting articles after publication

View all Post-publication discussions and corrections resources

Latest resources

- In the News: July Digest (News)
- In the news: April 2018 Digest (News)
- COPE Forum 26 February 2018: Expressions of concern (Resource)

Committee on Publication Ethics

Promoting integrity in research publication

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Cite as: J. Berg., P. Campbell, V. Kiermer, N. Raikhel, D. Sweet, *Science* 10.1126/science.aau0116 (2018).

Joint statement on EPA proposed rule and public availability of data

Jeremy Berg,[1]* Philip Campbell,[2] Veronique Kiermer,[3] Natasha Raikhel,[4,5] Deborah Sweet[6]

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We are writing in response to a proposed rule announced by the Environmental Protection Agency (EPA) in a 24 April 2018 press release (*1*). The release reads, "The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and that underlying scientific information is publicly available in a manner sufficient for independent validation."

Data sharing is a feature that contributes to the robustness of published scientific results. Many peer-reviewed scientific journals have recently adopted policies that support data sharing, consistent with the Transparency and Openness Promotion (TOP) standards. These standards, however, recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared. Exceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers.

We support maintaining the rigor of research published in our journals and increasing transparency regarding the evidence on which conclusions are based. As part of these goals, we require that all data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis. Importantly, the merits of studies relying on data that cannot be made publicly available can still be judged. Reviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results.

It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.

REFERENCE

1. U.S. Environmental Protection Agency, News Releases, "EPA Administrator Pruitt proposes rule to strengthen science used in EPA regulations" (2018); www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.

Published online 30 April 2018
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Joint statement on EPA proposed rule and public availability of data

Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel and Deborah Sweet

published online April 30, 2018

Message

From: Flowers, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4411C874D041B9A8BADFC32B91BD70-FLOWERS, LYNN]
Sent: 9/5/2018 8:08:51 PM
To: ORD-Exec-Council-Directors [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27ecb6069df540d1b77c19b84ba8dea4-ORD-Exec-Co]; ORD-Mgmt-Council [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d052b33344446a58a540f6b8c1ed50f-ORD-Mgmt-Council]
CC: ORD-IOAA-Front Office Support [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a6228178a264ebb9d4ed55c6b23d304-ORD-IOAA-Fr]
Subject: FW: STPC September Meeting (Sep 12, 2-4 pm)
Attachments: STPC September Meeting

Hi all: Please find attached the final agenda and attachments for the quarterly STPC meeting on September 12 (2-4 pm). The agenda is also copied below.

AGENDA

SCIENCE & TECHNOLOGY POLICY COUNCIL MEETING

Wednesday, September 12, 2018
2:00 – 4:00 PM ET

Conference Room (DC): Ronald Reagan Building 4th Floor Room 41213
Audio Conference Call-in Number: [redacted]
Conference Code: [redacted]

Adobe Connect Information: [redacted]

1. **Introductory Remarks and Roll Call** (10 minutes, to 2:10)
   Lead: Jennifer Orme-Zavaleta (Science Advisor)
   Roll Call: Anand Mudambi, STPC Coordinator (OSA)

2. **Updates:** (40 minutes, to 2:50)
   a. Strengthening Transparency Rule (Response to comment and rulemaking): Maria Doa (ORD)
   b. PFAS Coordination : OW
   c. Pb Coordination : Hayley Hughes and Valerie Zartarian (ORD)
   d. Contaminants of Emerging Concern Project : Jeff Frithsen (ORD)
   e. Standing Groups Status : Anand Mudambi (OSA)

3. **Voluntary Consensus Standard (VCS) Development - Draft EPA Guidance** (20 minutes to 3:10)
   Lead: Elise Owen (EPA Standards Executive, housed in OCSPP)
   Purpose: Brief the STPC on the development of Agency guidance regarding EPA personnel participation in private sector Voluntary Consensus Standards (VCS) development
   Outcome: Inform STPC input on the draft guidance

4. **Citizen Science** (25 minutes, to 3:35)
   Lead: Jay Benforado (OSA)
   Purpose: Discussion of Draft Charge to Implement NACEPT and OIG Recommendations
   Outcome: Get STPC input on the charge activities

5. **RAF Cumulative Risk Assessment (CRA) Technical Panel Products** (20 minutes, to 3:55)
   Lead: Lawrence Martin (OSA)
   Purpose: Inform STPC about the CRA Guidelines on Planning and Problem Formulation, and the Document updating Chemical Mixtures Additivity
   Outcome: Preparation for STPC concurrence on the RAF's CRA products for external peer review

6. **Summary of Action Items** (5 minutes, to 4:00)
   Report: Anand Mudambi (OSA)

Next STPC Meeting: Wednesday, December 5, 2018

Lynn Flowers, PhD, DABT
Associate Director for Science
Office of Science Policy/ORD
US EPA
Washington, DC
202-564-6293

Appointment

From: Science and Technology Policy Council Staff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C07FB189ABD94262B3BB92A42905193E-SCIENCE AND]
Sent: 9/5/2018 7:08:00 PM
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Attachments: 1_Agenda Sep 12 STPC Meeting_0905.docx; 2a_Strengthening Transparency in Regulatory Science presentation v4.pptx; 2c_STPC_Pbslides_09-12-18mtg_HH-VZ_DraftInternal.pptx; 3_EPA_NTTAA-Coordination_20170310.pdf; 3_NTTAA_CoP-Roster_by-AAship-Region_2018.pdf; 3_NTTAA_VCS-Participants_20180116.pdf; 3_Standards Participation Guidance - 1-page summary - 20180723.pdf; 3_STPC - NTTAA Participation Guidance - 20180827.pptx; 4_epaoig_20180905-18-P-0240_cert.pdf; 4_STPC meeting Citizen Science 9-04-2018.pptx; 4_Draft Charge for Citizen Science workgroup under STPC_081518.docx
Location: DC Location - Ronald Reagan Building Room 41213

Start: 9/12/2018 6:00:00 PM
End: 9/12/2018 8:00:00 PM
Show Time As: Tentative

AGENDA

SCIENCE & TECHNOLOGY POLICY COUNCIL MEETING

Wednesday, September 12, 2018
2:00 – 4:00 PM ET

Conference Room (DC): Ronald Reagan Building 4th Floor Room 41213
Audio Conference Call-in Number: [redacted]
Conference Code: [redacted]

Adobe Connect Information: [redacted]

1. **Introductory Remarks and Roll Call** (10 minutes, to 2:10)
   Lead: Jennifer Orme-Zavaleta (Science Advisor)
   Roll Call: Anand Mudambi, STPC Coordinator (OSA)

2. **Updates:** (40 minutes, to 2:50)
   a. Strengthening Transparency Rule (Response to comment and rulemaking): Maria Doa (ORD)
   b. PFAS Coordination : OW
   c. Pb Coordination : Hayley Hughes and Valerie Zartarian (ORD)
   d. Contaminants of Emerging Concern Project : Jeff Frithsen (ORD)
   e. Standing Groups Status : Anand Mudambi (OSA)

3. **Voluntary Consensus Standard (VCS) Development - Draft EPA Guidance** (20 minutes to 3:10)
   Lead: Elise Owen (EPA Standards Executive, housed in OCSPP)
   Purpose: Brief the STPC on the development of Agency guidance regarding EPA personnel participation in private sector Voluntary Consensus Standards (VCS) development
   Outcome: Inform STPC input on the draft guidance

4. **Citizen Science** (25 minutes, to 3:35)
   Lead: Jay Benforado (OSA)
   Purpose: Discussion of Draft Charge to Implement NACEPT and OIG Recommendations
   Outcome: Get STPC input on the charge activities

5. **RAF Cumulative Risk Assessment (CRA) Technical Panel Products** (20 minutes, to 3:55)
   Lead: Lawrence Martin (OSA)
   Purpose: Inform STPC about the CRA Guidelines on Planning and Problem Formulation, and the Document updating Chemical Mixtures Additivity
   Outcome: Preparation for STPC concurrence on the RAF's CRA products for external peer review

6. **Summary of Action Items** (5 minutes, to 4:00)
   Report: Anand Mudambi (OSA)

Next STPC Meeting: Wednesday, December 5, 2018

Integrated advice of the Open Science Policy Platform Recommendations

Date of Adoption: 22nd April 2018- Date of Publication: 29 May 2018

1. Introduction

Open Science is scholarly research that is collaborative, transparent and reproducible and whose outputs are publicly available. The European Union will not remain competitive at the global level unless it promotes Open Science, and relatedly, Open Innovation. The time to act is now.

At its core, Open Science aims at: "increasing research quality, boosting collaboration, speeding up the research process, making the assessment of research more transparent, promoting public access to scientific results, as well as introducing more people to academic research"[1]. By taking advantage of Open Science, researchers can enhance the quality of curiosity-driven research, maximise the value and potential impact of their work to create new avenues of knowledge, and drive scientific progress and Open Innovation within Europe and beyond[2]. Open Science also makes research more transparent and accessible to citizens, and helps involve citizens more actively in research activities. Open Science thus "provides policymakers, research institutions, funding bodies and researchers themselves with an opportunity to critically consider: what does and should count as high-quality research; what goals researchers should pursue; how research results should be evaluated and disseminated; and how research should be supported and embedded within society"[3].

For Open Science to be successful, it must become embedded at every level and in every aspect of the scientific endeavour and not be perceived as separate from (or even in competition with) current practice. Open Science needs to stimulate research integrity and quality, which includes sensitivity to disciplinary differences and confidentiality issues around knowledge sharing. Open Science requires a systemic shift in current practices to bring transparency across the system, to ensure ongoing sustainability for the associated social and physical infrastructures, and to foster greater public trust in Science. To enable this, *all* stakeholders in research and its communication need to take responsibility for supporting Open Science activities, which includes appropriate financial and administrative support to ensure its long-term sustainability and minimize the bureaucratic burden on researchers.

It is the responsibility of all stakeholders, Member States and the European Commission (EC) to act on and actively promote Open Science amongst their respective communities, and to regularly and openly monitor and report on progress[4]. This document provides a prioritised set of actionable recommendations from the Open Science Policy Platform (OSPP; see Annex B for members) to achieve it. The OSPP members strongly recommend their urgent inclusion into FP9.

These recommendations are the next step towards implementing the longer-term vision articulated by Open Science consultations and expert groups set up by the EC and other organisations in Europe and worldwide (see Annex C for a list of relevant documents). There will need to be further work done to advise on the implementation of the roadmap for Open Science, and to help identify a range of tools and approaches to monitor progress.

The following recommendations target the major stakeholder groups represented by the OSPP and focus on publicly funded research. The roles of other important players in this ecosystem, such as SMEs, industry and NGOs, need to be explored at a later date. We recognise that some individuals and groups may fall into two or more stakeholder categories listed below, and we ask readers to identify with all groups that are most relevant to their functions and activitie

[1] Friesike, S. & Schildhauer, T. (2015). Open Science: many good resolutions, very few incentives, yet. In: Welpe, I.M., Wollersheim, J., Ringelhan, S. & Osterloh, M. (Eds.). *Incentives and Performance. Governance of Research Organizations*. Springer.

[2] European Commission (2016) *Open Innovation, Open Science, Open to the World - A Vision for Europe*

[3] European Commission (2018), H2020 Policy Support Facility, Mutual Learning Exercise on Open Science: Altmetrics and Rewards. *Thematic Report on Incentives and Rewards to engage in Open Science Activities*.

[4] European Commission (2018) *Final Report of MLE Open Science: Incentives and Rewards*

2. Recommendations

2.1. General recommendations

In addition to the specific targeted recommendations in the matrix below, we call upon all Member States and stakeholders to:

1. Appoint national coordinators and task forces for the implementation of Open Science. This instrument must foster the development of funded national plans and the alignment of the Open Science policy agenda across all stakeholders involved including Member States to ensure the coordinated action required for tangible change towards an Open Science approach.

2. Ensure the scholarly infrastructure in Europe is highly interoperable to enable the simple and open sharing of metadata between systems, disciplines and countries, and that credit for research contributions is given to all participants (including citizen scientists). This will need all actors to require the use of standardised, unique persistent identifiers for researchers and outputs, and for the acknowledgement of diversity in researcher contributions. Components of the ecosystem (identifiers, metadata, vocabularies, data citations, repositories and other data-infrastructures) need to be developed where necessary, refined, standardized and implemented through dialogue with relevant research communities. Whatever standards/infrastructures are developed, they need to be capable of adapting to innovations in Open Knowledge practices.

3. Ensure the HR Strategy for Researchers (HRS4R) practices and FP9 evaluation reflect the principles required to effectively embed a culture of Open Science at the institutional level. These must involve research integrity (including the social, ethical and legal implications), researcher evaluation and the public availability of research outputs. Codes for Open Science, Research Integrity and Recruitment need to be incorporated into The European Charter for Researchers[5] and in the FP9 grant agreement. Institutions that apply for the 'Human Resources in Research Award' should be required to demonstrate explicitly how the best practices in Open Science are integrated into their HR processes and strategies.

4. Foster Open Science literacy as essential to European competitiveness at the global level, together with other digital and information competencies. Member States need to secure support for the development of an accredited curriculum for Open Science skills training that fosters Open Science behaviours such as IT and data literacy, from primary school through the whole educational system.

5. Implement a Europe-wide campaign, coordinated by the EC, to raise awareness and communicate the benefits of Open Science among decision makers, research and education bodies, private sector, industrial and citizen organisations.

[5] European Commission (2005) The European Charter for Researchers: The Code of Conduct for the Recruitment of Researchers

2.2. Prioritised recommendations for the eight ambitions of Open Science

Below are a set of actionable recommendations from the OSPP to be taken as the next step towards the longer-term vision articulated by Open Science consultations and expert groups set up by the EC and other organisations in Europe and worldwide. The recommendations have been split up into the eight priorities identified from the 5 areas of the European Open Science Agenda[6], namely:

- Rewards and Incentives
- Research Indicators and Next-Generation Metrics
- Future of Scholarly Communication
- European Open Science Cloud
- FAIR Data
- Research Integrity
- Skills and Education
- Citizen Science

The major stakeholder groups (as listed in the key below) who have the main responsibility to drive the actions stated in the recommendations have been listed alongside each one.


Research & E-Infrastructures

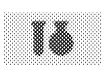

Research Libraries


Universities & Research Performing Organisations


Policy Making Organisations


Research Funding Organisations


Publishers


Researchers

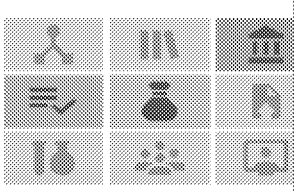

Scientific Societies & Academies


Citizen Science & Public Engagement Organisations

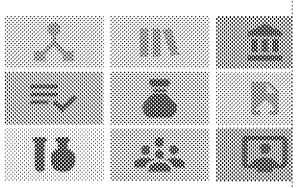
[6] Amsterdam Call for Open Science (2016)
https://www.government.nl/documents/reports/2016/04/04/amsterdam-call-for-action-on-open-science

Rewards and Incentives

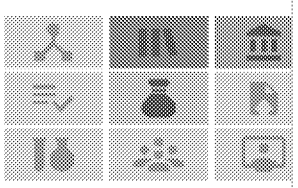
Funders, research institutions and other evaluators of researchers should actively develop/adjust evaluation practices and routines to give extra credit to individuals, groups and projects who integrate Open Science within their research practice.



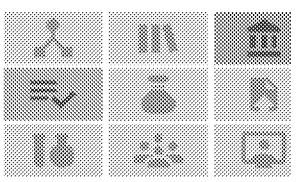
Studies must be commissioned and funded to propose guidelines for best practice and tools for research assessment by 2019, together with an active delivery plan and associated timeline for their implementation. These guidelines must take into account career stage and discipline, and be appropriately tailored to their target such as individual, institution and so forth. Exemplars of innovation and good open science practice must be collated, taking into account the DORA Declaration, the Leiden Manifesto, the OS-CAM and other relevant initiatives.



Public research performing and funding organisations (RPOs/RFOs) should provide public and easily accessible information about the approaches and measures being used to evaluate researchers, research and research proposals.



The traditional academic career structure disincentivises Open Science because of the current focus on tenured positions based solely or largely on publication output. Institutions need to have a career and reward structure for all researchers, and particularly for Early Career Researchers (ECRs), that values and promotes a diverse range of outputs, activities and career directions. This should include facilitating a means by which researchers can, for example, move between academia and industry or between national jurisdictions.



Research Indicators and Next-Generation Metrics

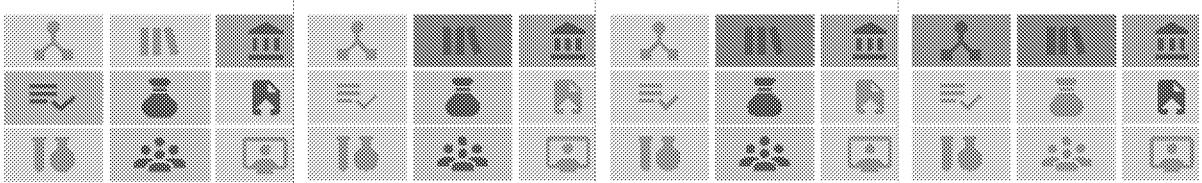
Evaluations of individual researchers or of research groups should not use journal brand or Impact Factor as a proxy for research quality. Those responsible for hiring, promotion, funding and/or the evaluation of researchers must use a broader, tailored range of quantitative and qualitative indicators of research activity, progression and impact that incentivises and rewards open research practice. All publication venues must prominently display a broad range of indicators for all research outputs.

Quantitative and qualitative indicators need to be identified and developed for research assessment that captures the full range of contributions to the knowledge system. These should reflect the complexity and varied context of the research environment, the specific characteristics of the research being undertaken, as well as the new kinds of questions and results that might emerge in an open system.

Experiments, pilots and case studies assessing the validity of such indicators need to be undertaken urgently, and included as part of FP9 with appropriate funding allocated to support them. The results and data of these pilots must be made publicly available as exemplars for further implementation.

All researchers need to be identified through an ORCID ID. Best practice for CV/biosketch evaluation should be developed and publicly showcased to encourage a broader recognition of the range of verifiable (and especially open) contributions individuals make to the knowledge system, including teaching and peer review, and the production of a broad range of output types. The career narrative should be central to the evaluation of individual researchers as it provides the crucial context in which indicators can be interpreted.

The data, metadata and methods that are relevant to research evaluation, including but not limited to citations, downloads and other potential indicators of academic re-use, should be publicly available for independent scrutiny and analysis by researchers, institutions, funders and other stakeholders.



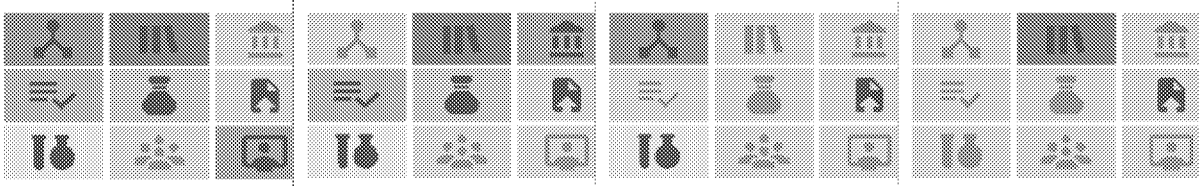
Future of Scholarly Communication

All published research outputs from public funding in Europe must be made public in a way that ensures both immediate Open Access and full text and data mining rights of that content, while being sensitive to disciplinary differences*. Venues used for the publication of research outputs must ensure long-term archiving and provide clear, consistent and easily accessible and machine-readable information on their Open Science policies.

Each Member State, together with its respective stakeholders, must develop policies to guarantee compliance with the EU Open Access mandate, including both incentives and enforcement, by 2020. This needs to happen in ways that are sensitive to disciplinary differences, the financial investment required and fast-changing publishing systems.

All authors must make their data and software (i.e. excluding, if relevant, data owned by third-parties, etc) appearing in their open access publications FAIR (Findable, Accessible, Interoperable and Reusable). To this end, a key requirement is deposition in a trusted repository that adheres to FAIR principles. In addition, all publications must include a statement of FAIR compliance for the source data underpinning their claims and the licence for its reuse.

All publication venues must prominently display their Open Access and FAIR data policies.



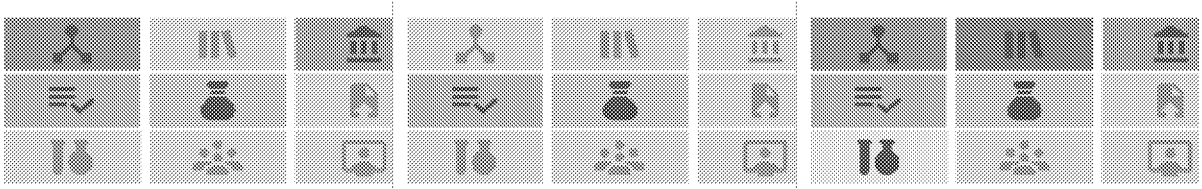
* Despite significant discussion between OSPP members, complete consensus could not be reached and STM and EUCHEMS do not agree to this recommendation.

EOSC

The European Open Science Cloud (EOSC) needs to implement a robust, transparent and participative governance structure to ensure that it has the trust and confidence of all stakeholders, including Member States. It must also support the diversity of requirements across all disciplines. The structure should provide clear channels for feedback, and be compatible with other related initiatives including national, European and Global Research infrastructures to ensure interoperability and the free movement of information across all national and international boundaries and between disciplines, while being sensitive to ethical, societal and legal issues. The EC has to take the lead in bringing the relevant parties together to agree on how this should be done, including the rules of engagement and a range of business models by end-2019.

EOSC must have a long-term baseline funding commitment to become trustworthy. An agreement on how this is to be done needs to be decided within 12 months (by April 2019). The EC must take the lead in bringing the appropriate funders together. EOSC must be free and easy to use for research and education purposes.

For FP9, all researchers must receive appropriate EOSC training and be required to deposit their research outcomes in EOSC-compliant infrastructures. This should be funded by a non-transferable allowable contribution from funders. To this end, access from all parties must be easy and inexpensive if it is to obtain universal support.

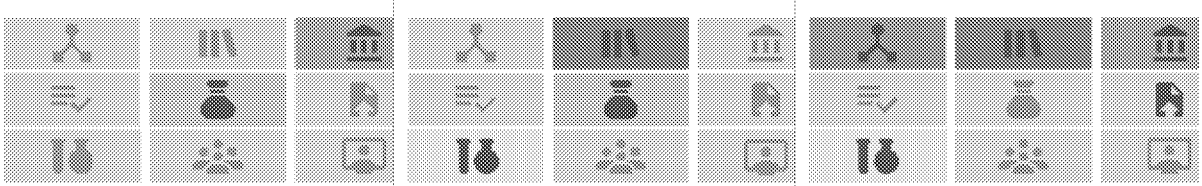


FAIR Data

Funders and Research Performing Organisations should give credit for Findable, Accessible, Interoperable and Reusable (FAIR) data resulting from research work, similar to publications, methods, code etc.

Output Management Plans (OMPs, including Data Management Plans, DMPs) and their implementation should be mandatory for all research projects. OMPs should be machine readable and regularly modified to reflect ongoing research developments.

Data resulting from publicly funded research must be made FAIR and citable, and be as open as possible, as closed as necessary.



Research Integrity

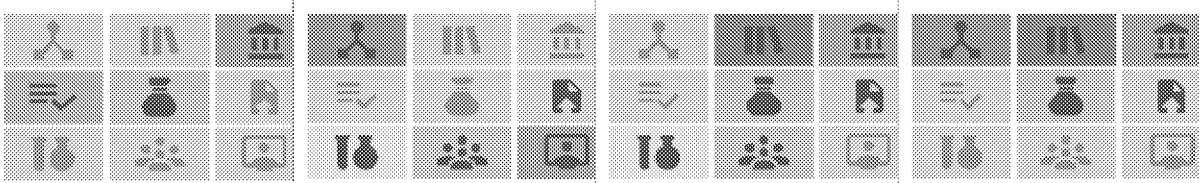
All research organisations must have a research integrity policy, including promotion of good research practices, clear procedures for dealing with allegations of research misconduct and a description of possible sanctions for proven cases of misconduct. This policy must be enforced and adequately staffed and financed to investigate any allegation pertinent to their staff. The processes for dealing with such issues should be public, transparent and prominently displayed. Outcomes should be published where the allegations are upheld, taking into account the sensitivity of the issues involved.

All published research outputs should be reported according to recognised community standards where they exist.

For any research project, researchers should define conditions by which their work can be replicated or otherwise verified by others.

All researchers must receive regular training and accreditation on research integrity pertaining to Open Science, including the ethical, legal and social implications of their research practices. Funders (including the EC through FP9) must ensure that there is adequate training given to the researchers they fund, either through the researcher's institution, or provided via other means.

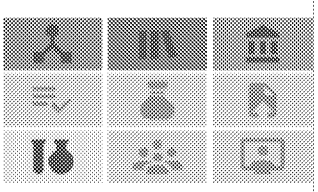
Publishers, data platform and infrastructure providers must agree a standardised set of minimum quality control checks on outputs and openly display the results. The task of undertaking these independent checks needs to be adequately funded. Outputs that pass these checks should be recognised and rewarded in research and researcher evaluation systems, such as FP9.



Skills and Education

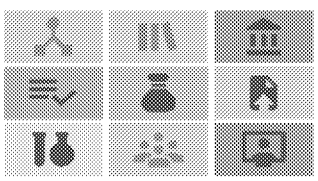
Research Performing Organizations (RPOs) need to work towards the design of appropriate Open Science training that is consistent across Member States, including data literacy, ethics and research integrity, for:

- All researchers, at all levels from early career researchers to senior researchers (R1-R4). Open Science skills need to be explicitly tailored to diverse career paths.
- Research managers and administrators, and other staff involved in the research ecosystem (librarians, repository managers, IT services, data stewards, etc.).
- Students (both undergraduate and graduate levels).



Policy makers, funders and institutions must provide incentives and support towards developing Open Science mentoring and training within a supportive culture and environment.

A fundamental part of a researcher's education is to have a common set of baseline skills on Open Science which must be integrated in the European Framework of Research Careers (EFRC) and the Innovative Doctoral Training Principles (IDTP).



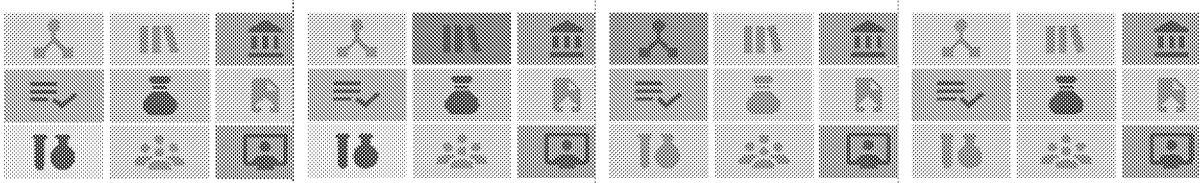
Citizen Science

Publicly funded Citizen Science projects (as part of FP9 projects) should actively apply the principles of Open Science (including openness and reuse of all research outputs, data and publications).

Research-performing organisations (RPOs) are encouraged to promote infrastructures and human capacity to create a supportive and open environment for Citizen Science, which can further strengthen the outreach of RPOs to society. Research libraries are well placed, amongst others, to contribute actively to the necessary coordination and communication infrastructures as well as relevant training, fostering skills such as community management, co-production of knowledge, Open Science standards and social diversity. Appropriate funding and incentives need to be put in place to support this endeavour.

The EC must support an online toolkit for Citizen Science in Europe. This tool must promote Citizen Science as a European asset, offering an entry point and mutual learning space, interconnecting with existing activities and infrastructures at the European, national and local level. It should highlight particular achievements and best practices, and promote a clear set of principles, guidelines & quality criteria for Citizen Science.

Funding for Citizen Science projects should be flexible, long-term and allow for small or experimental projects in collaboration with key stakeholders to be funded. A small section of FP9 should be set aside for citizens to propose research topics or projects. These should be chosen on the basis that they are high risk, beyond traditional research fields and conform to the rigorous standards expected of other projects. Successful proposers will need to work with compliant institutions.



Annex A
Glossary and Acronyms

DORA	Declaration on Research Assessment [a.k.a.: SFDORA] [See]
ECR	Early Career Researcher, typically R1-R2 level of researcher, often including researchers during their PhD up to 7-12 years after their PhD dissertation.
EOSC	European Open Science Cloud, a large infrastructure (cloud) for research data in Europe. EOSC is the vision of the EC to support and develop Open Science and Open Innovation in Europe and beyond, to give Europe a global lead in scientific data infrastructures and to ensure that European scientists reap the full benefits of data-driven science. [See]
EFRC	European Framework for Research Careers [See]
FAIR	Findable, Accessible, Interoperable and Reusable. Set of agreed principles applicable to Research Data. [See]
FP9	Framework Programme 9, the research framework programme that will succeed Horizon 2020. [See]
HLEG	High Level Expert Group. Related expert groups established by the Commission. [See Annex C]
HRS4R	The 'HR Strategy for Researchers', which supports research institutions and funding organisations in the implementation of the Charter & Code in their policies and practices. [See]
IDTP	Innovative Doctoral Training Principles [See]
NGO	Non-Governmental Organisation
OA	Open Access [See]
OMPs	Output Management Plans (includes Research Data Management Plans)
ORCID	Persistent digital identifier for researchers [See].
OS-CAM	Open Science Career Assessment Matrix [See]
OSPP	Open Science Policy Platform. High Level Advisory Group established by the Commission in May 2016 to provide advice on the development and implementation of Open Science in Europe. [See Annex B and See]
OSPP-REC	The prioritised set of actionable recommendations issued by the Open Science Policy Platform members in April 2018.

RFO	Research Funding Organisation
RPO	Research Performing Organisation
SFDORA	San Francisco Declaration On Research Assessment. [See: DORA]
SME	Small and Medium Enterprise
Trusted repository	For the purpose of these recommendations, a Trusted Repository means a data repository that meets the Core Trust Seal (CTS) requirements, a collaborative assessment system of the DSA Data Seal of Approval (Research Data Alliance – RDA) and the ICSU (International Council for Science) World Data System.

Annex B

Open Science Policy Platform (OSPP) members

Name	Representative organisation and Affiliation	Stakeholder Group
Sergio Andreozzi	The EGI Foundation	Open Science Platforms/Intermediaries
Michela Bertero	EU-LIFE (Alliance of 13 top research centres in life sciences to support and strengthen European research excellence), co-founder; Head of the International and Scientific Affairs Unit, CRG (Centre for Genomic Regulation, Barcelona, Spain)	Research Organisations
Kurt Deketelaere	League of European Research Universities (LERU), Secretary General	Universities
Paul Ayris	LERU co-Chair of the INFO Community (alternate representative)	
Jennifer Edmond	Digital Research Infrastructure for Arts and Humanities (DARIAH), Member of the DARIAH-IE steering committee	Open Science Platforms/Intermediaries
Manuela Epure	The Alliance of Central and East European Universities (ACEU), Vice-President	Universities
Michele Garfinkel	The European Molecular Biology Organization (EMBO), Manager of the EMBO Science Policy Programme	Research organisations
Tuija Hirvikoski	European Network of Living Labs (ENoLL), elected President	Research organisations

Kristiina Hormia Poutanen	Association of European Research Libraries (LIBER), President	Libraries
Matthias Kleiner	Science Europe, Member of Governing Board	Funding Organisations
Stephan Kuster	Science Europe, Secretary General (alternate representative)	
Wolfram Koch	European Association for Chemical and Molecular Sciences (EUCHEMS), Member of Executive Board	Academies/Learned Societies
Ernst Kristiansen	European Association of Research and Technology Organisations (EARTO), Treasurer and Member of Executive Board	Research organisations
Rebecca Lawrence (*OSPP-REC Chair*)	F1000, Managing Director	Open Science Platforms/Intermediaries
Sabina Leonelli (*OSPP-REC Rapporteur*)	Global Young Academy (GYA), elected Member	Academies/Learned Societies
Norbert Lossau	European University Association (EUA), Vice-President of the University of Göttingen	Universities
Karel Luyben	The Conference of European Schools for Advanced Engineering Education and Research (CESAER), Vice-President Research, and Chairman of the Task Force on Open Science	Universities
Michael Mabe	International Association of Scientific, Technical and Medical Publishers (STM), Chief Executive Officer	Publishers
Philip Carpenter	STM Board Member (alternate representative)	

Catriona J. MacCallum (*OSPP-REC Rapporteur*)	Open Access Scholarly Publishers Association (OASPA), Chair of Policy Committee; Director of Open Science (Hindawi)	Publishers
Paul Peters	OASPA President (alternate representative)	
Natalia Manola	OpenAIRE, an open access infrastructure, Managing Director	Open Science Platforms/Intermediaries
Eva Méndez Rodríguez	Young European Research Universities Network (YERUN); Deputy Vice-President for Scientific Policy, Open Science, Universidad Carlos III de Madrid	Universities
Christophe Rossel	European Physical Society (EPS), Past-President	Academies/Learned Societies
Matthew Scott	GÉANT (A pan-European collaboration on e-infrastructure and services for research and education), Chief Programmes Officer	Open Science Platforms/Intermediaries
Steve Cotter	GÉANT Chief Executive Officer (alternate representative)	
Michela Vignoli	Young European Associated Researchers Network (YEAR), Board Member	Academies/Learned Societies
Jan-Eric Sundgren	Business Europe	Open Science Platforms/Intermediaries
Michela Vignoli	Young European Associated Researchers Network (YEAR), Board Member	Academies/Learned Societies
Johannes Vogel (*OSPP Chair*)	European Citizen Science Association (ECSA), Chair	Citizen Science Organisations
Maike Weisspflug	European Citizen Science Association (alternate representative)	

John Wood	Research Data Alliance (RDA), Co-Chair, and Chair of RDA Europe	Open Science Platforms/Intermediaries

Annex C

EC High Level Expert Groups and outcomes (reports)

High-level Expert Group on European Open Science Cloud I (2016) Realising the European Open Science Cloud

High-level Expert Group on Next-Generation Metrics (2017) Next-generation metrics: Responsible metrics and evaluation for open science

High-level Expert Group on Rewards and Incentives (2017) Evaluation of Research Careers fully acknowledging Open Science Practices: Rewards, incentives and/or recognition for researchers practicing Open Science

High-level Expert Group on Education and Skills (2017) Providing researchers with the skills and competencies they need to practise Open Science: Report of the Working Group on Education and Skills under Open Science

Mutual Learning Exercise on Open Science - Altmetrics and Rewards (2017-2018)

Reports are in progress on:

- FAIR Data
- European Open Science Cloud (Report II)
- Future of Scholarly Communication
- Indicators

Previous reports by specific OSPP Working Groups

Recommendations on Open Science Publishing (adopted April 2017)

Report on the governance and financial schemes for the European Open Science Cloud (adopted May 2017)

Recommendations of the OSPP on Next-Generation Metrics (adopted October 2017)

Providing researchers with the skills and competencies they need to practise Open Science: Report of the Working Group on Education and Skills under Open Science (adopted October 2017)

Evaluation of Research Careers fully acknowledging Open Science Practices: Rewards, incentives and/or recognition for researchers practicing Open Science (adopted November 2017)

OSPP Combined Recommendations for the Embedding of Open Science (adopted March 2018)

Recommendations of the OSPP on Citizen Science (adopted April 2018)

Message

From: Interagency Working Group on Open Science [IWGOS@LISTSERV.NSF.GOV]
on behalf of Knezek, Patricia M. (HQ-DH000)[Federal Government Detailee] [patricia.m.knezek@NASA.GOV]
Sent: 7/31/2018 1:19:17 PM
To: IWGOS@LISTSERV.NSF.GOV
Subject: FW: Proposed EPA rule on open data / transparency
Attachments: EPA Proposed Rule Docket EPA-HQ-OA-2018-0259 NASEM Comment.pdf

FYI.

Pat

From: "Barbier, Louis M. (HQ-AE000)" <louis.m.barbier@nasa.gov>
Date: Tuesday, July 31, 2018 at 7:24 AM
To: "Knezek, Patricia M. (HQ-DH000)[Federal Government Detailee]" <patricia.m.knezek@nasa.gov>
Subject: Proposed EPA rule on open data / transparency

Pat,

I think the IWGOS members might like to see the letter from the National Academy Presidents to the EPA. I've attached it here.

Louis

Louis M Barbier, PhD
Associate Chief Scientist,
Office of the Chief Scientist
NASA Headquarters
Tel: 202 – 358 – 1421
Cell: 202 – 507 – 0110
Email: Louis.M.Barbier@nasa.gov
Twitter: @LouisBarbier12

##

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

July 16, 2018

Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259)

Dear Administrator Wheeler,

We are writing in regard to the proposed rule for Strengthening Transparency in Regulatory Science (April 30, 2018, 83 Federal Register 18768). The proposed rule stipulates that the U.S. Environmental Protection Agency (EPA) will ensure that the data and models underlying the pivotal science that informs significant regulatory actions are made publicly available, in a format that allows for outside analysis and validation. While that provision is generally consistent with advice from the National Academies of Sciences, Engineering, and Medicine, overly stringent requirements for transparency may cause valid evidence to be discarded and thereby pose a threat to the credibility of regulatory science.

The potential impacts of the proposed rule on the quality of regulatory science will depend on many aspects of the rule's implementation that are not described in detail in the Federal Register notice, including the following:

(1) Criteria and processes to make objective and transparent decisions about which studies will be included in scientific analyses used to inform federal regulations;
(2) Approaches for evaluating the data and models used to characterize the dose-response relationships underlying federal regulations; and
(3) Approaches for protecting the confidentiality of certain kinds of data while balancing the need to make data publicly available.

The National Academies were established by the president of the United States and the U.S. Congress as institutions independent of government to provide objective advice to the nation on matters involving science, engineering, and medicine. The National Academies conduct hundreds of activities and dozens of studies each year to provide advice on a wide variety of issues at the request of EPA and many other federal agencies. The committees that conduct the Academies' studies are carefully selected to provide the best available scientific, technical, and policy expertise while avoiding conflicts of interest. Committee members are experts in their fields who volunteer their time to gather information and review the scientific literature as well as to provide their findings and recommendations to address the issue at hand. These reports are independently peer-reviewed and modified, if necessary, before becoming publicly available.

The National Academies have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data. We have issued a number of reports, summarized below, that describe how EPA could improve transparency by documenting its procedures and methods for collecting, evaluating, and analyzing data, by specifying assumptions, and by characterizing uncertainties. In particular, the National Academies have provided advice on the transparency, selection, and evaluation of studies used in EPA's regulatory policy formulation.

However, we want to emphasize that although these earlier reports can serve as a valuable resource to help inform decisions about some elements of the proposed rule, they were not designed to address the full breadth of the issues raised by the proposed rule. The proposed rule's scope, complexities, and potential serious implications for regulatory science and action clearly warrant additional thorough, independent, objective, and context-specific evaluation and analysis.

Transparency and Study Selection and Evaluation

The National Academies have carried out numerous studies that advise EPA on the scientific bases of regulatory decisions related to human health and the environment. Examples of relevant reports that advise on dose-response analysis and models, as well as how to perform literature-based reviews, include:

- *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals* (NASEM, 2017a),
- *Review of EPA's Integrated Risk Information System (IRIS) Process* (NRC, 2014),
- *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic: Interim Report* (NRC, 2013),
- *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* (NRC, 2011),
- *Finding What Works in Health Care: Standards for Systematic Reviews* (IOM, 2011),
- *Science and Decisions: Advancing Risk Assessment* (NRC, 2009), and
- *Models in Environmental Regulatory Decision Making* (NRC, 2007).

These reports encourage EPA to consider all available science in the rule-making process and provide guidance about how the agency could be more transparent in describing how evidence is gathered and evaluated. Specifically, systematic-review methods should be adopted to ensure objectivity, rigor, and transparency in performing literature-based reviews (IOM, 2011; NRC, 2011, 2014). NASEM, 2017a, includes four case examples of systematic reviews.

Systematic-review methods should include a strategy for identifying and screening relevant studies and evaluating their quality. The strategy and methods are best established before undertaking the review to ensure objectivity in the search, screening of studies, and to make certain that studies are evaluated consistently. The evaluation criteria should be tailored to the type of evidence under consideration (human, animal, or mechanistic data). Individual study quality should be evaluated on the basis of information that is available in standard journal articles, such as the study design elements, analytical techniques, and statistical methods. Researchers may be contacted to answer questions about the conduct of the study or be asked to provide additional data. If the study data are not available, their

absence may affect how the study is rated and used in the analysis, but the study should not necessarily be eliminated from the assessment.

The Federal Register notice acknowledges that because of confidentiality concerns, exemptions from the proposed rule will be required because of the impracticality of making publicly available all data that underpin pivotal regulatory science. It is critical for EPA to define what "reasonable effort" would be required to make data publicly available before an exemption is granted. Decisions about exemptions should be based on formal agency guidance and not according to criteria established by a single EPA employee.

Dose-Response Data and Models

Several National Academies reports provide expert advice about how to evaluate dose-response relationships, as is mentioned in the proposed rule. For example, NRC, 2009, recommends that EPA unify the approach it takes to conducting dose-response assessments for cancer and non-cancer health effects, so that potential effects are evaluated based on the probability of harm. This approach will facilitate the assessment of risk management decisions. The recommended unified dose-response approach includes use of a spectrum of data from human, animal, mechanistic, and other relevant studies; a probabilistic characterization of health and environmental risks; explicit consideration of human heterogeneity; characterization of the most important uncertainties; evaluation of background exposure and susceptibility; use of probabilistic distributions when possible; and characterization of sensitive populations.

Making Data Publicly Available

The Federal Register notice cites National Academies reports that provide advice on issues related to data collected and acquired for and by federal statistical agencies to produce national statistics for the public good:

- *Innovations in Federal Statistics: Combining Data While Protecting Privacy* (NASEM, 2017b), and
- *Federal Statistics, Multiple Data Sources, and Privacy Protections: Next Steps* (NASEM, 2017c).

The EPA proposed rule references these reports to identify current approaches for protecting confidentiality while providing data for statistical purposes, such as those used by the Federal Statistical Research Data Centers. The reports consider the kinds of data that are typically collected and acquired under pledges of confidentiality for exclusively statistical purposes – pledges that are backed by strong statutory protections, with criminal penalties for violations.

There are several differences in the confidential microdata collected from individuals and businesses by federal statistical agencies through surveys, versus data and results from the kinds of studies that are within the scope of the EPA proposed rule. These differences have important implications about making data publicly accessible. What works well in the federal statistical environment may not translate effectively to EPA, where stakeholders might be strongly motivated to discount study results that run counter to their regulatory preferences.

In addition, EPA's proposed rule ignores the inherent risks involved in data disclosure, the ever-changing risk landscape, and the efforts needed to mitigate those risks – all of which are discussed in the cited National Academies reports. For example, the security of data held by federal agencies is exposed to new and evolving threats. In addition to cybersecurity concerns, computer scientists and cryptographers have demonstrated that statistical analyses of data sets that generate highly precise results – such as geographic specificity or other characteristics that identify respondents – may result in privacy breaches (NASEM, 2017b; NASEM 2017c). This presents a new challenge that federal statistical agencies are just beginning to address.

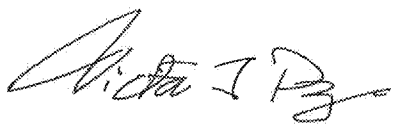
Conclusion

Much more clarity is required on these and many other issues. The potential negative consequences for EPA's ability to take needed regulatory action require more careful examination. We strongly encourage EPA to seek objective, expert guidance on the complexities of this rule and how it would be implemented. As independent and trusted advisers to the nation, the National Academies would be pleased to assist you in this effort.

Sincerely,

Marcia McNutt
President, National Academy of Sciences

C. D. Mote, Jr.
President, National Academy of Engineering



Victor J. Dzau
President, National Academy of Medicine

Message

From: Interagency Working Group on Open Science [IWGOS@LISTSERV.NSF.GOV]
on behalf of Sinks, Tom [Sinks.Tom@EPA.GOV]
Sent: 4/25/2018 12:01:26 PM
To: IWGOS@LISTSERV.NSF.GOV
Subject: Public Access to Data and Transparency in Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

Yesterday Administrator Pruitt signed this NPRM which should be posted in the Federal Register today or tomorrow. It is open for comment, I believe for 30 days. If possible, I'd like to ask the chairs for time on tomorrow's agenda to discuss this proposed rule and its connection to our work on open access to research data.

Thanks

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

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MINNESOTA

May 29, 2018

Tom Sinks
Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, DC 20460

Submitted under Docket ID No. EPA-HQ-OA-2018-0259 via www.regulations.gov

RE: The Minnesota Pollution Control Agency and Minnesota Department of Health's joint comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018, at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259.

Dear Tom Sinks:

The Minnesota Pollution Control Agency (MPCA) and the Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are deeply troubled by this proposed rule. The rule, seemingly written without the knowledge of career staff at EPA or EPA's existing scientific advisory boards, seems designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research – and to create suspicion significant enough to deter future use of health-based studies in regulatory decision making. Privacy of health data is a foundational ethic for the medical and health science research fields, and EPA's proposal ignores the historical context under which the privacy rules around health data were developed.

Attached to this letter is a document (enclosure) outlining, in greater detail, the concerns that MPCA and MDH have regarding both the intent behind the rule, as described in the General Information and Background sections of 83 FR 18768.

The enclosure discusses the following points:

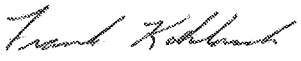
1. EPA provides no rationale regarding the need for, or reasonableness of, this proposal.
2. This proposed rule weakens longstanding privacy protections afforded US citizens.
3. This rule does not integrate, nor does it provide solutions for, the current work on data reproducibility within the scientific community.
4. This rule cannot be implemented within a reasonable timeframe.
5. This proposed rule is counter the current goal of Cooperative Federalism.
6. EPA must withdraw this proposal.

Promulgation of this rule would be a significant departure from EPA's core mission: to protect Americans' health and the environment. It would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision making. Although intended to "strengthen transparency", the Rule does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and will threaten the lives of real people.

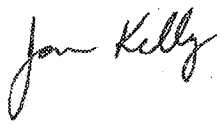
As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. EPA should immediately withdraw this dangerous and ill-conceived proposal.

If there are additional questions related to these comments, please contact Anne Jackson at the MPCA. She can be reached at anne.jackson@state.mn.us or at 651-757-2460.

Sincerely,



Frank Kohlasch, Manager
Air Assessment and Analysis
Environmental Analysis and Outcomes Division
Minnesota Pollution Control Agency



James Kelly, M.S., Manager
Environmental Surveillance & Assessment
Environmental Health Division
Minnesota Department of Health

AMJ/FK/JK:vs

Enclosure

cc: E. Scott Pruitt, U.S. Environmental Protection Agency
Cathy Stepp, U.S. Environmental Protection Agency, Region 5

Minnesota's comments on the proposed rule, "Strengthening Transparency in Regulatory Science" (83 FR 18768)

Docket ID No. EPA-HQ-OA-2018-0259

Agency support rather than regulatory action is the appropriate vehicle to improve data transparency.

Minnesota supports open data, and is a national leader in scientific and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data publically available, providing technical assistance for using that data, and engaging partners across communities and research institutions around effective data dissemination and utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state institutional review boards (IRBs).

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are concerned about this proposed rule leading to the censorship of health sciences research and epidemiological findings (see the MPCA's May 15 letter to Administrator Scott Pruitt at the end of this document). These studies are the basis for establishing standards and toxicity values to protect public health.

The proposed rule undermines the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, biota, or soil. Properly implementing this rule will require EPA to first address many legal aspects surrounding public and nonpublic data, significantly expand database tools and peer review capacity, and develop guidelines for the use of "independent validation" – all of which require considerable time and financial resources. As a result, the proposed rule does little to improve the transparency of current work and, in fact, will cloud the conduct and evaluation of health studies and delay the adoption of human health-based pollution standards for the foreseeable future.

The proposal casts doubt on EPA's prior judgement of, and dependence on, health research – and creates suspicion significant enough to interfere with the future use of existing health-based studies in regulatory decision making. More importantly, EPA's proposal flagrantly ignores the historical context and reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields, upheld by decades of US Supreme Court decisions.

EPA provides no rationale regarding the need for, or reasonableness of, this proposal.

It is appropriate that EPA continues its efforts to make data publically available[1], to ensure that agency decisions are supported by the best available scientific knowledge and research, and that deliberations are well-reasoned and explained to the public. In the context of this proposal, however, Minnesota is most concerned about the implementation of this rule, and censoring studies from use in EPA work because they could not be "independently validated" because of privacy issues. Such an outcome would result in regulatory records supporting unreliable, pre-determined outcomes or decisions.

The preamble is not clear about the problem this proposed rule will address. EPA states that the proposed rule is designed to "...change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis" (83 FR 18770). Changing agency culture does not occur through rulemaking, especially if few resources are given to new rule implementation. Agency culture and work practices are changed when agency administrators provide leadership, direction, and support of technical and career staff through adequate funding and, in the case of EPA, partnerships with the health and environmental research communities.

This proposed rule's focus on the epidemiology of dose-response data undermines "pivotal regulatory science". Although EPA's argument is that there should be a regulation to ensure increased access to dose-response data and models, EPA offers no evidence of an existing problem with dose-response data transparency that needs to be addressed, nor does EPA demonstrate how independent validation outside of existing peer review processes improves upon current data transparency practices and data availability. EPA offers no evidence that EPA's previous judgement, particularly in the development of dose-response functions, has been inadequate, invalid, or otherwise arbitrary. Frankly, we view this proposal, and its requirement of making publically available data for "independent validation", simply as a means of providing industries concerned with various studies an opportunity to reanalyze data to reshape or recast conclusions drawn by researchers and subsequent peer reviews, and to allow EPA to censor important studies without justification.

The proposed rule's provision to allow the Administrator to provide case-by-case exemptions in Part 30.9 does not resolve our concerns. The rule sets no criteria for the Administrator to censor a study other than whether the data can be made publically available, nor does the rule require the Administrator to explain or justify why a study was censored or used in the regulatory decision. Without expanded criteria or the requirement to describe how or why studies are included or excluded from a regulatory decision, the Administrator would be free to act in an arbitrary manner.

From a risk assessment perspective, excluding epidemiological studies in regulatory science is not sound or prudent. Laboratory work, toxicological research, and epidemiological studies are complementary, and each facet is necessary when it comes to understanding and quantifying the effects of a pollutant on

[1] EPA has an ongoing program to expand and improve open access for research. https://www.epa.gov/open

human health. Eliminating evidence from one of these three essential disciplines threatens the scientific basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in the impossible situation of relying primarily on animal or in-vivo models, which cannot be directly extrapolated to human dose-response estimates.

Minnesota, and other states, rely on the EPA to provide us with scientific information that is accurate and sound. If EPA's data begins to depart from being scientifically sound and reliable, the Agency's credibility in protection of human health and environment is diminished. States are left with a data gap that simply cannot be filled with our limited resources. EPA's strong leadership in unbiased scientific research and reasoned application promotes consistency for state agencies across the country, regulatory certainty for businesses, and provides the information, standards and guidelines necessary to provide health protections for US citizens. Minnesota, and others, continue to depend on EPA's leadership.

This proposed rule weakens longstanding privacy protections afforded to U.S. Citizens.

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analyses would effectively breach confidentiality requirements upheld by public and private research through IRBs. Data availability, as it would be under this rule, would disclose information such as geocoded latitude/longitude residential locations; demographic covariates; and repeated measures in longitudinal population-based studies. If made publicly available, as required by the proposed rule, the specificity of these non-private covariates would facilitate, with relative ease, the re-identification of individuals and their protected health information. Further, it is this very specificity in geographic, demographic, and health information that contribute to epidemiological studies with the most robust quantification of dose-response and uncertainty relationships. It is well documented that privacy assurances are essential to access population health information, recruit and maintain population-based cohorts, and to mitigate non-random selection bias. The proposed rule does not make clear how it would assess or address bias or systematic errors in population studies that were able to release un-masked analytic data to the public.

Ethical and legal frameworks protecting patient and study participant confidentiality are foundational to robust and unbiased analyses; requiring release of these data would effectively bar the most informative population-based studies from contributing to regulatory science. It does not seem that such epidemiological studies could fulfill obligations of IRB-mandated informed consent, patient confidentiality, and Health Insurance Portability and Accountability Act (HIPAA) data governance systems. Not every IRB study is done by a HIPAA covered entity, but nearly every IRB study that involves human health is covered by some legal privacy protections similar to those under HIPAA.

This rule does not integrate, nor does it provide solutions for, the current work on data reproducibility within the scientific community.

EPA points to a "replication crisis" (83 FR 18770) as one possible reason prompting this rule proposal. There are alternative mechanisms for addressing the so-called replication crisis, however, including

peer-review and supervised re-analysis, as well as utilizing or expanding longstanding expert bodies that would not flout, and do not weaken, accepted and effective data privacy systems. These existing, robust mechanisms are also the appropriate locus for discerning appropriateness and adequacy of quantitative models and methods, including non-linearity and effect measure modification of dose-response relationships, as referenced in the proposed rule.

Rather than writing and promulgating a costly rule, the EPA should engage with and support current work that promotes solutions that improve and maintain reproducibility in science. For instance, the list below includes a number of organized discussions by universities, research organizations, and federal agencies to address potential issues surrounding about the problems of reproducibility of scientific studies:

Yale School of Public Health - https://publichealth.yale.edu/ehs/research/conferences/reproducibility/,
Keystone Symposia - https://virtual.keystonesymposia.org/ks/live/39/page/201,
National Institutes of Health - https://www.nlm.nih.gov/news/reproducible-research-conference2016.html,
Society of Toxicology - http://www.toxicology.org/events/am/AM2016/ss.asp,
Health Effects Institute - https://www.healtheffects.org/annual-conference.

Should EPA believe that more formal and defensible research data practices are needed, it would be more appropriate to follow past practice and request the National Academy of Sciences to develop guidance, similar to its request to develop risk assessment guidance, than to promulgate a new rule.

This rule is cannot be implemented in a reasonable timeframe.

We are not certain that this rule can be implemented within a reasonable timeframe, nor is there any evidence that EPA is currently making plans to implement this rule. To that end, if this rule is promulgated, we recommend that any application be only prospective. This rule must not be applied retrospectively; such application would only serve to create confusion with the intent of undermining existing public health regulations.

As the proposed rule offers no instruction as to how or whether EPA use the public's efforts in conducting "independent validation", we recommend that existing EPA programs evaluating human health studies continue under current practices until implementation is completed, including providing sufficient funding for developing open access to databases, establishing guidance as to how and when EPA is to assess or use unsupervised validation studies submitted by the public, as well as determining and resolving public and nonpublic data issues (securing permissions if necessary).

This proposed rule is counter to the current goal of Cooperative Federalism.

As an example, the MPCA manages facility air toxics emissions through modeling and risk-based assessments, with support from MDH. Specifically, we compare modeled air concentrations to inhalation health benchmarks. In order to keep our approach systematic and non-biased, the MPCA and MDH pre-select information sources of inhalation health benchmarks in the form of a hierarchy. Approximately 40% of the inhalation health benchmarks that the MPCA uses to manage air toxics

emissions are from EPA's Integrated Risk Information System (IRIS) or Provisional Peer-Reviewed Toxicity Values (PPRTV) programs. Our understanding of this proposed rule leads us to believe that the dose-response information used to develop these values could become mired in redundant and unnecessary review, should the rule be enacted. Any delay in the review of IRIS or PPRTV data greatly compromises the MPCA's ability to assess and appropriately set permit conditions for industries, or to determine clean up requirements for site remediation projects.

The MPCA and MDH do not disagree that it is worth looking at data practices for all research conducted by EPA, and that there may be opportunities for improvement. EPA would be better served making existing data easier to understand, better communicating the scientific research that is being done at the agencies, and how strong partnerships with third parties strengthens EPA's regulatory authority and its public image.

EPA must withdraw this proposal.

EPA claims in this proposal that it does not need to address EO 13045 (protecting children) nor EO 12898 (Environmental Justice in Minority Populations) because "this action does not concern an environmental health risk or safety risk" (83 FR 18773). This is an inaccurate and unsupported claim. The implementation of this rule would indirectly impact the rules and guidelines that are set to protect children, people of color, the elderly, low-income, and other underserved populations.

This action was correctly identified as a "significant regulatory action" under Executive Orders 12866 and 13563, which then requires a regulatory impact analysis (RIA). The RIA would include an estimate of costs of implementing this rule, and an estimate of resulting benefits. EPA claims benefits outweigh costs, but there is no published record or analysis to demonstrate that this claim is valid. This proposed rule is nearly a mirror image of the proposed HONEST Act (H.F. 1430). The Congressional Budget Office was able to estimate an implementation cost for the first two years of rule implementation, at a cost of $100 million each year[2]. It follows that this proposal would have initial implementation costs of more than $200 million, while having no benefit.

The intent of this rule is ill-considered, and its potential for implementation is severely limited. EPA asked for input in the public notice that would have been better addressed through an Advanced Notice of Proposed Rulemaking. The record provided with the docket for this proposed rule is nonexistent, and EPA has failed to meet many of the basic requirements in preparing rule proposals for public notice and comment. The rule will likely be determined to be arbitrary and capricious, and is certain to be challenged legally. EPA should withdraw this proposed rule immediately.

[2] Congressional Budget Office, March 29, 2017. " If the EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions, then CBO estimates that the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data to the level required by H.R. 1430". https://www.cbo.gov/publication/52545

MINNESOTA

May 15, 2018

The Honorable E. Scott Pruitt, Administrator
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Mail Code 1101A
Washington, D.C. 20460

Re: Comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018 at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Pruitt:

The Minnesota Pollution Control Agency (MPCA) and Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science," published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259. This proposed rule to "strengthen transparency" does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and it will threaten the lives of real people. EPA should withdraw this dangerous proposal.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are appalled by the specious and brazen attack on health sciences research and the field of epidemiology. The proposed rule was clearly designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, or soil. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research – and to create suspicion significant enough to deter future use of health-based studies in regulatory decision-making. EPA's proposal flagrantly ignores the reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields.

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analysis would effectively breach confidentiality requirements upheld by public and private research through Institutional Review Boards (IRB). It is well documented that privacy assurances are essential to including people in health studies.

From a risk assessment perspective, not including epidemiology studies in regulatory science is not sound or prudent. Laboratory, toxicology, and epidemiology are complementary and necessary pieces of understanding and quantifying effects of a pollutant on human health. Excluding evidence from one of these three essential disciplines threatens the science basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in an impossible situation of relying primarily on animal models or in-vivo models that cannot be directly extrapolated to human dose-response estimates.

Minnesota supports open data access and is a national leader in science and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data available, providing technical assistance for using data, and engaging partners across communities and research institutions

around effective dissemination and data utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state IRBs.

Based on the lack of meaningful information and articulated or demonstrated need for the proposed rule, EPA has not made the case for a new regulation at 40 CFR Part 30.

The promulgation of this proposed rule would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision-making. As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. The EPA should immediately announce that it is withdrawing this proposal.

Our agencies will be submitting additional, substantive comments to the rulemaking record.

Sincerely,

John Linc Stine, Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, Minnesota 55155

Jan Malcolm, Commissioner
Minnesota Department of Health
625 Robert Street North, Box 64975
St. Paul, Minnesota 55155

Message

From: Fitter, E. Holly H. EOP/OMB [E._Holly_Fitter@omb.eop.gov]
Sent: 8/27/2018 1:21:02 PM
To: Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]
Subject: FINAL edits to LRM [EHF-115-242] EPA Qs and As from Pruitt Budget Hearing
Attachments: 07-25-2018 - EPA_HEC_4.26_QFR_Pruitt_Responses_OMB V1 - EPA V3_EBR.docx

See two final edits/comments. Cleared with these changes. Thanks.

Deliberative Process / Ex. 5

August 16, 2018

Docket ID No. EPA-HQ-OA-2018-0259
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science

To Whom it May Concern:

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to offer comments on the notice for "Strengthening Transparency in Regulatory Science" as published in the April 30th *Federal Register* (Volume 83 Number 83). ASDWA is the independent, nonpartisan, national organization representing the collective interests of the drinking water program administrators in the 50 states, five territories, the District of Columbia, and the Navajo Nation who implement the Safe Drinking Water Act (SDWA) every day to ensure the protection of public health and the economy. ASDWA supports and represents the collective interests of the states, territories, and the Navajo Nation in their administration of national drinking water program requirements within their states or territories. The following ASDWA comments are intended to broadly address the proposed rule, but they do not necessarily reflect the concerns of individual states.

Federal regulations are the basis for the actions of state drinking water programs in protecting public health. These regulations must be based on sound science to appropriately protect public health. The Safe Drinking Water Act (SDWA) has clear statutory language on the use of sound science, and states support the use of sound science in the SDWA regulatory development process. While states may disagree at times with details of the final regulations, states are generally comfortable with the transparency of the regulatory development process as practiced by the Office of Ground Water and Drinking Water (OGWDW). ASDWA does not recommend making significant changes in that process. In fact, if other environmental programs do not currently have a robust science-based regulatory development process, the process used by OGWDW would be a good model.

The SDWA statutory language in Section §1412(b)(3) requires the use of "best peer reviewed science and supporting studies conducted in accordance with sound and objective scientific practices". Therefore, a statutory requirement that the drinking water regulations have a strong scientific basis already exists. This section of the SDWA also outlines the way this information must be shared with the public, so the process is currently transparent. EPA has followed this statutory mandate since the 1996 SDWA Amendments and has relied not only on peer reviewed scientific studies but has also directly involved the scientific community in supporting rule

1401 WILSON BLVD · SUITE 1225 · ARLINGTON, VA 22209
PHONE (703) 812-9505 · FAX (703) 812-9506 · info@asdwa.org · www.asdwa.org

development. States have also been active participants in this science-based process. The rule development currently underway for perchlorate is a good example of the process at work. Recommendations from the Science Advisory Board (SAB) helped guide the methodology to develop the Maximum Contaminant Level Goal (MCLG). EPA has held two peer reviews to help refine the models and determine how best to apply the modeling to determine the appropriate MCLG. The SAB and the peer review process are all open and the recommendations are public, providing full transparency to the deliberations and decisions.

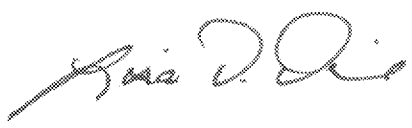
The references listed at the end of the preamble of any proposed drinking water regulation, and any other supporting documentation, is currently shared on the Water Docket, and the Docket provides open access and transparency now for states to examine the basis for new rules. States can review what scientific studies were used in the preparation of the proposed rule and enough detail is provided to judge whether these studies support EPA's conclusions. Since only peer reviewed studies are used, states already have assurances that the results are valid.

Regardless of the pivotal regulatory science used to support a proposed rule, states can openly question the validity of these studies during the comment period for the proposed rule. During this time, states can also recommend additional studies that they believe EPA should consider in developing the final regulations. In the future, EPA can enhance the opportunity for input by consistently allowing a minimum 90-day comment period for new/revised rules. Early involvement by states, as co-regulators, in the early stages of the regulatory development process (pre-proposal) will allow states even more opportunity to provide input on the science used to support the new rules. Beyond the science, involving states as early as possible in the regulatory development process means the resulting regulations can be effectively implemented and public health protection enhanced.

Thank you for considering these comments. As always, ASDWA is willing to continue to work with EPA to develop the best possible drinking water regulations. We encourage EPA to continue the current open and science-based development process and continue to actively involve states. While ASDWA's comments are intended to capture the diverse perspectives of states and state drinking water programs, EPA should also consider the comments/recommendations that may come directly from individual states and territories.

If you have questions or would like to discuss these comments in more detail, please contact me at ldaniels@pa.gov or contact Alan Roberson, ASDWA's Executive Director at aroberson@asdwa.org .

Sincerely,



Lisa Daniels, ASDWA President and Director, Bureau of Safe Drinking Water Director, Pennsylvania Department of Environmental Protection

Cc: Jennifer Orme-Zavaleta, EPA ORD
David Ross, EPA OW
Peter Grevatt, EPA OGWDW
Betsy Behl, EPA OST

Message

Sent: 8/22/2018 2:45:43 PM
To: Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]
Subject: + selected comments
Attachments: Comment (1).pdf; ACC Comments on Strengthening Transparency in Regulatory Science Comment Final 2018 08 16.pdf; ASDWA Comments on Regulatory Transparency 08152018 Final.docx; Letter to EPA re proposed science rule.pdf; 2018.08.15 Comment Letter re Transparency in Science (FINAL FOR FILING).pdf; Coons_Comment_EPA_Transparency_Rule.pdf; Comment.pdf; Comment.pdf

Maria here are some additional comments you might consider posting on the share point site. I'm not adept enough with pdf to know how to rename them so they often have the title "comment" which isn't very helpful. But this is what they include listed in order …

Chlorine Institute
ACC
ASDWA
UCS
11 attorneys general letter
Senate letter
AWWA
Alternate attorney generals letter

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
Personal Email / Ex. 6
email: sinks.tom@epa.gov

Fri Jun 29 16:00:51 EDT 2018
CMS.OEX@epamail.epa.gov
FW: EPA-HQ-OA-2018-0107. ANPRM -- Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process
To: "cms.oex@domino.epamail.epa.gov" <cms.oex@domino.epamail.epa.gov>

From: Pruitt, Scott
Sent: Friday, June 29, 2018 8:00:50 PM (UTC+00:00) Monrovia, Reykjavik
To: CMS.OEX
Subject: FW: EPA-HQ-OA-2018-0107. ANPRM -- Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process

From: Frank, Andrew [mailto:Andrew.Frank@ag.ny.gov]
Sent: Monday, June 18, 2018 5:15 PM
To: Pruitt, Scott <pruitt.scott@epa.gov>
Subject: EPA-HQ-OA-2018-0107. ANPRM -- Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process

Dear Administrator Pruitt:

Please find attached a letter from the Attorneys General of New York, Iowa, Maryland, Massachusetts, New Jersey and the District of Columbia requesting an extension of the public comment period for the above-referenced advance notice of proposed rulemaking.

Sincerely,

Andrew G. Frank

Assistant Attorney General

New York State Attorney General's Office

28 Liberty Street

New York, NY 10005

Telephone: 212-416-8271

Facsimile: 212-416-6007

E-mail: andrew.frank@ag.ny.gov

ATTORNEYS GENERAL OF NEW YORK, IOWA, MARYLAND, MASSACHUSETTS, NEW JERSEY, AND THE DISTRICT OF COLUMBIA

June 18, 2018

BY E-MAIL AND REGULATIONS.GOV
E. Scott Pruitt, Administrator
United States Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code 1101A
Washington, DC 20004
Pruitt.scott@epa.gov

Re: Advance Notice of Proposed Rulemaking – Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process
83 Fed. Reg. 27524 (June 13, 2018)
Docket ID No. EPA-HQ-OA-2018-0107

Dear Administrator Pruitt:

The undersigned Attorneys General are deeply concerned by the Environmental Protection Agency's advance notice regarding a possible rulemaking that may limit EPA's consideration of the benefits of environmental regulation and otherwise interfere with the agency's ability to properly analyze the benefits and costs of such regulation. For the reasons set out below, we write to ask that you extend the public comment period from 30 days to 120 days.

Where and how benefits and costs are analyzed in connection with environmental regulations is vitally important to protecting human health and the environment. We are concerned both about the compressed timeline under which EPA seeks to consider fundamental changes in policy that could affect many of EPA's rulemaking and other activities, and about the vagueness and potentially detrimental consequences of the proposal for those activities. As you know, EPA rules and other EPA actions are key elements of environmental protection that states rely on to safeguard the health of their citizens and natural resources. Under the cooperative federalism approach that underlies the Clean Air Act, the Clean Water Act and other federal environmental laws, states implement EPA's decisions regarding emissions and effluent standards and other regulatory matters, and thus those EPA decisions have a significant effect on the states' ability to protect their citizens and environment from toxic pollution and other harm. Thus, to the extent that consideration of benefits and costs is called for in connection with EPA actions, our states have a strong interest in ensuring that any EPA regulation or guidance governing the analysis of those benefits and costs is consistent with governing law and best practices and otherwise appropriate.

In light of the far-reaching impact the proposal could have on EPA's and the states' ability to protect public health and the environment, we ask that you extend the comment period for the advance notice by 90 days to provide for appropriate input from the public at large as well as from independent environmental experts, economists, and organizations with expertise in analysis of environmental benefits and costs. Given the extremely broad scope and impact of this proposal, the 30 days allowed for public comment in the advance notice is insufficient to give the affected public adequate opportunity to participate in the rulemaking and comment on the proposal as required by the Administrative Procedure Act. 5 U.S.C. § 553(c). Under section (2)(b) of Executive Order 13563, a standard comment period should be at least 60 days, but this tremendously consequential proposal calls for an even more deliberate pace given the profound potential impacts on the regulatory processes for many of the statutes EPA implements and enforces.

A full four-month comment period would be consistent with past practice for matters of similar importance and complexity, and is necessary to provide the public and other stakeholders a meaningful opportunity to evaluate the proposal and its implications for the agency's ability to meet its obligation to protect public health and the environment under federal environmental laws. We therefore request that EPA extend the comment period by 90 days, to October 11, 2018.

We appreciate your consideration of this important matter.

Respectfully submitted,

BARBARA D. UNDERWOOD
Attorney General of New York

THOMAS J. MILLER
Attorney General of Iowa

BRIAN E. FROSH
Attorney General of Maryland

MAURA HEALEY
Attorney General of Massachusetts

GURBIR S. GREWAL
Attorney General of New Jersey

KARL A. RACINE
Attorney General of the District of Columbia

August 16, 2018

Dr. Thomas Sinks
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Submitted electronically to www.regulations.gov

Re: EPA Docket EPA-HQ-OA-2018-0259;
Comments of the American Chemistry Council on EPA's Strengthening Transparency in Regulatory Science Proposed Rule

Dear Dr. Sinks:

The American Chemistry Council is pleased to submit the attached comments on the Environmental Protection Agency's proposed rule, Strengthening Transparency in Regulatory Science.

Please contact me should you have any questions regarding these comments at 202-249-6406 or Christina_Franz@americanchemistry.com.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council

Comments of the American Chemistry Council on EPA's Strengthening Transparency in Regulatory Science Proposed Rule

EPA Docket EPA-HQ-OA-2018-0259

August 16, 2018

Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second Street, NE
Washington DC 20002
(202) 249-6406
Christina_Franz@americanchemistry.com

Table of Contents

Executive Summary

The American Chemistry Council (ACC) is pleased to provide the following comments on the Environmental Protection Agency's (EPA) proposed rule, Strengthening Transparency in Regulatory Science (Strengthening Transparency), published in the Federal Register on April 30, 2018.[1] ACC and its members are directly impacted by the science-based regulatory actions of EPA under a myriad of federal environmental statutes. As such, ACC has a keen interest in EPA's adoption and implementation of a proposal as important as this one, which will reach across the breadth of the Agency's authority.

In the following comments, ACC offers its support for the proposed rule; responds to a number of questions posed by EPA in its preamble; and provides a number of specific recommendations regarding how the proposed rule can be improved and strengthened. Specifically, ACC suggests the following:

- Implementation of the rule would benefit from policy and/or guidance regarding the weight to be accorded the science informing significant regulatory decisions
- EPA should provide better historical context and applicability to the proposed rule
- EPA has not in all circumstances properly identified from where its authority is derived under the various federal environmental statutes cited in the proposed rule
- The regulation should apply to Executive Order 12866 significant regulatory actions at the proposal stage
- Key regulatory definitions and regulatory text require greater clarity
- Clarifications to the preamble are needed
- Implementation of the rule should be statute specific
- The proposed rule should apply to enforcement and permit proceedings
- EPA should incorporate stronger data and model access requirements into its Cooperative Agreements and Grants while complying with privacy and confidentiality requirements and laws
- The rule should apply to all EPA programs, including its IRIS program
- Methodologies and technologies providing protected access to confidential and sensitive data should be employed

[1] 83 FR 18768 (April 30, 2018).

- The rule should generally apply prospectively to EPA decision making
- Bias should not be presumed
- EPA should work with entities where scientific data are not publicly available in a manner sufficient for independent evaluation

I. Introduction and Background

ACC strongly supports EPA's demonstrated commitment in this proposal to build upon the principles underlying the Administrative Procedure Act (APA), Executive Orders 12866, 13777, and 13783, and guidance of Office of Management and Budget (OMB). In addition, ACC supports the proposal's expansion of the 2013 "Increasing Access to the Results of Federally Funded Scientific Research" memorandum directing federal agencies and offices to develop and submit plans to the White House Office of Science and Technology (OSTP) that ensure peer-reviewed publications and digital scientific data resulting from federally-funded scientific research are accessible to the public, the scientific community, and industry—to the extent practicable.

The OSTP directive required each agency to develop a public access plan that maximizes access to federally-funded "digitally formatted scientific data"[2] while also protecting confidentiality, personal privacy, confidential business information (CBI), intellectual property rights, and U.S. competitiveness.[3] In 2016, EPA issued its Plan to Increase Access to Results of EPA-funded Scientific Research in response to the OSTP directive.[4] Importantly, EPA's Strengthening Transparency proposal appears to extend such commitments beyond the government-funded requirement of the OSTP directive to "dose response data and models underlying pivotal regulatory science regardless of the source of funding or identity of the party conducting the regulatory science."[5]

ACC believes that EPA's proposal correctly codifies an important good governance principle—that government agencies should be as transparent as possible, within the bounds of the law, about scientific information relied upon and the justifications for the significant regulatory decisions they make.

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[2] As defined in OMB circular 110 as "the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support scholarly publications. . ." It is a definition consistent with that of "research data" in the regulatory text of EPA's proposal.

[3] More than 20 federal agencies have developed and implemented Data Access Plans, including EPA, the National Institutes of Health (NIH), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA).

[4] Plan to Increase Access to Results of EPA-Funded Scientific Research (USEPA, November 29, 2016) https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[5] ACC suggests improvements to EPA's terminology in the preamble that are described later in these comments in sections VI and VII.

The Agency's focus on dose-response data and models appropriately reflects the evolution of toxicology from a largely observational science to a discipline that applies advanced scientific techniques and knowledge. Research programs within academia, government, and private sector labs have greatly improved our ability to investigate and understand the underlying biological mechanisms, modes of action, and dose responses of toxicants. We can now evaluate biological events leading to toxicity and consider how (in a dose-response manner) these biological events relate to potential risks to human health. This was not possible 10-to-20 years ago. This improvement should directly translate to the application of transparent weight-of-the-evidence approaches to the assessment of human relevance; the development of points of departure; and the derivation of protective human health equivalent dosages that minimize the use of uncertainty factors and variability. A goal has been to apply this knowledge to improve the scientific basis of government regulatory policies and industry product stewardship.

For environmental concerns, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. Toxicity information and—when available—knowledge of mechanisms, are integrated with exposure-response models for risk-based environmental safety decision making.

Despite significant scientific progress in the understanding of mechanisms of action (MOA) and adverse outcome pathways (AOP), the movement away from default precautionary assumptions has been slow to occur, particularly in certain EPA programs. Significant investments by government, academia, and the private sector into toxicological research are counteracted by the failure to move away from default assumptions toward science-based decisions.

ACC encourages EPA to implement best available scientific procedures under this rulemaking. The Agency should move away from the outdated linear concept of how biology operates toward biologically-based mechanisms, i.e., mode of action (MOA) and adverse outcome pathways (AOP) for both cancer and non-cancer effects, that clearly establish the threshold nature of toxicological endpoints for derivation of points of departure for establishing regulatory values and making regulatory decisions.[6] [7]

In the following discussion, ACC offers its comments to help clarify and strengthen the proposed rule.

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[6] Critics of this proposed policy appear to overlook the fact that the call to evaluate different dose response models is entirely consistent with the Agency's Cancer Guidelines, which have been in place since 2005. See Guidelines for Carcinogen Risk Assessment https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3038594/

II. Implementation of the Rule Would Benefit from Policy and/or Guidance Regarding Weight Accorded the Science Informing Significant Regulatory Decisions

As EPA has noted, the proposed rule is consistent with and builds upon the EPA policies implemented by previous administrations. Implementation would be aided by a policy statement or guidance that indicates greater weight will be given to studies using validated test methods and procedures, models, and approaches when and where those data are based on publicly accessible data, and transparent computer algorithms.

Other scientifically relevant and reliable studies and data should not be eliminated from consideration, but rather, accorded less weight when integrating evidence from multiple studies within and across different lines of evidence. Any guidance and other relevant documents developed to assist EPA staff to comply with this rule should include specific examples and/or case studies, perhaps drawing from recent EPA rulemakings, to demonstrate what constitutes regulatory science that is material to EPA's significant regulatory decisions.

III. EPA Should Provide Better Historical Context and Applicability to the Proposed Rule

EPA is proposing to add this rule to 40 C.F.R. 30, contained in Chapter 1, Subchapter B, dedicated to "Grants and Other Federal Assistance," without explaining how or why this rule fits within this subchapter, thereby creating potential confusion regarding its applicability. The potential for confusion was enhanced by the fact that EPA's public website currently contains information regarding the content that was formerly within 40 C.F.R. 30 but was repealed on December 19, 2014, i.e., general terms and conditions applicable to grant recipient and sub-recipients.[8] In addition, a number of questions on which EPA seeks comment relate solely to EPA cooperative agreements and grants or access to EPA-funded data.

In contrast, Section 30.3 of the proposed regulatory text state that "the provisions of this section apply to dose-response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science." Stakeholders would benefit greatly from EPA providing clarification regarding the applicability of Subchapter B and whether and to what extent this rule applies to government-funded and/or beyond government-funded scientific research. We believe the broader approach is warranted.

[8] https://www.epa.gov/grants/epa-general-terms-and-conditions-applicable-40-cfr-part-30-and-31-recipients-effective and see, 79 Fed. Reg. 244 at 76054 (Dec. 19, 2014).

IV. EPA Authority under Federal Environmental Statutes

The provisions cited by EPA under the Clean Air Act (CAA), the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Emergency Planning and Community Right-To-Know Act (EPCRA) in support of its authority to develop and implement its proposed rule all provide broad regulatory authority to promulgate regulations "as are necessary to carry out [the Administrator's] functions" under the statute. The citation to the Resource Conservation and Recovery Act (RCRA) speaks to Labor Standards in the issuance of grants, and does not appear applicable to this rulemaking authority. EPA cites Section 25(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which does provide the Agency with broad authority to "prescribe regulations to carry out the provisions of this subchapter [FIFRA]." It should be noted, however, that the statutory language is a bit different from the other cited statutes and does not read as "as are necessary to carry out....". In addition, FIFRA Section 136r(a) does not relate to rulemaking and instead provides the Agency broad authority to undertake research necessary to carry out the purposes of FIFRA. As such, EPA may mistakenly have included Section 136r(a) to support the proposal as cited on 83 Fed. Reg. 18769. EPA's reference to section 10 under the Toxic Substances Control Act (TSCA) also does not appear on-point. ACC believes EPA's authority to implement this rule is derived from TSCA Section 26(h), which speaks directly to scientific information and standards to which the Agency must adhere in the administration of its work under TSCA Sections 4, 5, and 6.

V. The Regulation Should Apply to E.O. 12866 Significant Regulatory Actions at the Proposal Stage

A. Definitions in E.O. 12866 Are Well-Established, Understood, and Applied.

The proposed rule would apply to significant regulatory actions as defined by E.O. 12866 at Section 3(f) as:

> (f) ''Significant regulatory action'' means any regulatory action that is likely to result in a rule that may:
>
> > (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
> > (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> > (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> > (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

This definition has been applied by the Executive Branch since the Clinton Administration promulgated E.O. 12866 in 1993. Its meaning is well-established with more than twenty-

five years of use. The underlying principles, however, precede its adoption. For example, the E.O. carried over the threshold of an annual $100 million effect on the economy that had been in place since 1978. This (3)(f)(1) threshold for economically significant regulatory actions is the same threshold that requires cost-benefit review for proposed and final regulations considered by OIRA.

A significant benefit of using the E.O. 12866 definition in the final rule is that EPA can easily apply it, against substantial practice and precedent, in a reliable, consistent, and predictable manner. This reduces the burden on the agency, and importantly, provides greater predictability to stakeholders and the public so they can understand to which agency actions the regulation will apply.

B. Conformity with E.O. 12866 Definitions Promotes Efficient OIRA Review.

Similarly, the process by which significant regulatory actions are identified under E.O. 12866 is also well-established. Here, with respect to application of the proposed rule, EPA would retain primary responsibility to identify the significant regulatory actions to which the rule should apply. OIRA would assess EPA's identification against the criteria set out in E.O. 12866. Neither EPA nor OIRA would be charged with applying a new or unfamiliar definition, nor a new process for review.

C. The Range of Agency Actions to Which the Rule Will Apply Should Not be Narrowed.

The significant regulatory elements of E.O. 12866 already require OIRA review and have for the past 25 years of established practice. The proposed rule respects that principle, and indeed, leverages it for maximum efficiency.

EPA specifically invites comment on whether a narrower definition might be appropriate, such as final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under E.O. 12866. Either of these approaches would lose the efficiency and predictability benefits of using the E.O. 12866 definition—and would increase work for both EPA and OIRA. Further, many significant and precedential agency actions do not meet the "economically significant" threshold. For example, many federal agencies administer environmental, health and safety requirements for workers, consumer products, and environmental media—air, water, soil. It should never be the case that EPA, or EPA and other agencies, establish and/or enforce conflicting and irreconcilable health values for the same compound; require the use of different personal protective equipment; or simultaneously prohibit and permit use or discharge of a particular compound. The same rigorous scientific standards, best available science and weight-of-the-evidence approaches should be applied across programs and media to protect human health and the environment. Adoption of the E.O. 12866 definition of significant regulatory action helps avoid inconsistent regulatory decisions by federal agencies that might interfere with policies designed to protect human health and the environment, unfairly burden businesses, and impede the protection of human health and the environment.

D. The Final Rule Should Apply to Significant Guidance Documents.

OMB's Final Bulletin for Agency Good Guidance Practices defines a "significant guidance document" as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

> (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
> (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866, as further amended.

EPA already maintains and publishes a list of significant guidance documents that meet the OMB definition.[9] [10] Applying the rule to EPA's significant guidance allows for greater parity and consistency with respect to the application of scientific principles in regulatory and guidance contexts. It ensures that the same quality and rigor will underpin decision making. It also helps ensure that EPA will apply the same principles to both regulatory requirements and implementing guidance, which provides greater certainty to the regulated community and the public.

VI. Key Regulatory Definitions and Regulatory Text Require Greater Clarity

EPA's terminology and regulatory definitions should be more concise and applied consistently to achieve greater clarity regarding the meaning and proposed application of the rule. For example, proposed section 30.2 refers to "**pivotal** regulatory science as the studies or analyses that **drive** the requirements and/or quantitative analysis of EPA final significant regulatory decisions." [Emphasis added]. This definition is distinguished from "regulatory science," defined as "scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions." These two definitions can be interpreted as simultaneously referencing something identical as well as one being a subset of the other. Therefore, the definitions are vague and need clarification.

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[9] See https://www.epa.gov/laws-regulations/significant-guidance-documents

[10] Notably, EPA's list of significant guidance documents include guidance that applies directly to the regulated community, such as the agency's *2017 Guidance To Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act* (EPA-HQ-OPPT-2017-0341-0002) and *Interpretive Guidance for the Real Estate Community on the Requirements for Disclosure of Information Concerning Lead-Based Paint in Housing, Part I* (EPA-HQ-OPPT-2007-0765-0001).

Assuming the intent is to define and distinguish the subset of scientific studies and analyses that form the scientific foundation for EPA's regulatory decisions from the larger universe of *all* the scientific information reviewed and considered by the agency, a more precise word than "pivotal" would be "material." In other words, those scientific studies and analyses that are material to its regulatory decision must be or be made publicly available in a manner sufficient for independent validation.

The regulatory text in 30.4 and 30.5 should be clarified. Section 30.4 appears to apply to EPA's use of studies (or other regulatory science) relied upon when EPA takes *any* final agency action (emphasis added). In those instances, EPA should make all such studies available to the public to the "extent practicable." Section 30.5 refers specifically to the requirements that apply when "EPA uses dose response data and models underlying "pivotal" (which ACC believes is more aptly expressed as "material") regulatory science." ACC interprets this to mean that in these specific circumstances, the dose response data and models must be "publicly available in a manner sufficient for independent validation," which EPA defines as in a manner "consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." Information considered "publicly available in a manner sufficient for independent validation" when it includes the information "necessary for the public to understand, assess, and replicate findings." As noted above, for environmental safety, exposure-response is the more appropriate relationship to evaluate because most of the environmental test guidelines require quantifying concentrations in media external to the organism for use as the exposure metric. EPA should provide greater clarity regarding what it intends to do in circumstances where raw data cannot be made publicly available.

EPA should include a discussion in the final rule regarding how it proposes to address exposure assessments and risk characterization data and models in the future extensions of related rules on Transparency in Regulatory Science.

Section 30.7 appears to be missing one or more words in the header to the section. It states: "What role does independent peer review in this section?" ACC believes the missing word is likely "have," but EPA should clarify and correct this section in the final rule.

EPA uses the word "justify" frequently throughout the various sections of proposed regulatory text when referencing the use of regulatory science to make its decisions. For example, section 30.7 states: "EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions.*" ACC suggests that there are more precise words that EPA should use to link "pivotal regulatory science" with "regulatory decisions," such as "underpin" or constitute the "foundation" of the "scientific basis" of its regulatory decisions.

ACC has offered some additional, specific language suggestions in a redline version of the proposed regulatory text that is included in these comments in Appendix A.

VII. Clarifications to the Preamble are Needed

A. Definition of "Pivotal Regulatory Science" is needed.

The definition in the proposed regulatory text and may lead to confusion among stakeholders. We recommend consistency between the preamble and the regulatory text and that EPA clarify its terminology.

Importantly, in footnote three on page 18769 of the preamble, EPA states:

> EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use [of] non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n v. EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'n v. EPA,* 283 F.3d 355, 372 (D.C. Cir.2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

ACC believes that this footnote should be clarified to be consistent with the regulatory text that provides that there are exemptions to this policy outlined in sections 30.5 and 30.9. EPA's preamble should not be at odds with the regulatory text.

Invariably there will be circumstances where underlying data no longer exist for studies and/or models that are high quality and reliable. For example, most organizations have data retention policies that have resulted in the disposal of underlying data. Furthermore, Good Laboratory Practices (GLP) regulations include defined periods of time to retain data and study records.[11] EPA should address how it will continue to use those studies and models in light of these policies.

B. Assertions about proposal not "directly regulating entities outside of federal government" and not having "substantial direct effects" on the states.

On page 18769 under section A, EPA states that the proposed regulation does not "directly regulate any entity outside the federal government" and on page 18772, EPA states under section E that "this action imposes no enforceable duty on any state, local or tribal governments or the private sector." Under Section F, EPA asserts that this action does not have federalism implications and will not have "substantial direct effects on the states." ACC is not certain that these statements are accurate. Consider, for example, the establishment of water quality standards (WQS).

[11] 40 C.F.R. 160.

Under Section 303(c) of the CWA, states and authorized tribes must develop WQS and submit them to EPA for its approval or disapproval. To help them develop the standards, EPA provides scientific guidance through its "Section 304(a) National Criteria Recommendations," which specify quantitative concentrations/level and qualitative measures of pollutants that, if not exceeded, generally will ensure acceptable water quality. In developing these recommendations, EPA evaluates acceptable water quality. When developing these recommendations, EPA evaluates available scientific data on a pollutant's effects on public health and welfare, aquatic life, and recreation. EPA recommends that states and tribes consider the Agency's water quality criteria when developing their WQS, though states and tribes may also consider other scientific criteria that differ from EPA's recommendations.

While EPA's national water quality criteria recommendations are not regulations and do not impose binding requirements, they do serve as the scientific basis for the development of water quality standards and WQS are the foundation of a number of CWA programs. As EPA states in its Water Quality Standards Handbook, these standards "establish the baseline used for measuring the success of the CWA programs, so adequate protection of aquatic life and wildlife, recreational uses, and sources of drinking water, for example, depends on developing and adopting well-crafted WQS."[12]

C. Publications should be cited.

ACC suggests that EPA revise its statement that the proposed rule "takes into consideration the policies or recommendations of third-party organizations who [sic] advocated for open science." The recommendations referenced by EPA actually emanate from a survey of the members of three professional organizations whose memberships represent repositories of knowledge and experience in regulatory assessment.[13] As such, reference 10 in EPA's proposal should also be revised to cite the publication, Expert Opinion on Regulatory Risk Assessment, A Survey by the Center for Media and Public Affairs (CMPA) and Center for Health and Risk Communication (CHRC) at George Mason University" (December 6, 2013).[14]

D. Definition of "reproducibility" is needed.

EPA uses the term "reproducibility" in the preamble, but never defines the term and does not include the term in the definitions in the proposed regulatory text. It is unclear what constitutes a reproducible versus non-reproducible finding. It is important to consider that there are different types of reproducibility, such as methods reproducibility, results reproducibility, and reproducibility of conclusions.

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[12]Water Quality Standards Handbook, Office of Water, EPA 820-B-14-008, September 2014, at p. 2.
[13] The Risk Assessment Specialty Section of the Society of Toxicology (SOT-RASS), the Dose Response Section of the Society for Risk Analysis (SRADRS), and the International Society for Regulatory Toxicology and Pharmacology (ISTRP).
[14] https://cmpa.gmu.edu/wp-content/uploads/2013/12/GMU-Study-Report.pdf.

For example, OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies defines "capable of being substantially reproduced" as "independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision." [15] However, the inability to reproduce research studies can be related to issues of study design, variability or differences in biological test systems, data integrity, data analyses, and in some cases, scientific misconduct. As Carl Sagan stated, "extraordinary claims require extraordinary evidence." Accordingly, new or novel findings that purport to indicate effects that have little or no biological basis, based on the weight of the evidence coupled to first principles of relevant scientific disciplines, should be subjected to suitable reproducibility requirements, which could include causal analytics.

E. Definition of "publicly available" is needed.

EPA does not define what it means by its use of the term, "publicly available." There is more than one definition of the term currently in use by federal agencies.[16] EPA should clarify the level of access and disclosure to the public that is intended. If it intends to determine this on a case-by-case basis, that also should be made clear.

F. Greater clarity on data refinement issues is needed.

Another important aspect relevant to "public availability" is the level of data refinement EPA will require. The National Academies of Science, Engineering, and Medicine (NAS) held a workshop in 2016 to discuss obstacles for sharing data.[17] The NAS defined several key terms to ensure clarity at the workshop. EPA should consider adopting a similar lexicon to increase the clarity of its regulation. (See Table 1 in Appendix B). In addition, the NAS Report suggests a "cleaned dataset" would be acceptable to use for all routine analyses and verification. (See Table 2 in Appendix B). EPA should establish clear standards on the acceptability of "*cleaned datasets*." This will help to standardize data reporting and formatting. It will also prevent over- and under-reporting.

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[15] https://obamawhitehouse.archives.gov/omb/fedreg_final_information_quality_guidelines/

[16] Publicly available information means "any information that you reasonably believe is lawfully made available to the general public from: (i) Federal, state or local government records;(ii) Widely distributed media; or (iii) Disclosures to the general public that are required to be made by federal, state or local law." 17 CFR 160.3 [Title 17 -- Commodity and Securities Exchanges; Chapter I -- Commodity Futures Trading Commission; Part 160 -- Privacy of Consumer Financial Information]. Publicly available information is information that has been published or broadcast for public consumption, is available on request to the public, is accessible on-line or otherwise to the public, is available to the public by subscription or purchase, could lawfully be seen or heard by any casual observer, is made available at a meeting open to the public, or is obtained by visiting any place or attending any event that is open to the public. Office of the Director of National Intelligence & Office of the Director of National Intelligence, National Counterintelligence and Security Center, CI Glossary 2011.

[17] National Academies of Sciences, Engineering, and Medicine. 2016. Principles and obstacles for sharing data from environmental health research: Workshop summary. Washington, DC: The National Academies Press. doi: 10.17226/21703.

VIII. Implementation of the Rule Should be Statute-Specific

EPA requested comment on the effect this proposed rule may have on individual EPA programs. Each of the federal environmental statutes referenced by EPA as a source for its authority to propose this rule, was enacted and designed to achieve a specific environmental goal and purpose (e.g., TSCA regulates new and existing chemicals, CAA controls air pollution on a national level, and SDWA regulates public drinking water supplies across the nation). Each statute confers its unique authority upon the agency, requiring agency review according to different scientific standards; each has its own regulations designed to effectuate the specific corresponding program's mission; and, in many cases, each statute relies on different and variable scientific disciplines. As such, ACC believes that this rule, while applicable to all the statutes identified, should be implemented by regulations specific to the objectives and scientific disciplines of each statute. ACC believes that just as the Freedom of Information Act (FOIA), which is overseen by the US Department of Justice (DOJ), is implemented by each agency with specific and separate regulations relevant to the requirements of each statute, this policy rule should be implemented by each EPA program office charged with implementing a given statute in a manner consistent with the authorities granted and requirements unique to that statute.[18]

IX. The Proposed Rule Should Apply to Enforcement and Permit Proceedings

EPA should apply the final rule to both ". . . enforcement activities or permit proceedings (including site-specific permitting actions) . . ." 83 Fed. Reg. 18768, 18771. In both these areas, EPA staff routinely use scientific evidence to make case-specific policy decisions that raise the same type of problems that occur when EPA promulgates regulations; therefore, this proposed regulation should apply to those to ensure that decisions in those areas are made appropriately.

For example, in both administrative and civil judicial enforcement programs, EPA routinely makes discretionary decisions targeting cases to pursue on the basis of scientific data on exposure of humans and ecological resources to pollutants. To do so, EPA relies on data regarding the inherent hazards of the chemical pollutants, and then estimates exposure potential and risks in a manner essentially the same as the approach EPA used to craft the regulations under the applicable environmental statute. Then, on an enforcement case-specific basis, EPA enforcement staff routinely use exposure/risk information to determine whether violations of the law (for regulatory enforcement under the CAA, CWA, RCRA, FIFRA, etc.) or releases to the environment (CERCLA, RCRA corrective action, OPA) have occurred warranting enforcement and determining the extent of sanctions and relief EPA will seek in an enforcement proceeding.

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[18] See, for example, the discussion of CWA criteria earlier in these comments under section VII. B., which is a good example of why it is important that EPA consider each statute it regulates when applying this proposed rule.

In CAA New Source Review enforcement cases, EPA must decide whether a violation of the program occurred by constructing a "major modification" to a source by assessing whether the pollutant-specific regulatory thresholds were exceeded; analyze emissions calculations using emission factors and/or test data collected from engineering studies; and then extrapolate to the specific plant. To identify the remedial action to impose, EPA must decide which Best Available Control Technology (BACT) limits are for the modifications and that decision, in turn, requires a complex analysis of data regarding costs and efficacies of various control technologies.

In a CWA enforcement case, EPA must decide whether a facility is subject to CWA jurisdiction by determining if a discharge into a jurisdictional "waters of the United States" is subject to the National Pollutant Discharge Elimination System (NPDES) permitting and then whether the discharge violates effluent discharge requirements. If so, EPA must analyze what remedial measures are necessary, including to the receiving waters. In both the CAA and CWA cases, EPA must also prepare proposed civil penalty and pollution "mitigation" assessments, each of which require the analysis of complex economic and environmental data. This policy will require EPA to be more transparent regarding its assessment and analysis of this complex data, which is much needed.

In a CERCLA enforcement case, EPA has to decide what the removal or remedial action should be, which necessitates among other things, a site-specific risk assessment and remedial technologies selection, using a wide variety of environmental and engineering data, which should be publicly available to be verified and replicated.

Similarly, for permitting purposes under environmental statutes, EPA must routinely analyze scientific studies to decide whether to grant a permit and, if so, what conditions to impose in the permit to mitigate environmental impacts to acceptable levels. For example, in a CWA NPDES permit review, EPA determines the level of each pollutant that would be discharged to waters of the United States, whether the proposed discharge will comply with effluent limits required by technology-based effluent guidelines and water-quality standards (including Total Maximum Daily Load programs), and whether control technologies will ensure that the effluent limits will be achieved consistently. Each of those decisions requires analyzing complex environmental/engineering data on a case-specific basis.

X. Incorporate Stronger Data and Model Access Requirements into Cooperative Agreements and Grants while Complying with Privacy and Confidentiality Requirements and Laws

EPA requested comment on how EPA can incorporate stronger data and model access requirements into the terms and conditions of Cooperative Agreements and Grants. ACC believes EPA can accomplish this by implementing requirements that all models and results developed under EPA Cooperative Agreements and Grants be open access and not proprietary. EPA should also require all grant proposal applicants to include as part of any

grant proposal a data management plan, similar to those required by the National Institutes of Health (NIH).[19] EPA may elect to exclude from these requirements grants/agreements of some specified annual amount, but that annual amount should be reasonable and ensure that the vast majority of models and results developed under grants/agreements is shared.

EPA should adopt model evaluation criteria to apply the greatest weight and credibility to models that are open access, describe the endpoint predicted clearly, are based on unambiguous open access computer algorithms, have a defined domain of applicability, have been transparently verified with publicly available datasets, and are shown to be robust and scientifically sound for the intended use.

In addition, EPA should develop common data templates and digital platforms for the most common types of research studies to be used by entities subject to Cooperative Agreements and Grants to facilitate public use and validation.

XI. The Rule Should Apply to all EPA Programs, including its IRIS Program

EPA established the Integrated Risk Information System (IRIS) in 1985 to develop and maintain a database of human health hazard assessments for chemicals. EPA's website states: "The goal of the IRIS Program was to foster consistency in the evaluation of chemical toxicity across the Agency."[20] However, the IRIS Program has been plagued for years by its slow pace generating IRIS assessments and lack of scientific transparency and reproducibility, among other deficiencies. The U.S. Government Accountability Office included IRIS in its High Risk Report, which noted that EPA has not "developed sufficient chemicals assessment information under these programs to limit exposure to many chemicals that may pose substantial health risks"[21] Although the IRIS Program has initiated changes to address some of these deficiencies, no final IRIS assessment to date reflects the full panoply of recommendations issued by the NAS in its review of the IRIS program in 2011.

Appendix C offers several specific examples of IRIS assessment that failed to reflect the best available science. We strongly recommend that the Agency apply this rule to any IRIS assessment that could be used as the basis for significant regulation.

XII. Methodologies and Technologies Providing Protected Access to Sensitive or Confidential Data

In circumstances where company CBI and other intellectual property may be implicated, EPA should confer with the CBI data owner to determine how to make that data available to the greatest extent possible without disclosing the CBI within that data, study, or model. How this is handled will likely be impacted by the type of

[19] https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
[20] See https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system
[21] https://www.gao.gov/highrisk/transforming_epa_and_toxic_chemicals/why_did_study#t=0

regulatory decision and statute involved.

For example, under TSCA, while the summarized study results, analysis, and final report may be publicly available, the underlying data in a health and safety study may qualify as CBI when the underlying data are not in the public domain and that data provides a commercial value to its owner.[22] In such circumstance, it is the availability of the underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data owner of the value of its investment in the underlying data. Current EPA regulations require chemical manufacturers to submit health and safety studies under some circumstances. However, it is noteworthy that none of these regulations routinely require study submitters to submit underlying data along with a final report. This indicates that the final report likely communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting.[23]

ACC believes that making a final study report publicly available where the underlying data are CBI would, in most circumstances, be an effective way to make relevant information publicly available about studies and data EPA may rely on, but which must be protected as CBI in circumstances triggering this policy. In these situations, EPA can access the underlying data to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If necessary, when specialized expertise is needed, EPA could contract with an independent third-party science reviewer to confirm those findings, although we believe this would likely only be necessary in unusual circumstances. In addition, EPA might also consider an approach followed under FIFRA where Data Evaluation Records of studies are made publicly available, but not full studies.[24] Another approach is that of the European Union's REACH program, which makes Robust Study Summaries (RSS) publicly available, while protecting from disclosure the competitively sensitive underlying data of health and safety studies.

When protecting data while also promoting data access, NIH guidelines should be consulted.[25] ACC believes many of these guidelines could be applied in EPA's implementation of this proposed policy under each of the statutory programs EPA administers to ensure the guidelines adopted suit the specific needs of each statute.

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[22] See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996).

[23] 40 C.F.R. §720.50(a)(3)(i) requires that if data do not appear in the open scientific literature, the submitter must provide a full study report, including the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

[24] See, e.g., https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf

[25] See https://osp.od.nih.gov/2016/05/02/protecting-data-promoting-access-improving-our-toolbox/; https://www.niaid.nih.gov/research/data-security; and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5302472/

EPA should ensure that it implements its final rule in a manner that enables it to use confidential health records that may exist with certain kinds of studies, such as long-term air pollution and workplace exposure studies that involve confidential health records. Several agencies and organizations, in addition to NIH, have successfully addressed the issue of data access while maintaining confidentiality that should be considered by EPA. For example:

- The existing rule requiring federally funded research to be made available to other researchers. This standard could be adopted and applied to third-party funded researchers.
- Health care claims and related data are now being made available to researchers in de-identified form by some health insurance companies, such as Optum, which offers a "proprietary research database of health care and administrative data that links patient, physician, and treatment attributes from millions of geographically diverse individuals in the U.S." Optum appears to have developed methods and procedures to appropriately address confidentiality concerns.
- Medicare claims data are already available to researchers in de-identified form. Algorithms and methods developed by the Center for Medical Services should be examined by the EPA.
- Several professional societies have guidance on the protection of health data and de-identification, such as the Institute of Electrical and Electronic Engineers and the International Association of Privacy Professionals. [26]

EPA should develop clear guidance on protecting privacy, de-identifying data, and settling disputes should a breach occur. It may also want to consider establishing an office similar to that of NIH's Office of Research Integrity to adjudicate any issues that may arise in the administration of its practices under this rule.[27]

XIII. The Rule Should Generally Apply Prospectively to EPA Decision Making

ACC does not support retrospective application of the final rule in cases where the Agency follows a periodic review schedule for updating regulations, which includes review of underlying scientific assessments. Retrospective application of any regulation (and its underlying scientific evaluations) is rife with complication, confusion, and significant ambiguity for EPA and stakeholders alike. For example, each NAAQs review under the CAA is based on a substantial amount of scientific and policy information used to inform EPA's determinations of appropriate levels for each standard. The retroactive application of this proposal to those administrative records would only serve to confuse, distress, and impede a NAAQS review process that is already severely overburdened. For example, it is unclear which administrative NAAQS records would be covered by the proposal and how far back it would apply.

[26] http://www.ehealthinformation.ca/wp-content/uploads/2014/08/2010-Risk-based-de-identification-of-health-data.pdf and https://iapp.org/media/pdf/knowledge_center/Perspectives_on_Health_Data_De-Identification_final.pdf

[27] https://ori.hhs.gov/

Without a clear statement, the proposal could potentially cover more than a decades' worth of NAAQS administrative records and scientific analyses. The value of such an application is similarly uncertain. While ACC remains supportive of increased transparency in significant regulatory actions in the future, we encourage EPA to avoid the creation of unnecessary ambiguity and burdens and refrain from the application of this proposal to previous administrative NAAQS records. ACC recommends the final rule be applied prospectively in a manner that integrates its application within the periodic review schedule established for each criteria air pollutant.

However, in cases where EPA has developed analytical tools and models, e.g., ECOSAR, in the past that incorporate dose response data, it may be valuable to apply this rule retrospectively. In other cases, such as IRIS assessments, where the Agency has yet to articulate a periodic review schedule for updating scientific assessments dating back 10-20 years or longer, EPA should develop appropriate mechanisms for application of the rule.[28]

XIV. Bias Should not be Presumed

EPA requested comment on how application of the proposal might inadvertently introduce bias regarding the timeliness and quality of the scientific information available. If EPA uses a weight-of-the-evidence approach (as required under TSCA)[29] and EPA has concerns about bias having been introduced, it can evaluate this using a sensitivity analysis by evaluating the impact of each study and/or model on the overall outcome of the analysis.[30] That said, bias should not be inferred if newer, more scientifically robust studies based on modern, up to date knowledge of biology and dose response are determined to be of better quality, relevance, and evidentiary value.

XV. EPA Should Work with Entities Where Scientific Data are not Publicly Available in a Manner Sufficient for Independent Evaluation

Where data are not available in a manner sufficient for independent evaluation, EPA should attempt to work with data owners to reach an agreement to make the information available to the public to the greatest extent practicable without

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[28] In addition, stakeholders who seek to urge EPA to undertake a retrospective review do have options at their disposal, e.g., they can develop a voluntary new evaluation under TSCA, petition EPA, or file an Information Quality Request (IQA) requesting a correction.

[29] The TSCA Risk Evaluation rule provides an excellent definition of "weight-of-the-scientific-evidence" that should be adopted across the federal government, but certainly across EPA, at a minimum. That definition is: " a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." See 82 Fed. Reg. 33726, 33733 (July 20, 2017).

[30] EPA's implementation and adherence to systematic review in the implementation of this proposal as it has committed under TSCA, will serve to guard against the introduction of bias. See EP's *Application of Systematic Review in TSCA Risk Evaluations* at https://www.epa.gov/sites/production/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf

jeopardizing the privacy, confidentiality, or the proprietary interests that deserve protection. In circumstances where there is significant difficulty making data available in a meaningful way, EPA should consider contracting with external experts in the scientific discipline at issue, have them sign confidentiality agreements, analyze the data, and prepare a confidential report with a non-confidential summary for EPA to share publicly.

APPENDIX A: Proposed Regulatory Text

Section 30.1 What is the purpose of this subpart?
This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

Section 30.2 What definitions apply to this subpart?
As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meaning given them.

- **Dose Response data and models** – the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a measured or predicted response or health or environmental impact.

  A dose response and concentration response can be empirical, e.g., it can describe the measured relationship from experimental measurements. A response can be just a response and not an actual "impact."

- **Material Regulatory Science** – specific scientific studies and analyses that represent the best available science that, based on weight-of-the-evidence, are material to and represent the scientific basis of the requirements and/or quantitative analyses of EPA final significant regulatory decisions.

- **Regulatory decisions** – final regulations determined to be "significant regulatory actions" by OMB per EO 12866, which is defined as any regulatory action that is likely to result in a rule that may:

  - Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health, or safety, or state, local, or tribal governments or communities;
  - Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
  - Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
  - Raise novel legal or policy issues arising out of legal mandates, the president's priorities, or the principles set forth in the Executive Order 12866.

- **Regulatory science** – scientific information, including assessments, models, criteria documents, and regulatory impact analyses that provide the basis for EPA's policies, procedures, guidance, proposed and final significant regulatory decisions.

- **Research data** – as defined by UAR is: the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This ''recorded'' material excludes physical objects (e.g., laboratory samples).

  "Research data" do not include:

  (i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
  (ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

Section 30.3 How do the provisions of this subpart apply?
"To dose response data and models underlying pivotal regulatory science that are used to justify significant regulatory decisions regardless of who funded it or the identity of the party conducting the regulatory science." These provisions do not apply to "physical objects (like laboratory samples), drafts, and preliminary analyses." Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of regulatory action, including enforcement actions and permit proceedings, etc.

Section 30.4 What requirements apply to EPA's use of studies when taking final action?
EPA shall clearly identify all studies or other regulatory science relied upon when it takes any agency action and make all studies available to the public to the "extent practicable."

Section 30.5 What requirements apply to use of dose response data and models?
When promulgating significant regulatory actions, the Agency shall ensure that the dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation, **verification,** and analysis.
This may include:

- Data (where necessary, could be subject to access and use restrictions)
- Associated protocols
- Computer algorithms and models[31]
- Recorded factual materials
- Detailed descriptions of how to access and use such information

But in a manner consistent with law, protects privacy, confidentiality, CBI, and is sensitive to national and homeland security.

[31] We suggest substituting "algorithms" in place of "codes" because specific computer codes can be proprietary.

Information is "publicly available in a manner sufficient for independent evaluation" when it includes the information necessary for the public to "understand, assess, and replicate findings."

Section 30.6 What additional requirements pertain to the use of dose response and models underlying pivotal science?
EPA shall describe and document any assumptions and methods used and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold response, on a case-by-case basis. EPA shall clearly explain scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high-quality studies that explore: a broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models the incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

Section 30.7 What role does independent peer review [have] in this section?
EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions, consistent with OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions therein apply. EPA will ask peer reviewers to articulate the strengths/weaknesses of EPA's justification for assumptions applies and the implications of those assumptions for the results.

Section 30.8 How is EPA to account for cost under this subpart?
EPA shall implement the provisions of this subpart in a manner that minimizes costs.

Section 30.9 May the EPA Administrator grant exemptions to this subpart?
Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:
(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or
(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

Section 30.10 What other requirements apply under this subpart?
EPA shall implement the provisions of this section consistent with the definition of ''research data'' in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in Public Law 89–487, and other applicable federal laws. Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

ACC notes here its support for the text of Public Law 89-487, which is incorporated by reference in Section 30.10 provides the following exemptions are applicable to this proposed regulation:

1) Specifically required by Executive Order to be kept secret in the interest of national defense or foreign policy;
2) Related solely to the internal personnel rules and practices of any agency;
3) Specifically exempted from disclosure by statute;
4) Trade secrets and commercial or financial information obtained from any person and privileged or confidential;
5) Inter- or intra-agency memorandums or letters which would not be available by law to a private party in litigation with the agency;
6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
7) Investigatory files compiled for law enforcement purposes except to the extent available by law to a private party;
8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of any agency responsible for the regulation or supervision of financial institutions; and
9) Geological and geophysical information and data (including maps) concerning wells.

Where appropriate, data-sharing agreements and data-masking techniques may be used.

APPENDIX B: Definitions of NAS Principles

Definitions in NAS Principles and obstacles for sharing data from environmental health research: Workshop summary.
Definition: meta-analysis *Meta-analysis* is a way of quantitatively combining data from many different studies using a statistical process.
Definition: reanalysis The term "*reanalysis*" is defined as conducting further analyses of the exact same data to determine if the same results are obtained and may include use of the same programs and statistical methodologies that were originally used to analyze the data or may use alternative methodologies.
Definition: replication The term "*replication*" is the repetition of a scientific experiment or a trial using exactly the same protocols and statistical programs but with data from a different population to determine if consistent results are obtained with data from a different population.
Definitions: reproduction The term research "*reproduction*" refers to an experiment conducted to addresses the same research question as the original work, but examines the question from a different angle.
Definition: raw data The term "raw data" is defined as the unmodified or unprocessed data that is obtained directly from a survey or experiment (modified from NAS, 2016 P6)
Definition: cleaned-up data *Cleaned-up data* consist of the raw data modified to remove obvious errors.
Definition: processed data The term "processed data" refers to information that has been computed and analyzed to extract relevant information (NAS, 2016), and may include: • Aggregation – combining multiple pieces of data. • Analysis – collection, organization, analysis, interpretation and presentation of data • Classification – separation of data into various categories. • Reporting – list detail or summary data or computed information. • Sorting – the arrangement of items in some sequence and/or in different sets. • Summarization – reducing detail data to its main points. • Validation – Ensuring that supplied data is correct and relevant. (wiki https://en.wikipedia.org/wiki/Data_processing)
Definition: final clean data set

The term "*final clean data set*" is the information provided with a scientific publication (modified IOM, 2016 P6)
Definition: metadata *Metadata* is a set of data that describes other data

TABLE 2 – Data flow from NAS Report

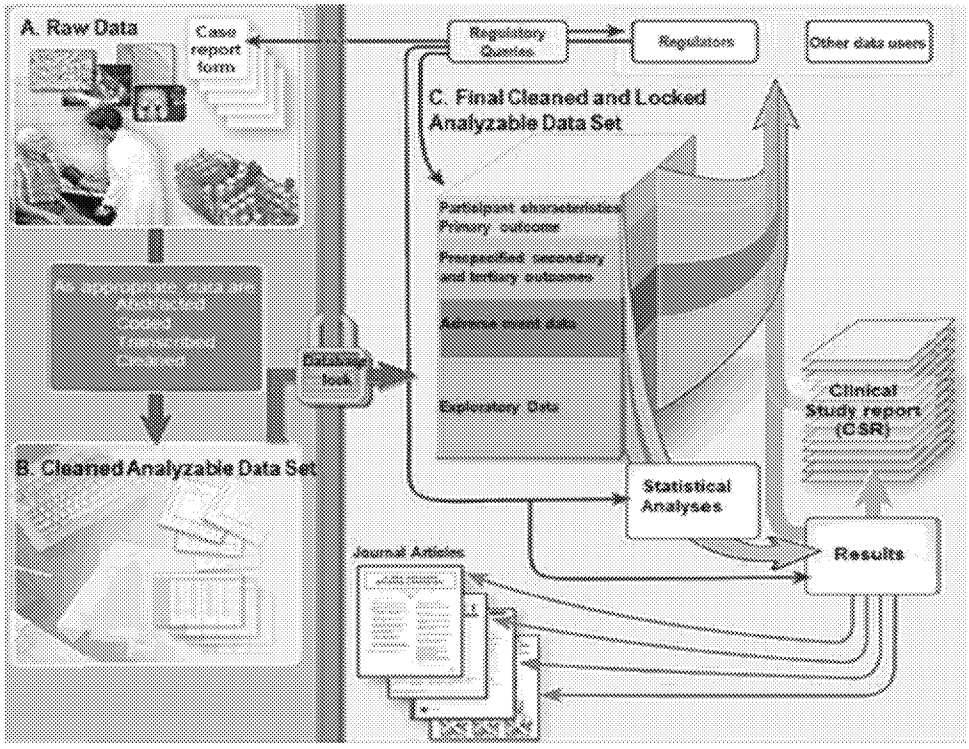


FIGURE 2-1 Data flow from participant to analyzed data and reporting.
SOURCE: IOM, 2014.

APPENDIX C: Chemical-Specific Case Studies

Case Study 1: Trimethylbenzenes (TMBs)

On September 9, 2016, EPA issued its final report on the IRIS assessment of Trimethylbenzenes (TMBs), which addresses the potential non-cancer and cancer human health effects from long-term exposure to TMBs. Humans are not exposed to individual TMB compounds, but to complex mixtures. According to EPA, the primary uses for TMBs are: as a blending agent in gasoline formulations (C9 aromatic fraction); solvents; and paint thinner.

In its review of TMBs, the EPA fell far short in meeting its obligations to improve its IRIS processes and assessment reports. Without explanation, EPA failed to respond to public comments on the draft TMBs assessment, even though the IRIS process for developing assessments explicitly includes a response to comments element.

The IRIS assessment of TMBs does not accurately represent the health effects associated with exposure to TMBs because it failed to utilize a consistent and transparent data evaluation procedure for evaluating and weighing the full body of evidence.
In particular, EPA failed to rely on available guideline studies on commercial complex C9 aromatic mixtures that industry conducted under EPA's TSCA program. The entire commercial C9 aromatic blend, which contains a high percentage of TMBs, has similar toxicological properties and health effects as the individual isomers of TMB. Thus, guideline studies on the commercial complex of aromatic mixtures are highly relevant to assessing the toxicology of TMBs.
EPA's Office of Pesticide Programs (OPP) has also reviewed the toxicology of TMBs and determined that the health effects of TMBs can be efficiently assessed by relying on C9 aromatic mixture studies. OPP reached different scientific conclusions, including different quantitative health effect numbers, than that of EPA's IRIS Program. EPA, however, did not resolve these differences during the IRIS assessment of TMBs.

Case Study 2: Formaldehyde

Formaldehyde occurs naturally in every living system – from plants to animals to humans – all of which produce formaldehyde as a normal part of metabolism. In addition, its unique and versatile chemical properties make it a common and beneficial part of modern life. Formaldehyde has been the subject of extensive and robust scientific inquiry. EPA has been involved in assessing the human health risk of formaldehyde since the late 1970s. Large numbers of epidemiology, toxicology and biomechanical studies have informed the science surrounding formaldehyde, so that there a rich body of data exists.

The most recent draft Integrated Risk Information System (IRIS) formaldehyde assessment (2010) proposed exposure limits so low that the trace levels of formaldehyde found in human breath would present a cancer risk. The 2010 draft assessment also noted that: *"Human epidemiological evidence is sufficient to conclude a causal association between formaldehyde exposure and nasopharyngeal cancer, nasal and paranasal cancer, all*

leukemias, myeloid leukemia and lymphohematopoietic (LPH) cancers as a group." The National Academy of Sciences (NAS) then conducted a peer review of this draft and issued its final report in April 2011. The NAS report was critical of the draft IRIS assessment---an assessment that the IRIS program took 12 years to develop.

The NAS stated that EPA's claims regarding all leukemias, myeloid leukemia or related hematopoietic cancers were not supported. It noted that EPA's preliminary conclusions appeared subjective and that no clear scientific framework had been used by EPA to reach its conclusion. The NAS recommended that EPA revisit its determination of causality for specific LHP cancers, using methodology that integrates lines of evidence and addresses the specific criticisms in the NAS report. The NAS also made numerous recommendations for the improving the overall process and application of science used in all assessments generated by the IRIS program. Now, seven years since that NAS report was published, EPA continues to revise its assessment while not disclosing how emerging scientific evidence or modern risk assessment methods are being employed.

Meanwhile, newly published research based on the recommendations in the NAS report has advanced the state of the science. Raw data (made available after multiple years of FOIA requests) from studies conducted by the Federal government ---and upon which EPA relied on for its previous assessment conclusions--- were re-analyzed and the findings contradicted the original study conclusions. Today our knowledge regarding formaldehyde is much greater; yet it does not appear that this new knowledge has been applied in the EPA's assessment of formaldehyde risk. Published research demonstrates that inhaled formaldehyde cannot reach the bone marrow where leukemia occurs and that safe thresholds for formaldehyde exposure exist. This formaldehyde case study is an example of the long-term problems with the lack of consistent, transparent application of modern scientific knowledge regarding chemical exposures and human health risk.

Case Study 3: Ethylene Oxide

The Integrated Risk Information System (IRIS) assessment of ethylene oxide (EO) originated with a carcinogenicity assessment in 1985. The first comprehensive draft was published in 1998. An external review draft was issued in 2006, followed by a Science Advisory Board (SAB) review in 2007. Revisions of the EO assessment were made in 2011 and 2013, and an additional SAB review was conducted in 2014-2015. The final IRIS assessment for EO was posted in December 2016.

Using unsupportable and un-reviewed conservative risk assessment modeling, the IRIS assessment concludes that the one-in-a-million lifetime cancer risk value associated with exposure to EO is less than 1 part per trillion (ppt). This value is far below both EO background levels in the environment and EO levels naturally converted from ethylene in humans through breathing. This conclusion is not plausible and not scientifically supportable. It is based on an inadequate evaluation of a body of evidence from human studies that include historical exposure levels to EO that are far higher than current occupational exposure limits. Other, more accurate data sources are available, and alternative scientific risk assessment modeling approaches could have been used, but the

IRIS Program did not systematically integrate all of the evidence. Public comments on the EO IRIS assessment can be found in Docket No. EPA-HQ-ORD-2006-0756.

EO has dozens of important applications, including the manufacture of ethylene glycol based antifreeze, aircraft deicers, and PET plastics. EO is also used to produce higher-value derivatives such as ethoxylates, ethanolamines, glycol ethers, and polyether polyols. A small but critical use of EO is for the sterilization of medical equipment.

EPA's SAB 2007 review concluded that substantial revisions were needed to the draft IRIS assessment including:

- Acquiring and using individual data for modeling rather than grouping populations, which results in overly conservative estimated cancer risks;
- Considering using both linear and non-linear approaches to estimate cancer risk due to the distribution of and questionable association with certain cancer types; and
- Providing more transparency and correcting flaws associated with inappropriately grouping lymphohematopoietic cancers and combining genders for the dose-response analysis.

Meeting materials, including public comments, can be found at https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/7E3E313F627541D78525711400470D01.

The 2015 SAB Committee that reviewed the revised 2013 EO draft IRIS assessment did not conduct an independent, unbiased review. Problems included:

- Several SAB members made inaccurate public statements indicating industry produced scientific studies should be not be considered due to potential industry influence, although no evidence of biased data sponsored by industry was ever presented.
- SAB members did not understand new evidence-based medicine concepts regarding mutagenicity of cancer cells and the contribution of naturally occurring EO in DNA repair mechanisms.
- The SAB recommended using epidemiology data sets with questionable or scientifically unsound characteristics to estimate cancer risk and rejected alternative data sets that are as or more robust than those selected.

EPA still did not use individual data for modeling as recommended by the SAB in 2007, and did not adequately explore alternatives to the linear low dose modeling approach.

Meeting materials, including public comments, can be found at https://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/17F305EC43EB1A6585257E2D0050255F.

The IRIS Program used a spline approach (piecewise linear model that was not presented during either SAB review) for exposure-response analyses for each of the lymphoid and breast cancer endpoints and ultimately combined the results. This approach results in higher risk at lower exposure levels and leads to proposed regulatory levels that are orders of magnitude lower than what the epidemiologic and genotoxicity scientific evidence would support.

Further, the IRIS Program did not fully consider all available evidence in finalizing the EO assessment. Scientific evidence clearly indicates that EO is a weak mutagen and a unit risk factor of less than 1 ppt is not realistic or reliably measurable, and is orders of magnitude lower than levels of EO in ambient air and the normal, endogenous levels of EO present in human bodies. Moreover, the assessment fails to consider the difference between exposures to EO produced outside the human body and exposure to EO produced within the human body as a normal metabolic product.

Agenda
ORD Team Meeting
Strengthening Transparency in Regulatory Science
September 5, 2018

1) Overview
2) Issues
    a. PII
    b. Dose-response models
    c. Assessing the validity of prior epidemiologic studies (without public access to data and analytic methods)
    d. Infrastructure
    e. Requirements for cooperative agreements and grants
    f. Replication/reproducibility
    g. Proprietary models
    h. Specific chemicals

Attachments

Public comments (examples)

1) Yale Law School/Yale School of Medicine/Yale School of Public Health Collaboration for Research Integrity and Transparency (CRIT)
    a. Highlighted Issues: 1) Data sharing; 2) Replication/reproducibility; 3) Non-linear dose-response models
2) American Chemistry Council
    a. Highlighted issues: 1) Reproducibility; 2) Data and model access requirements for Cooperative Agreements and Grants; 3) Providing protected access to sensitive and confidential data; 4) IRIS
3) Electric Power Research Institute, Inc (EPRI)
    a. Highlighted issues: 1) PII; 2) Dose-response models; 3) Costs associated with making information public; 3) Definition of data; 4) Use of standardized methodology
4) NRDC
    a. Highlighted issues: 1) Proprietary models; 2) Chemicals

EPRI | ELECTRIC POWER RESEARCH INSTITUTE

COMMENTS OF THE ELECTRIC POWER RESEARCH INSTITUTE ON

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-9977-40-ORD]

Strengthening Transparency in Regulatory Science

August 7, 2018

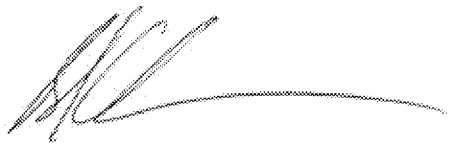
The Electric Power Research Institute, Inc. (EPRI) respectfully submits the enclosed comments on the U.S. Environmental Protection Agency's (EPA's) proposed rule titled *Strengthening Transparency in Regulatory Science*. EPRI appreciates the opportunity to comment on this rule.

EPRI is a nonprofit corporation organized under the laws of the District of Columbia Nonprofit Corporation Act and recognized as a tax-exempt organization under Section 501(c)(3) of the U.S. Internal Revenue Code of 1986, as amended, and acts in furtherance of its public benefit mission. EPRI was established in 1972 and has principal offices and laboratories located in Palo Alto, Calif.; Charlotte, N.C.; Knoxville, Tenn.; and Lenox, Mass. EPRI conducts research and development relating to the generation, delivery, and use of electricity for the benefit of the public. As an independent, nonprofit organization, EPRI brings together its scientists and engineers as well as experts from academia and industry to help address challenges in electricity, including reliability, efficiency, health, safety, and the environment. EPRI also provides technology, policy and economic analyses to inform long-range research and development planning, as well as supports research in emerging technologies. As a tax-exempt research organization, EPRI makes its research results widely available to the interested public through license, purchase or other dissemination.

These comments on the proposed rule reflect EPRI's opinions derived from its research and development experience over the last 40 years in the field of human health effects. In particular, EPRI has robust research programs investigating exposure- or dose-response questions of relevance to the electric power industry and its stakeholders, including criteria air pollutants, trace metals and organic compounds, low dose ionizing radiation, and electromagnetic fields. These comments reflect EPRI's research activities in that they are technical rather than legal in nature. The enclosed comments reflect only EPRI's opinion and expertise and do not necessarily reflect the opinions of those supporting and working with EPRI to conduct collaborative research and development.

EPRI hopes its comments and technical feedback will be valuable to EPA.

Sincerely,



Robert Chapman
Vice President, Energy and Environment

COMMENTS

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA-HQ-OA-2018-0259; FRL-9977-40-ORD]

Strengthening Transparency in Regulatory Science

Submitted by:
ELECTRIC POWER RESEARCH INSTITUTE
3420 Hillview Avenue
Palo Alto, CA 94304

August 7, 2018

INTRODUCTION:

The Electric Power Research Institute, Inc. (EPRI) respectfully submits the enclosed comments on the U.S. Environmental Protection Agency's (EPA's) proposed rule titled *Strengthening Transparency in Regulatory Science*. EPRI appreciates the opportunity to comment on this rule.

EPRI has robust research programs investigating exposure- or dose-response questions of relevance to the electric power industry and its stakeholders, including criteria air pollutants, trace metals and organic compounds, low dose ionizing radiation, and electromagnetic fields. EPRI's research in the area of human health effects spans more than 40 years.

The proposed rule focuses on dose-response data. Such data can be generated in *in vitro* or *in vivo* toxicological studies, controlled human exposure studies (also termed clinical studies), and observational epidemiology studies in humans. In the case of toxicological data, making information publicly available is generally straightforward. However, human data present unique challenges due to privacy and confidentiality. Detailed study protocols are required that outline steps that will be taken by the researchers to protect confidential information, and in any study involving humans, approval by an Institutional Review Board (IRB) is required. An IRB

is a committee that evaluates the ethics of a given research endeavor, with the goal to protect human subjects from any physical or psychological harm. Universities and other research organizations cannot conduct research that involves human subjects without IRB approval.

EPRI understands the importance of transparency in scientific research, and supports efforts to make datasets available for use by the scientific community to the extent possible. For example, EPRI has funded an extensive air quality monitoring campaign – the Southeastern Aerosol Research and Characterization Study (SEARCH) – for more than a decade (see Hansen et al., 2003 for a description). This rich dataset includes detailed daily data from multiple sites on criteria pollutants, PM components, volatile and particle-phase organic compounds, and pollen and mold spores, over varying time periods. The data have been utilized in more than 300 peer-reviewed articles, including multiple time-series epidemiological analyses, and are available free of charge at https://www.dropbox.com/sh/o9hxoa4wlo97zpe/AACbm6LetQowrpUgX4vUxnoDa?dl=0. In fact, EPRI encourages use of these data by the broader community as EPRI believes they are a tremendous resource for both physical and health sciences researchers.

EPRI conducts research in the public benefit. To this end, EPRI supports efforts to improve transparency and to allow the best science to be used to protect public health and the environment. This includes transparency in dataset availability, methodologies, models, and other aspects of scientific research. In the past, EPRI has commented on a variety of regulatory activities along these lines, including recent comments encouraging transparency in modeling of the social cost of carbon (e.g., EPRI, 2014a; 2014b).

More specifically, to achieve EPRI's public benefit mission, it is vital that EPRI be able to provide its research results to inform regulatory discussions, such as those with the EPA and other stakeholders. In many studies, EPRI employs data originating from publicly available sources. However, some of EPRI's work involves data that may not be publicly shared, including proprietary material from member companies and other collaborators, data that EPRI must purchase or obtain through special arrangements to facilitate research, personally identifiable information (PII), and data that are classified because of national security considerations. As such, EPRI has two primary comments on the proposed rule. The first focuses on the objective of providing sound scientific input to ensure that standards, rules, and other regulatory actions are scientifically defensible and are health-protective while minimizing cost. EPRI will provide examples of its past, existing, and future work to illustrate how the rule may impact the utilization of such scientific input to inform these aspects of the regulatory process. EPRI's other comment focuses on the alternative dose-response models referred to in the proposed rule. EPRI also has six questions and issues for clarification.

COMMENTS:

1. **Confidential/Personal Health Information:** EPRI has funded, is funding, and plans to fund a number of studies involving primary data used in epidemiological analyses evaluating dose-response relationships. These data can consist of exposure information as well as individual-level health outcome information. In some cases, EPRI-funded researchers collect data directly (e.g., panel epidemiology studies), and EPRI would typically own the collected data. In other cases, however, EPRI-funded research involves the use of datasets owned by other institutions, which EPRI obtains through permissions or, at times, licenses. And in other studies, EPRI purchases access to data from a third party, subject to stringent license terms and use thereof limited to specific purposes under strictly controlled conditions.

   Given that the proposed rule requires data to be publicly available "in a manner sufficient for independent validation", this may present a challenge for a number of these studies to the detriment of the public if they are excluded from consideration. Complete exclusion of an entire study could limit access to scientifically defensible information to regulators and other stakeholders to achieve desired regulatory aims. EPRI research cannot inform deliberations on proposed regulation or provide new learning to EPA if the study cannot comply with the requirements of the proposed rule given the placement of undue burden on the study investigators to provide required documentation (e.g., redacted death certificates in cohort mortality studies), complete additional IRB applications, or submit additional applications to other originators of data for permission to share publicly. An unintended outcome of the rulemaking could be elimination from consideration of not only EPRI's but also other past, present, and future research that could be useful to regulators and other stakeholders.

   Examples of past and current research that EPRI believes are important for consideration in regulatory activities are described below (note that this is not an exhaustive list.) Each example provides an explanation of the potential issues associated with making data required to understand human health effects and dose-response relationships publicly available.

   a) *Medicare Cohort Study to Understand Air Pollution Health Effects*: EPRI has funded the purchase and analysis of a large Medicare beneficiary dataset to investigate important questions related to air pollution health effects (Pun et al., 2017; Eum et al., 2018; additional papers forthcoming). Analyses of this dataset are expected to continue into the future. The health outcome data (mortality) were obtained from the Centers for Medicare and Medicaid Services (CMS) via a costly, labor-intensive, and protracted process. Deidentification of these data to a form that would be acceptable for sharing by CMS would preclude their use in meaningful air pollution epidemiological research. This is because identifying information such as the ZIP

codes of residence is required to assign pollutant exposures, and identifying information such as age, gender, and race is required to allow adjustment for these factors in epidemiological models.

The proposed rule also mentions data research centers that facilitate secondary data usage by the public. If the CMS data are considered to fall in this category, EPRI would encourage EPA to work with CMS to streamline and simplify the data acquisition process and make the data available to the public free of charge. Otherwise, the cost and security requirements of obtaining these data may place an undue burden on stakeholders seeking to replicate analyses, since the data for EPRI's project were acquired at a significant cost (> $100,000) and a comprehensive data management plan that outlined rigorous security protocols was required. Clearly, these requirements would make replication of the work untenable for many researchers. EPRI has concerns that the challenges of making these data available in an equitable fashion may result in the data and insights from this study being removed from consideration in standard-setting activities for $PM_{2.5}$, ozone, and NO_2.

b) *Occupational Epidemiology Study of Hexavalent Chromium Cancer Risk*: EPRI funded a study to update the mortality, exposure reconstruction and dose-response modeling for a cohort of workers from the Painesville, Ohio Chromate Production Plant who were exposed to hexavalent chromium, resulting in elevated rates of lung cancer (Proctor et al., 2017). This cohort is associated with significant regulatory precedent as it updated a study used by the Occupational Safety and Health Administration for risk assessment when the hexavalent chromium Permissible Exposure Limit was lowered in 2006. The current EPA inhalation cancer slope factor, originally set in 1984, was also based on an earlier study of workers from the Painesville plant, but the EPRI study uses more robust data and included short-term workers, thus allowing examination of the dose-response relationship in the low-exposure range.

Clearly this study is of interest for risk assessment (in particular, the EPA's Integrated Risk Information System [IRIS] program); however, the original data are not publicly available as they are owned by the company that employed the workers, and EPRI's research was subject to a strict confidentiality agreement. EPRI believes it could be possible to prepare a publicly available analytical file that provides individual-level deidentified data with dose measures for each unidentified cohort member, with the occurrence of lung cancer, the occurrence of significant covariates used in the model (e.g., smoking), approximate date of birth (e.g., birth year in a 2-year range)

and other variables needed to calculate expected number of deaths (race, gender and approximate date of death, within a range). However, whether or not the file is ultimately made publicly available would depend on the availability of resources to create the file, likely permission from the data owner to distribute the information, even in its deidentified form, and possibly an additional IRB application. If these requirements were met, the information could be used to reproduce the published dose-response model without violating agreements with the original IRB's approval of the study or agreement with the Centers for Disease Control (CDC) for use of National Death Index (NDI) data. However, complete study validation, as expressed in the proposed rule (i.e., data to be publicly available *in a manner sufficient for independent validation*), would not be possible. The raw data required to reconstruct exposures or identify causes of death are not sharable because the information is protected (due to ownership by the employer). To reconstruct the cohort-specific Job Exposure Matrix, inclusion of PII regarding the work history, including job titles over time as well as starting and termination dates, is needed. This information could not be made publicly available without disclosing PII. Also, it is not possible to provide the raw data to reconstruct the outcome (lung cancer death occurrence in this case). In some cases, cause of death was identified by death certificate, which could be redacted, although with significant effort by the researchers; however, NDI data were destroyed upon completion of the study, consistent with the agreement that the Centers for Disease Control (CDC) had with the researchers for use of the data. Thus, to recreate those raw data, significant PII would be required to search the NDI records again. This would not only be extraordinarily time-consuming and costly but would have to be approved by CDC and would require a new IRB review and approval. EPRI is concerned that this important study, which reported a different inhalation cancer slope factor for hexavalent chromium as compared with previously published studies, would be eliminated from consideration in the IRIS process or other proceedings in which toxicity factors are determined.

c) *Children's Air Pollution Asthma Study (CAPAS)*: EPRI funded a panel study of asthmatic children involving residential exposure assessment and collection of pulmonary function and symptom data. Several papers resulted from the research related to the associations between indoor and outdoor $PM_{2.5}$ and its individual components and asthma exacerbation (Habre et al., 2014a, 2014b; Rohr et al., 2014; Schachter et al., 2015; additional paper forthcoming). The consent form utilized in the study stated that indoor exposure data as well all questionnaire data would be kept strictly confidential. This would preclude the consideration of all data from this study with the exception of the ambient monitoring data which were obtained

through a combination of a state-operated monitoring network and an EPRI-funded fixed monitoring site. EPRI is concerned that this body of research would be eliminated from consideration in standard-setting activities. Additionally, CAPAS provided important information on the role of PM components in the health effects, which is a topic of interest to EPA and others, given that it is unlikely that all PM components are equally toxic.

d) *Low Dose Radiation Exposure Health Effects*: EPRI has for nearly 10 years worked to increase the understanding of effects from low doses of ionizing radiation. In this arena, EPRI faces problems similar to those that EPA identifies, because the primary datasets of individualized data for human epidemiological studies of the atomic bomb survivors and workers at early production and utilization facilities are not readily available. These observational studies have been well-utilized and form the basis for radiation protection standards around the world (Ozasa et al., 2012; Richardson et al., 2015). The detailed data of the survivors of the atomic bombings of Hiroshima and Nagasaki are controlled by the Radiation Effects Research Foundation, and cannot be released to those outside of the Foundation under agreements with Japan and the United States. Similarly, studies of early cohorts of workers from the United States, England, France, and other countries are pooled and controlled by the International Agency for Research on Cancer. Since many of the data from human radiation studies are managed by other research organizations that have highly restrictive data access policies, it is unclear that special arrangements can be made with these entities to release the data for public access. EPRI is concerned that these seminal studies may be eliminated from future consideration as a result of this proposed rule.

2. **Dose-Response Models: Shape and Uncertainty:** The proposed rule states that EPA should give appropriate consideration to high-quality studies that explore a broad range of concentration-response modeling approaches, in addition to linearity. EPRI has been conducting research on different models and agrees that a variety of models should be applied to dose-response data, including linear, linear threshold, non-linear non-threshold, and non-linear threshold, with the objective to determine the best-fitting model. EPRI research on both hexavalent chromium and inorganic arsenic, for example, has suggested the presence of a threshold for the carcinogenicity of these trace metals (e.g., Thompson et al., 2015, 2017; Gentry et al., 2014; Efremenko et al., 2015). EPRI agrees that complete model fit statistics should be included in papers for transparency. However, it should be noted that "best fit" may not always be clear. For example, a common method of evaluating model fit is the Akaike Information Criterion (AIC). In some cases, the difference in the AIC

between models may be very small, which makes it challenging to determine which model truly represents the underlying data. In evaluating model fit, EPRI encourages the development and/or application of other methods so that consistency across approaches can be determined. However, regardless of the amount of information available on the best-fitting model for a particular dose-response relationship, there still may be some level of subjective judgement. The proposed rule should consider emphasizing the importance of conveying this judgment and associated uncertainty in a transparent manner.

It is also important that priority not be given to any particular dose-response model. The optimal dose-response curve should be dictated by the best available science and the degree of uncertainty present. The proposed rule states that EPA should incorporate the concept of model uncertainty; EPRI further suggests that studies should present uncertainty in the different model fits and that this information should be presented in a transparent manner. Further, uncertainties should be assessed both for the dose, and for the effect, so that a complete picture of uncertainties is presented. EPRI has supported the development of an Integrated Uncertainty Analysis (IUA) tool for air pollution risk assessment (Smith and Glasgow, 2017). This tool has the capability to comprehensively and simultaneously consider multiple sources of uncertainty in a given exposure-outcome relationship. Such a tool or approach could be useful in achieving the goal expressed in the proposed rule.

ISSUES AND QUESTIONS FOR CLARIFICATION:

1. **Timeliness of Public Access:** It is not clear whether *study validation/replication* would be required for consideration of any given research results in regulatory activities, or whether *data accessibility* is sufficient. A situation could be envisioned whereby a dataset is made publicly available just prior to a regulatory action/process component, e.g., publication of an Integrated Science Assessment for a NAAQS review. In this case, there may be a previously published study using these data, but insufficient time for another investigator to replicate the study methodology. It is not clear how this situation would be dealt with, i.e., whether the original study would then be excluded from the ISA. EPRI requests clarification of this issue.

2. **Costs Associated with Making Information Public:** It is unclear how the costs of obtaining data would be paid. For example, if researchers are required to expend significant effort and resources to deidentify datasets for dose-response modeling (which, as discussed above, is likely insufficient to fulfill the intent of the proposed rule in most cases), what recovery mechanisms would be in place to assist with the costs?

Would the federal government offer resources to assist with attempts to meet the new requirements for existing and future research efforts? Further, if data are purchased and then required to be shared (note that as discussed above, this is an unlikely scenario given privacy and confidentiality issues), will the original investigator be able to recoup costs associated with that purchase from subsequent researchers of the now-publicly available information? The additional costs associated with complying with the proposed rule may place an undue burden on research organizations and efforts such that research in these areas is not conducted at all to the detriment of the public. EPRI requests that the issue of funding for data accessibility be addressed.

3. **Use of Standardized Methodology:** The proposed rule states that EPA will utilize standardized test methods. It is not clear how new test methods or analytical methods would be factored into considerations. In some cases, new analytical approaches may not yet have reached the status of standard methods, but such techniques may be very informative in understanding the implications of data for use in a rulemaking. EPRI requests that EPA clarify that scientifically-grounded alternative testing methods and evaluations may be included in developing regulatory actions.

4. **Definition of "Data":** Section 30.5 of the proposed rule specifies the type of information that would be made public to allow independent validation. As discussed in some parts of Comment #1 above, the interpretation of the term "data" has critical implications. For complete independent validation and analysis, as stated in the proposed rule, the primary data record would be required. This could include, for example, raw death certificates and raw chemical monitoring data, both of which are subject to transcription error during creation of an analytical file, as well as, in the case of death certificates, challenges related to mortality coding. Notwithstanding privacy concerns, which is the subject of other portions of the proposed rule, public posting of these large quantities of data would be unwieldly. EPRI requests clarification of this issue.

5. **Independent Peer Review:** Section 30.7 of the proposed rule states that EPA shall conduct independent peer review of pivotal regulatory science. The proposed rule lacks any detail of this process, including selection criteria for peer reviewers, decision criteria, and how this compares to existing processes through the Science Advisory Board (SAB) and third-party contractor-managed peer reviews. EPRI requests clarification and additional detail related to this key provision of the proposed rule.

6. **Exemption Process:** Section 30.9 of the proposed rule states that the Administrator may grant exemptions on a case-by-case basis. While a reasonable exemption process could allow certain excluded research to be considered in regulatory proceedings, no detail is

provided regarding the process by and criteria under which such exemptions would be granted. EPRI requests clarification and additional detail related to this key provision of the proposed rule. EPRI also requests clarification and additional information on the process by which organizations or investigators can seek to resolve a situation where high quality scientific data/studies might be excluded.

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Collaboration for Research Integrity and Transparency

A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

August 13, 2018

Acting Administrator Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
submitted electronically

Re: Docket EPA-HQ-OA-2018-0259-0025, Strengthening Transparency in Regulatory Science

Thank you for the opportunity to comment on this proposed Environmental Protection Agency (EPA) regulation.

The Collaboration for Research Integrity and Transparency (CRIT) at Yale is dedicated to promoting health by improving the integrity and transparency of biomedical and clinical research. Although we are strong proponents of responsible data sharing, and seek to make data available to researchers, we request that the EPA withdraw the proposed regulation.

We believe that the proposed regulation will not advance transparency in regulatory science. Instead, we suspect that the proposed regulation may limit the EPA's ability to rely on many well-designed longitudinal and cross-sectional scientific studies. First, there are concerns that the preamble and proposed regulation are not aligned with existing data sharing policies and that the proposed rule directly contradicts established policy and law. Second, although the proposed regulation outlines the importance of "reproducibility", it does not provide a framework for how the reproducibility of an individual study can or should be assessed. Lastly, there are opportunities to promote data sharing without requiring that all data be made publicly available.

Consistent with the larger societal move toward open science, the U.S. federal government, including the EPA, has adopted policies that facilitate data sharing. For instance, the National Institutes of Health (NIH) requires that researchers conducting agency-funded research pre-register clinical trials, pre-specify study endpoints and statistical plans, and report research results. Moreover, all NIH applications for $500,000 or more in direct funding in any given year must contain a data sharing plan, and some

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institutes of the NIH share data with researchers via a secure website.[1] Many federal agencies, including the EPA, require that any published articles based on federally-funded research be made available via the PubMed Central (PMC) website.[2] In addition to government entities, professional societies and journals have also adopted transparency policies. For instance, the International Committee of Medical Journal Editors (ICMJE) has adopted a policy requiring pre-registration of clinical trials, and publication of a data-sharing statement.[3] In 2015, the Institute of Medicine (IOM) published a report recommending that trials be registered prospectively (i.e., at or before the time of first patient enrollment), that summary-level results be shared with the public after trial completion, and that the metadata and patient-level data be responsibly shared with researchers 6 months after scientific publication, or 30 days after regulatory approval.[4] **None of these policies require that all individual-level underlying data and models be made available to the public.**

The EPA's mission necessitates the use of research findings from a variety of sources: research funded or conducted by the EPA or other U.S. government agencies; research funded or conducted by other governments; and research conducted without EPA or other government funding. With regard to studies conducted with human subjects, data may contain personal health information, and particularly with regard to longitudinal studies, may contain such detailed and specific information regarding each individual that the data cannot be properly de-identified for release to the public. In addition, the move toward data-sharing is relatively new, and historical studies with human subjects used written informed consent that did not contemplate sharing of data. Making data from such studies available to the public would violate federal Human Subjects regulations.

The EPA has already embarked on a well-thought-out plan to require and promote research transparency, as described in the EPA's 2016 *Plan to Increase Access to Results of EPA-Funded Scientific Research* ("*Plan*"). Although the preamble to the proposed regulation cites and "applies concepts and lessons learned" from the *Plan*, there are some concerning differences.

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[1] U.S. Department of Health and Human Services, National Institutes of Health. *NIH Data Sharing Policy and Implementation Guidance* (Updated: March 5, 2003). https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm. (Last accessed August 13, 2018).

[2] U.S. National Library of Medicine, *Funders and PMC*. https://www.ncbi.nlm.nih.gov/pmc/about/public-access. (Last accessed August 13, 2018).

[3] De Angelis C, Drazen JM, Frizelle FA, et al. Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. *N Engl J Med.* 2004;351(12):1250-1251.

[4] Institute of Medicine (IOM). *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk.* Washington, DC: The National Academies Press; 2015.

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First, the *Plan* indicates that it does not apply to "scientific research data collected before its implementation."[5] In contrast, the preamble and the proposed regulation suggest that the regulation may apply retrospectively:

> …EPA seeks comments on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available.[6]

We do not recommend any retroactive application of this regulation. It is well-established that agency rules cannot be applied retroactively unless Congress expressly granted the agency that power.[7] There is no specific grant of power to apply this proposed regulation retroactively. Moreover, the two bills upon which this proposed regulation is modeled, the Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (H.R. 1430 – 115th Congress, 2017-2018), and the Secret Science Reform Act of 2015 (H.R.1030 – 114th Congress 2015-2016), were not enacted.

Second, the preamble and proposed regulation appear to suggest that peer-reviewed studies are only valid if the underlying data and models are publicly available. In contrast to the *Plan*, the proposed regulation proceeds from the erroneous assumption that peer-reviewed research is only valid if it is able to be replicated by others. However, many key environmental studies cannot be replicated, for ethical or practical reasons. For example, the federal Office of Management and Budget has stated:

> OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data. For example, it may not be ethical to repeat a ''negative'' (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident.[8]

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[5] Environmental Protection Agency, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, Version 1.1 (Nov. 29, 2016), p. 5. Available at https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf. (Last accessed July 31, 2018).

[6] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18772 (Apr. 30, 2018).

[7] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988); *see also* Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 Admin. L. Rev. 59, 76 (1995).

[8] *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication*, 67 FR 8452, 8456 (Feb. 22, 2002).

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Furthermore, according to the *Plan*, not all research can be made fully, thus publicly, available:

> It is important to recognize that some research data cannot be made fully available to the public but instead may need to be made available in more limited ways, e.g., establishing data use agreements with researchers that respect necessary protections. Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications.[9]

The preamble and proposal also acknowledge this concern, and highlight that strategies need to be identified for data that cannot be made publicly available:

> —EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may include: requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.[10]

Over the past few years, there have been growing efforts to promote the transparency and reproducibility of science.[11] However, the nomenclature surrounding "reproducibility" is complex.[12] Historically, there has been no clear criteria for what constitutes "successful replication and reproduction",[13] which makes certain components of the current proposal concerning. We believe that it is important to ensure that the "reproducible research" movement is not being co-opted for political purposes. Without a clear understanding of

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[9] *Id.* at pp. 4-5.
[10] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18771 (Apr. 30, 2018).
[11] Munafò MR, Nosek BA, Bishop DVM, et al. A manifesto for reproducible science. *Nature Human Behaviour*. 2017;1:0021.
[12] Goodman SN, Fanelli D, Ioannidis JPA. What does research reproducibility mean? *Science Translational Medicine*. 2016;8(341):341ps312.
[13] *Id.*

research reproducibility, different standards (i.e., "case-by-case" decisions) can be applied to discredit individual studies.

According to a recent effort to standardize the language of reproducibility,[14] there are three key areas of reproducibility:

1. Methods reproducibility
   - This is when a study provides enough information about the experimental and/or computational procedures so that future authors can repeat the study using the same data to obtain the same results.
2. Results reproducibility
   - This is when a new study produces corroborating results using experiment methods that are closely matched to a previous study.
3. Inferential reproducibility
   - This is when a new study draws qualitatively similar conclusions from either an independent replication or re-analyses.[15]

These three areas of reproducibility can have different meanings for various areas of scientific research. "Methods reproducibility" may be realistic for laboratory-based studies, where it is possible to implement the exact experimental and computation procedures with the same (or very similar) tools to obtain the same results. However, new clinical or environmental studies may use procedures that are closely matched, but not identical, to previous evaluations. When it comes to observational research, it is well known that some weaknesses are unavoidable. For instance, it is often difficult to eliminate all potential sources of confounding, or to adjust for the same confounders across studies from different time periods. Therefore, it would be unfair to argue that all aspects of a study, including the design and analyses characteristics, need to be reproduced exactly.

The goal of repeating a study should be to increase the total amount of evidence. Furthermore, if a hypothesis being tested has strong evidence from an existing study (i.e., rigorous methods, large sample sizes, transparent reporting), a considerable amount of high quality evidence is necessary to change prior reasoning. Moreover, one small study that does not validate the results of a previous study should not automatically imply that the original study lacks reproducibility.

The emphasis in the proposed regulation on accepting only reproducible studies with publicly available data could eliminate EPA reliance on well-conducted longitudinal studies such as the Six Cities Study, an example of rigorous and robust observational

[14] *Id.*
[15] *Id.*

research, which established the association between fine-particulate air pollution and mortality.[16] After the results were published, an independent group of investigators re-analyzed the results, assessed the robustness of the findings, and confirmed the original results.[17] We believe that similar rigorous re-analyses and replications are possible without mandating public availability of all data.

While data sources that do not pose significant human subject re-identification concerns should be shared publicly using existing data repositories, such as those employed by the National Center for Health Statistics, the Centers for Disease Control and Prevention, and the NIH's NHLBI Biologic Specimen and Data Repositories Information Coordinating Center (BioLINCC), the EPA should focus on creating a data sharing system for long term human subject studies where privacy concerns exist. Under the model that we proposed, only properly deidentified data should be shared, and redaction and de-identification needs to ensure anonymity of research participants according to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). P.L. No. 104-191, 110 Stat. 1938 (1996).

In order to make data available to external researchers for scientific purposes, the EPA should follow previous efforts to facilitate the sharing of data.[18] In particular:

1. An independent intermediary group should be created and should partner with the EPA to oversee data requests. By allowing an independent group to have full jurisdiction to make decisions regarding data access, potential political motivations can be avoided.

2. The independent group should ensure that data are made available for scientific research that is aimed at advancing knowledge. Data requestors should provide basic information about the principal investigators, all study personnel and

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[16] Dockery DW, Pope CA, Xu X, et al. An Association between Air Pollution and Mortality in Six U.S. Cities. *New England Journal of Medicine.* 1993;329(24):1753-1759. doi: 10.1056/NEJM199312093292401.

[17] Krewski D, Burnett RT, Goldberg MS, et al. Overview of the reanalysis of the Harvard Six Cities Study and American Cancer Society Study of Particulate Air Pollution and Mortality. *J Toxicol Environ Health A.* 2003;66(16-19):1507-51. doi: 10.1080/15287390306424. *See also* Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, Special Report, July 2000.* 2000. https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air (Last accessed July 31, 2018).

[18] Krumholz HM, Ross JS. A Model for Dissemination and Independent Analysis of Industry Data. *JAMA.*2011;306(14):1593–1594. doi:10.1001/jama.2011.1459; Yale Open Data Access Project, *Welcome to the YODA Project.* 2018. http://yoda.yale.edu/welcome-yoda-project. (last accessed Aug. 10, 2018).

funders, and submit a detailed proposal outlining specific aims and specifying study methodology. All data requests should undergo external review, to facilitate feedback from independent experts in the field to verify scientific merit. To ensure transparency, the independent group should make all of the data requests publicly available, along with the reasons for granting or denying data requests.

3. All requestors should be required to sign a Data Use Agreement (DUA), which states that access to the data will be used to enhance knowledge and that all findings will be made publicly available through publications and meetings.

4. The independent group should ensure that the scope of the analyses is limited to the specific aims set out in the proposal and that additional objectives are outlined in new submissions.

Responsible data sharing is a complex endeavor and should be done in a manner that is safe and in the best interest of society. Although the IOM report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* focuses on clinical trial transparency, some of the conclusions are applicable to the EPA proposed rule:

> The committee's position is that the benefits of data sharing belong primarily to the public in the form of valid scientific knowledge and improvement of clinical practice and public health. However, these benefits are not necessarily best attained by full open transparency…If full open transparency of clinical trial data carries on balance more risk than benefits, it does not serve the public good.[19]

Furthermore, the language in the EPA proposal is dangerous as it may allow for "case-by-case" determinations that would permit the Administrator to "exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable."[20] Well-established legal precedent frowns upon case-by case determinations where, as here, a general rule would be appropriate.[21] In addition, this provision would allow the EPA to selectively choose studies to rely on and to disregard by granting exemptions to the public availability requirement. Moreover, CRIT believes

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[19] Institute of Medicine (IOM). *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk.* Washington, DC: The National Academies Press; 2015, p. 42.
[20] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18772 (Apr. 30, 2018).
[21] *Securities Exchange Commission v. Chenery Corporation*, 332 U.S. 194, 202-03 (1995); *see also* Warren E. Baker, *Policy by Rule or Ad Hoc Approach- Which Should It Be?*, 22 L. & Contemp. Probs. 658, 659 (1957).

that any new regulation involving reproducibility and transparency proposed by the EPA should be applied to research from all sources, including studies conducted by industry.

Lastly, we are also concerned about the lack of scientific justification for the emphasis in the proposed regulation on privileging non-linear models for dose-response over the well-accepted linear models, and the inclusion of the previously non-existent concept of "pivotal regulatory science."[22] The preamble to the proposed regulation makes an unsupported claim that there is "growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects;"[23] and establishes new priorities for EPA funding of research that privilege non-linear models, in direct opposition to the accepted scientific methodology. The proposed regulation states:

> When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.[24]

It is inappropriate to establish major changes in research priorities through insertion of additional language in a proposed regulation ostensibly on another topic, as was done here, rather than to use the normal channels of consultation with stakeholders, advisory boards, and reference to prior commissioned studies from the National Academies of Sciences.[25] These proposed changes are antithetical to the governing law, existing regulations, and well-established agency practice.

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[22] *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18770 (Apr. 30, 2018).
[23] *Id.* at 18773.
[24] *Id.* at 18774.
[25] National Research Council. 2009. *Science and Decisions: Advancing Risk Assessment.* Washington, DC: The National Academies Press. https://doi.org/10.17226/12209.

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C R I T

Collaboration for Research Integrity and Transparency

A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

Thank you for the opportunity to comment. We urge you to withdraw the proposed regulations.

Sincerely,

Margaret E. McCarthy
Executive Director, CRIT

Joseph S. Ross
Associate Professor of Medicine, Yale School of Medicine

Joshua D. Wallach
Research Fellow, CRIT
Assistant Professor of Epidemiology, Department of Environmental Health Sciences, Yale School of Public Health (appointment effective September 1, 2018)

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approximately 15 percent of students receive their education exclusively through distance education while 68.3 percent took no distance education courses. However, at proprietary institutions almost 59.2 percent of students were exclusively distance education students and 30.4 percent had not enrolled in any distance education courses.[1] The delay in a clear State authorization rule for distance education may slow the reshuffling of the postsecondary education market or the increased participation of small entities in distance education, but that is not necessarily the case. Distance education has expanded over recent years even in the absence of a clear State authorization regime.

In the analysis of the 2016 final rule, we noted that the Department estimated total State Authorization Reciprocity Agreement (SARA) fees and additional State fees of approximately $7 million annually for small entities, but acknowledged that costs could vary significantly by type of institution and institutions' resources and that these considerations may influence the extent to which small entities operate distance education programs. Small entities that do participate in the distance education sector may benefit from avoiding these fees during the delay period. If 50 percent of small entities offer distance education, the average annual cost savings per small entity during the delay would be approximately $3,280, but that would increase to $6,560 if distance education was only offered by 25 percent of small entities. This estimate assumes small entities have not already taken steps to comply with the State authorization requirements in the 2016 final rule. The Department welcomes comments on the distribution of small entities offering distance education, the estimated costs to obtain State authorization for their programs, and the extent to which small entities have already incurred costs to comply with the 2016 final rule.

The Department also estimated that small entities would incur 13,981 hours of burden in connection with information collection requirements with an estimated cost of $510,991 annually. Small entities may be able to avoid some of the anticipated burden during the delay. To the extent small entities would need to spend funds to comply with State authorization requirements for distance education, the proposed delay would allow them to postpone incurring those costs. And although institutions may have incurred some of the $510,991 annual costs to prepare for the information collection requirements, it is possible that institutions could avoid up to that amount during the period of the delay.

Paperwork Reduction Act of 1995

As indicated in the Paperwork Reduction Act section published in the 2016 final regulations, the assessed estimated burden was 152,565 hours affecting institutions with an estimated cost of $5,576,251.

The table below identifies the regulatory sections, OMB Control Numbers, estimated burden hours, and estimated costs of those final regulations.

Regulatory section	OMB control No.	Burden hours	Estimated cost $36.55/hour institution
600.9	1845–0144	160	5,848
668.50(b)	1845–0145	151,715	5,545183
668.50(c)	1845–0145	690	25,220
Total	.....	152,565	5,576,251
Cost savings due to delayed effective date	.....	152,565	5,576,251

This notice proposes to delay the effective date of the all of the cited regulations.

Accessible Format: Individuals with disabilities may obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects

34 CFR Part 600

Colleges and universities, Foreign relations, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Student aid, Vocational education.

34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Selective Service System, Student aid, Vocational education.

Dated: May 22, 2018.

Betsy DeVos,

Secretary of Education.

[FR Doc. 2018–11262 Filed 5–24–18; 8:45 am]

BILLING CODE 4000–01–P

[1] 2017 Digest of Education Statistics Table 311.15: Number and percentage of students enrolled in degree-granting postsecondary institutions, by distance education participation, location of student, level of enrollment, and control and level of institution: Fall 2015 and fall 2016. Available at *https://nces.ed.gov/programs/digest/d17/tables/dt17_311.15.asp?current=yes.*

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA–HQ–OA–2018–0259; FRL–9978–31–ORD]

RIN 2080–AA14

Strengthening Transparency in Regulatory Science; Extension of Comment Period and Notice of Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period; notice of public hearing.

SUMMARY: On April 30, 2018, the Environmental Protection Agency (EPA) proposed a rule titled, "Strengthening Transparency in Regulatory Science." The EPA is extending the comment period on the proposed rule, which was scheduled to close on May 30, 2018, until August 16, 2018. The EPA is also announcing a public hearing to be held for the proposed rule. The hearing will be held on July 17, 2018 in Washington, DC. The EPA is making these changes in response to public requests for an extension of the comment period and for a public hearing.

DATES: The public comment period for the proposed rule published in the **Federal Register** on April 30, 2018 (83 FR 18768), is being extended. Written comments must be received on or before August 16, 2018. The public hearing will be held on July 17, 2018.

ADDRESSES: The EPA has established a docket for the proposed rulemaking (available at *http://www.regulations.gov*). The Docket ID No. is EPA–HQ–OA–2018–0259. Submit your comments, identified by the appropriate Docket ID, to the *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make.

For additional submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html.*

Public hearing: The public hearing will be held at the Environmental Protection Agency, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, DC 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST or one hour after the last registered speaker has spoken, whichever is earlier. The EPA will make every effort to accommodate all speakers that arrive and register. Because this hearing is being held at a U.S. government facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff to gain access to the meeting room. No large signs will be allowed in the building, cameras may only be used outside of the building, and demonstrations will not be allowed on federal property for security reasons.

If you would like to present oral testimony at the public hearing, please register online at *https://www.epa.gov/osa/strengthening-transparency-regulatory-science* or contact Tom Sinks, Environmental Protection Agency, Office of the Science Advisor, (MC 8105R), 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (202) 564–0221, *staff_osa@epa.gov,* no later than 2 business days prior to the public hearing. The last day to register will be July 15, 2018. If using email, please provide the following information: Time of day you wish to speak (8:00 a.m.–12:00 p.m., 12:00 p.m.–4:00 p.m., 4:00 p.m.–8:00 p.m.), name, affiliation, address, email address, and telephone and fax numbers.

FOR FURTHER INFORMATION CONTACT: Questions concerning the proposed rule, "Strengthening Transparency in Regulatory Science" should be addressed to Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564–0221; email address: *staff_osa@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period for the proposed rule to ensure that the public has sufficient time to review and comment on the proposal. EPA is proposing this rule under authority of 5 U.S.C. 301, in addition to the authorities listed in the April 30th document.

The public hearing provides the public with an opportunity to present oral comments regarding EPA's proposed regulation entitled "Strengthening Transparency in Regulatory Science." This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. EPA is proposing this rule under authority of 5 U.S.C. 301, in addition to the authorities listed in the April 30th document.

The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposal. EPA solicits comments on all aspects of the proposal and specifically on the issues identified in Section III of the April 30th document. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing.

Oral testimony will be limited to 5 minutes for each commenter. The EPA encourages commenters to provide EPA with a copy of their oral testimony electronically via email or in hard copy form.

The hearing schedules, including lists of speakers, will be posted on EPA's website *https://www.epa.gov/osa/strengthening-transparency-regulatory-science.* Verbatim transcripts of the hearings and written statements will be included in the docket for the rulemaking. EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule.

Dated: May 21, 2018.

Tom Sinks,

Director, Office of the Science Advisor.

[FR Doc. 2018–11316 Filed 5–24–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2018–0008; FRL–9978–63-Region 5]

Air Plan Approval; Wisconsin; Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a January 4, 2018, request by the Wisconsin Department of Natural Resources (Wisconsin) to revise its state implementation plan (SIP) for fine particulate matter ($PM_{2.5}$). Wisconsin updated its ambient air quality standards for $PM_{2.5}$ to be consistent with EPA's 2012 revisions to the $PM_{2.5}$

will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0242 to read as follows:

§ 165.T09–0242 Safety Zone; Blazing Paddles 2018 SUP Race; Cuyahoga River, Cleveland, OH.

(a) *Location.* The safety zone will encompass all waters of the Cuyahoga River in Cleveland, OH, beginning at position 41°29′36″ N and 081° 42′13″ W to the turnaround point at position 41°28′52″ N and 081°40′33″ (NAD 83).

(b) *Enforcement Period.* This rule is effective from 8:30 a.m. until 11:30 a.m. on June 23, 2018.

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: April 23, 2018.

J.S. Dufresne,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2018–08979 Filed 4–27–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 30

[EPA–HQ–OA–2018–0259; FRL–9977–40–ORD]

RIN 2080–AA14

Strengthening Transparency in Regulatory Science

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation. In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

DATES: Comments must be received on or before May 30, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2018–0259, at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tom Sinks, Office of the Science Advisor, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 564–0221; email address: *staff_osa@epa.gov.*

SUPPLEMENTARY INFORMATION:

Submitting CBI. Do not submit information that you consider to be CBI electronically through *https://www.regulations.gov* or email. Send or deliver information identified as CBI to only the following address using U.S. Postal Service: U.S. Environmental Protection Agency, EPA Docket Center, EPA–HQ–OA–2018–0259, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. For other methods of delivery, see *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the

outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information

A. Does this action apply to me?

This proposed regulation does not directly regulate any entity outside the federal government. However, any entity interested in EPA's regulations may be interested in this proposal. This proposal may be of particular interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity.

B. What action is the Agency taking?

This notice solicits information and comment from the public on a proposed regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. In this notice, EPA solicits comment on this proposal and how it can best be implemented in light of existing law and prior statements of policy that have called for increasing public access to data and influential scientific information used to inform federal regulation. EPA has not previously implemented these policies and guidance in a robust and consistent manner. This proposal will help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust and understand.

C. What is the Agency's authority for taking this action?

The Agency proposes to take this action under authority of the statutes it administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency's functions under these statutes and provisions specifically addressing the Agency's conducting of and reliance on scientific activity to inform those functions, including Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j–1, 300j–9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609. This action is also consistent with requirements in the Administrative Procedure Act to ensure public participation in the rulemaking process. As noted in Section III below, EPA solicits comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation.

II. Background

The best available science must serve as the foundation of EPA's regulatory actions.[1] Enhancing the transparency and validity of the scientific information relied upon by EPA strengthens the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions. By better informing the public, the Agency in enhancing the public's ability to understand and meaningfully participate in the regulatory process.[2] In applying the best available science to its regulatory decision-making, EPA must comply with federal transparency and data integrity laws, and must also ensure that its decision-making is marked by independence, objectivity, transparency, clarity, and reproducibility. Although these standards are important in all scientific endeavors, they are of paramount importance when the government relies on science to inform its significant regulatory decisions that will affect the public. When EPA develops significant regulations using public resources, including regulations for which the public is likely to bear the cost of compliance, EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public. This proposed rule is designed to increase transparency in the preparation, identification, and use of science in policymaking.

This proposed rule is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions.[3] This proposed rule is also consistent with Executive Orders 13777[4] and 13783,[5] and the focus on transparency in OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*[6] (the Guidelines) and OMB

[1] See Exec. Order No. 13563, 76 FR 3821 (Jan. 21, 2011). "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science."

[2] See Memorandum for the Heads of Executive Department and Agencies on Scientific Integrity (Mar. 9, 2009). "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking."

[3] EPA has the authority to establish policies governing its reliance on science in the administration of its regulatory functions. Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support of its regulatory actions. *See Coalition of Battery Recyclers Ass'n* v. *EPA,* 604 F.3d 613, 623 (D.C. Cir. 2010); *American Trucking Ass'ns* v. *EPA,* 283 F.3d 355, 372 (D.C. Cir. 2002). EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.

[4] Exec. Order No. 13777, 82 FR 12285 (Mar. 1, 2017). Regulatory reform efforts shall attempt to identify "those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility."

[5] Exec. Order No. 13783, 82 FR 16093 (Mar. 31, 2017). "It is also the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics."

[6] February 22, 2002 (67 FR 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) *https://www.federalregister.gov/documents/*

Continued

Memorandum 13–13: Open Data Policy—Managing Information as an Asset.[7] It builds upon prior EPA actions[8] in response to government-wide data access and sharing policies, as well as the experience of other federal agencies in this space.[9] In particular, this proposal applies concepts and lessons learned from its ongoing implementation of the 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research to significant regulatory decisions. The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science.[10] These policies are informed by the policies recently adopted by some major scientific journals,[11] spurred in some part by the "replication crisis."[12]

Today, EPA is proposing to establish a clear policy for the transparency of the scientific information used for significant regulations: Specifically, the dose response data and models that underlie what we are calling "pivotal regulatory science." "Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.

With this notice, EPA is soliciting public comment on a proposed regulation designed to provide a mechanism to increase access to dose response data and models underlying pivotal regulatory science in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests. The proposal takes comment on how to ensure that, over time, more of the data and models underlying the science that informs regulatory decisions (over and above the dose response data and models underlying "pivotal regulatory science") is available to the public for validation[13] in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification. As such this proposed regulation is designed to change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis.

Regulatory determinations based on science should describe and document any assumptions and methods used, and should address variability and uncertainty. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. EPA's regulatory science should be consistent with the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review.*[14] Robust peer review plays a critical role in independently validating key findings and ensuring that the quality of published information meets the standards of the scientific and technical community.

In addition, this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity. EPA should also incorporate the concept of model uncertainty when needed as a default to optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models.

Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency. It is the charge of regulators to ensure that key findings are valid and credible, as required by OMB's Guidelines[15] (which apply to "third party" information—*e.g.,* non-government scientific research—if the agency use of that information provides the appearance of representing agency views). Using scientific information that can be independently validated will lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions.

EPA believes that concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government.[16] Nothing in the proposed rule compels

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2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

[7] *Memorandum for the Heads of Executive Departments and Agencies on Open Data Policy—Managing Information as an Asset* (*https://project-open-data.cio.gov/policy-memo/*). "Specifically, this Memorandum requires agencies to collect or create information in a way that supports downstream information processing and dissemination activities. This includes using machine-readable and open formats, data standards, and common core and extensible metadata for all new information creation and collection efforts. It also includes agencies ensuring information stewardship through the use of open licenses and review of information for privacy, confidentiality, security, or other restrictions to release."

[8] Plan to Increase Access to Results of EPA-Funded Scientific Research; EPA Open Government Plan 4.0; Open Data Implementation Plan; EPA's Scientific Integrity Policy; Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.

[9] For example, see related policies from the National Science Foundation, National Institute of Science and Technology, the National Institutes of Health; and the U.S. Census Bureau, which provides secure access to data from several agencies in an environment that protects against unauthorized disclosure (*https://www.census.gov/fsrdc*).

[10] These include policies and recommendations from: The Administrative Conference of the United States' Science in the Administrative Process Project; National Academies' reports on *Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data,* and *Access to Research Data in the 21st Century;* the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project.

[11] For example, see related policies from the *Proceedings of the National Academy of Sciences, PLOS ONE, Science,* and *Nature.*

[12] See: *https://www.nature.com/articles/s41562-016-0021; http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124; http://science.sciencemag.org/content/343/6168/229.long; https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-world-now-it-needs-change-itself-how-science-goes-wrong.; http://stm.sciencemag.org/content/8/341/341ps12.full.*

[13] EPA has not consistently followed previous EPA policy (*e.g,* EPA's Scientific Integrity Guidance, referenced above) that encouraged the use of non-proprietary data and models.

[14] *https://www.whitehouse.gov/wp-content/uploads/2017/11/2005-M-05-03-Issuance-of-OMBs-Final-Information-Quality-Bulletin-for-Peer-Review-December-16-2004.pdf.*

[15] February 22, 2002 (67 FR 8453) *OMB's Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information* (2002) *https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.*

[16] See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

the disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections. Other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines.[17] The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century and that "Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach." [18] More recently, both the National Academies and the Bipartisan Commission on Evidence Based Policy [19] have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts.

Considering the breadth of dose response data and models used in the development of significant EPA regulations, the requirements for availability may differ. These mechanisms may range from deposition in public data repositories, consistent with requirements for many scientific journals,[20] to, for certain types of information, controlled access in federal research data centers that facilitate secondary research use by the public.[21] EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: Requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements.[22]

Implementation of this proposed rule will be consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in Public Law 89–487, and other applicable federal laws.

This proposed regulation is intended to apply prospectively to final regulations that are determined to be "significant regulatory actions" pursuant to E.O. 12866. The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.

III. Request for Comment

EPA solicits comment on all aspects of the proposed regulation and the bases articulated for it above. Specifically, EPA believes that it has identified appropriate sources of statutory authority for this proposed regulation in Section I(c) above, and solicits public comment on whether additional or alternative sources of authority are appropriate bases for this proposed regulation. EPA further believes that a generally applicable regulatory provision of the type proposed here is the appropriate vehicle to establish and implement the policies articulated in Section II above, in the interests of consistency, predictability, and transparency across the functions that EPA performs.

EPA solicits comment on whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles at the programmatic or statutory level would be appropriate as alternative or additional steps the agency may take to further the policies articulated in Section II above.

EPA solicits comment on the effects of this proposed rule on individual EPA programs, including whether certain activities are appropriate to be excepted or if other requirements would affect implementation. EPA also seeks comments on which criteria the Agency should use to base any exceptions, including whether case-by-case exceptions may be appropriate.

Although the proposed regulatory text would impose requirements specifically on final regulations determined to be "significant regulatory actions" under E.O. 12866, EPA solicits comment on whether and to what extent these requirements, or other provisions and policies, should apply to other stages of the rulemaking process, including proposed rules, as well as to other types of agency actions and promulgations, such as guidance. EPA also solicits comment on whether a narrower scope of coverage would be appropriate, such as only final regulations that are determined to be "major" under the Congressional Review Act, or "economically significant" under E.O. 12866. EPA also requests comment on whether certain categories of regulations should be excluded from coverage, such as those that merely reaffirm an existing standard, or some other category. For instance, we request comment on whether the provisions of the proposed rule should apply to individual party adjudications, enforcement activities, or permit proceedings when EPA determines that these provisions are practical and appropriate and that the actions are scientifically or technically novel or likely to have precedent-setting influence on future actions. EPA seeks comment on whether the Agency should apply the provisions of the proposed rule to these actions or to specific types of actions within these categories. The Agency also seeks comment on whether other agency actions, beyond significant final regulatory actions under E.O. 12866, should be included, such as site-specific permitting actions or non-binding regulatory determinations.

EPA solicits comment on the definitions of "*pivotal regulatory science,*" and "*dose response data and models*" and how to implement such definitions.

EPA also solicits comment on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants. EPA solicits comments on how it can build upon other federal agencies' policies regarding grantee and cooperator requirements for data access and data sharing. EPA also solicits suggestions for a platform that would enable the Agency to implement the provisions of this proposal related to increasing public access to EPA-funded data. EPA also seeks comment on methodologies and technologies designed to provide protected access to identifiable and sensitive data, such as individual health data, and on commenters experience with the use of such methodologies and technologies and their strengths and limitations. Similarly, EPA seeks comment on how to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science. EPA also requests comment on whether there are other compelling interests besides privacy, confidentiality, national and homeland

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[17] *https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.*

[18] *https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.*

[19] *https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.*

[20] For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature.

[21] For example: *https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc.*

[22] These recommendations are consistent with those of Lutter and Zorn (2016). *https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re.*

security that may require special consideration when data is being released.

EPA solicits comment on implementation of the proposed regulation, including which parts of the Agency should be responsible for carrying out these requirements. EPA seeks comment on the effective date of a rule as well as on whether the Agency should seek to phase-in the requirements for certain significant regulatory actions or seek to prioritize specific actions. For regulatory programs, like the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews—particularly where the governing statute requires repeated review on a fixed, date-certain cycle—EPA seeks comment on the manner in which this proposed rule should apply to that previous record. EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date. In addition, EPA seeks comment on how the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available. EPA seeks comment on how to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist. EPA also seeks comment on any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them.

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to ensure that all dose response data and models underlying pivotal regulatory science are publicly available in a fashion that is consistent with law, protects privacy and confidentiality, and is sensitive to national and homeland security, or in instances where OMB's Information Quality Bulletin for Peer Review provides for an exemption (Section IX). The agency requests comment on whether these exemptions are appropriate, and on whether there are other situations in which specific significant regulatory actions, or specific categories of significant regulatory actions should be exempted.

EPA also requests comment on whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems.

IV. Statutory and Executive Orders Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA believes the benefits of this proposed rule justify the costs. The benefits of EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets; this is consistent with the conclusions of the National Academies [23] This action should be implemented in a cost-effective way and is consistent with recent activities of the scientific community and other federal agencies, which will help to lower costs of implementation. The proposed rule directs EPA to make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making dose response models and data underlying pivotal regulatory science used in significant regulatory decisions available to the public in a manner sufficient for independent validation, consistent with law and protection of privacy, confidentiality, and national and homeland security. However, it does not compel the Agency to make that information available where it concludes after all such reasonable efforts that doing so in way that complies with the law and appropriate protections is not possible.

By limiting the proposed rule to pivotal regulatory science for final significant regulatory actions pursuant to E.O. 12866, the proposed rule ensures that this standard for transparency affects a smaller subset of regulations which are economically significant, create inconsistency for other federal agencies, alter budgetary impacts, or raise novel legal or policy issues. One recent analysis found that: "Improvements in reproducibility can be thought of as increasing the net benefits of regulation because they would avoid situations in which costs or benefits are wrongly estimated to occur or in which regulatory costs are imposed without corresponding benefits. . . ." They concluded that "an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available." [24]

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel."

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national

[23] *https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.*

[24] *https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.*

government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 30

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

Dated: April 24, 2018.

E. Scott Pruitt,

Administrator.

For the reasons set forth in the preamble, EPA proposes to add 40 CFR part 30 as follows:

PART 30—TRANSPARENCY IN REGULATORY DECISIONMAKING

■ 1. Add part 30 to read as follows:

PART 30—TRANSPARENCY IN REGULATORY DECISIONMAKING

Sec.

Authority: Clean Air Act sections 103, 301(a), 42 U.S.C. 7403, 7601(a); Clean Water Act sections 104, 501, 33 U.S.C. 1254, 1361; Safe Drinking Water Act sections 1442, 1450(a)(1), 42 U.S.C. 300j–1, 300j–9(a)(1); Resource Conservation and Recovery Act sections 2002(a)(1), 7009, 42 U.S.C. 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act (as delegated to the Administrator via Executive Order 12580) sections 115, 311, 42 U.S.C. 9616, 9660; Emergency Planning and Community Right-To-Know Act section 328, 42 U.S.C. 11048; Federal Insecticide, Fungicide, and Rodenticide Act sections 25(a)(1), 136r(a), 7 U.S.C. 136r(a), 136w; and Toxic Substances Control Act, as amended, section 10, 15 U.S.C. 2609.

§ 30.1 What is the purpose of this subpart?

This subpart directs EPA to ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.

§ 30.2 What definitions apply to this subpart?

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act or in subpart A; and the following terms shall have the specific meanings given them.

Dose response data and models means the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.

Pivotal regulatory science means the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.

Regulatory decisions mean final regulations determined to be "significant regulatory actions" by the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory science means scientific information, including assessments, models, criteria documents, and regulatory impact analyses, that provide the basis for EPA final significant regulatory decisions.

Research data means "research data" as that term is defined in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

§ 30.3 How do the provisions of this subpart apply?

The provisions of this subpart apply to *dose response data and models* underlying *pivotal regulatory science* that are used to justify significant *regulatory decisions* regardless of the source of funding or identity of the party conducting the regulatory science. The provisions of this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses. Except where explicitly stated otherwise, the provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings.

§ 30.4 What requirements apply to EPA's use of studies in taking final action?

EPA shall clearly identify all studies (or other regulatory science) relied upon when it takes any final agency action. EPA should make all such studies available to the public to the extent practicable.

§ 30.5 What requirements apply to EPA's use of dose response data and models underlying pivotal regulatory science?

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered "publicly available in a manner sufficient for independent

validation" when it includes the information necessary for the public to understand, assess, and replicate findings. This may include, for example:

(a) Data (where necessary, data would be made available subject to access and use restrictions).

(b) Associated protocols necessary to understand, assess, and extend conclusions;

(c) Computer codes and models involved in the creation and analysis of such information;

(d) Recorded factual materials; and

(e) Detailed descriptions of how to access and use such information.

The provisions of this section apply to dose response data and models underlying pivotal regulatory science regardless of who funded or conducted the underlying data, models, or other regulatory science. The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with those parties to endeavor to make the data available in a manner that complies with this section.

§ 30.6 What additional requirements pertain to the use of dose response data and models underlying pivotal regulatory science?

EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty. EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

§ 30.7 What role does independent peer review in this section?

EPA shall conduct independent peer review on all *pivotal regulatory science* used to justify *regulatory decisions,* consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review (70 FR 2664) and the exemptions described therein.

Because transparency in regulatory science includes addressing issues associated with assumptions used in models, EPA shall ask peer reviewers to articulate the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results.

§ 30.8 How is EPA to account for cost under this subpart?

EPA shall implement the provisions of this subpart in a manner that minimizes costs.

§ 30.9 May the EPA Administrator grant exemptions to this subpart?

Yes. The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because:

(a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or

(b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.

§ 30.10 What other requirements apply under this subpart?

EPA shall implement the provisions of this section consistent with the definition of "research data" in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, exemptions in Public Law 89–487, and other applicable federal laws. Where appropriate, data sharing agreements and state-of-the-art data-masking techniques may be employed to facilitate access to information.

[FR Doc. 2018–09078 Filed 4–27–18; 8:45 am]

BILLING CODE 6560–50–P

STATEMENT OF WORK

TITLE: Support for EPA Proposed Rule on "Strengthening Transparency in Regulatory Science" Management and response Support for EPA Docket Comments and Public Hearing.

CONTRACT NO.: EP-D-14-033, Work Assignment 3-05

PERIOD OF PERFORMANCE: Time of Award – September 30, 2018

WORK ASSIGNMENT MANAGER (WAM):
Robin R. Clarke
1200 Pennsylvania Avenue, NW (Mail Code 8101R)
Washington, DC 20460
Phone: 202-564-6493
Fax: 202-564-2070
Email: clarke.robin@epa.gov

TECHNICAL POINT OF CONTACT:
TBD

Cheryl A. Hawkins
1200 Pennsylvania Avenue, NW (Mail Code 8105R)
Washington, DC 20460
Phone: 202-564-7307
Fax: 202-564-2070
Email: hawkins.cheryla@epa.gov

BACKGROUND

On April 30, 2018, the U.S. Environmental Protection Agency (EPA) published a Notice of Proposed Rulemaking in the Federal Register titled ***Strengthening Transparency in Regulatory Science.*** [EPA-HQ-OA-2018-0259; FRL-9977-40-ORD]. The proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, it should ensure that the data underlying the regulation are publicly available in a manner sufficient for independent validation. EPA solicited comments on this proposal until May 30, 2018. However, the agency has received many comments to extend the comment period and will likely grant an extension through August 16, 2018. In addition, requests have been received for a public hearing to solicit public testimony on this proposed rule. EPA is anticipating that a public hearing will be conducted.

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PURPOSE AND SCOPE

The purpose and scope of this Statement of Work is for the contractor to provide technical support to EPA in sifting, analyzing, organizing, and summarizing public comments received in the EPA Docket and managing the public hearing. In order to prepare the deliverables, EPA anticipates that the contractor staff will familiarize themselves with the public comments in the

EPA docket and review and consider all comments and any other relevant information provided by EPA to the contractor to help with the development of a comment response document, the public hearing and support in developing a final agency product.

Task 1: Prepare Work Plan

The Contractor shall prepare a work plan and cost estimate in accordance with the terms and conditions of the contract. The Contactor shall provide a work plan outlining the approach, resources, timeline, and estimated costs for all tasks listed below. Estimates of costs and hours shall be presented by task, professional staff level and estimated month of completion. The Work Assignment Manager (WAM) will review the work plan and will request revisions and or changes as needed. If necessary, the Contractor shall incorporate EPA comments into the final work plan.

Task 2: Support for Public Hearing

The contractor shall support the Agency in providing logistical and other support for a 1-day public hearing to be held in Washington DC. EPA will provide the list of public members that have requested to testify at the public hearing and the contractor shall organize and provide the logistical support at the public hearing to ensure that the public has an opportunity to provide comments. The contractor shall provide the AV equipment for a large meeting room and a court reporter (or equivalent) that can transcribe the comments from the public. The contractor shall also gather any written, electronic or other materials that the public offers in coordination with their comments.

The contractor shall provide the transcribed comments and a report from the meeting that summarizes the number of commenters, the substantive comments, and other information for review by the WAM prior to submission to the docket.

Task 3: Support with Organization and Review of Public Comments and Development of a Comment Response Document

The contractor shall support the Agency by organizing comments received in the public docket into a searchable excel table (to include all comments provided during the public hearing). The contractor will develop a template for EPA to approve that contains, at a minimum, fields for: the name of the commenter(s), the comment, whether the comment is considered editorial or substantive, and the proposed response to the comment. The comments shall be organized by theme area, based on the initial review of the public comments. The contractor shall provide a draft of the comment response document and work with EPA to develop the responses to public comments.

The contractor shall also provide a summary of the substantive comments organized by theme and with references to the comment identifier in the docket. Substantive comments are ones that contain comprehensive arguments, analyses and data. The comment summaries developed by the contractor will be provided to EPA in an excel table format. The contractor will use the excel table to document key information about substantive comments including commenter name, organization, organization type, regulated sector, affected EPA office, statute, Federal Register citation, primary contact, and supporting details. The contractor shall provide the WAM a

proposed template for approval before developing the comment summaries. The contractor shall provide a draft of the substantive comments document to the WAM for review. Based upon the review the contractor shall update the products to ensure consistency.

The contractor will provide a count of all non-substantive comments received and categorize the non-substantive comments by theme. Non-substantive comments are mass mailings/form letters or individual comments lacking comprehensive arguments related to the proposed rule, analyses or data.

Task 4: Support for the Development of a Final Action

The contractor shall support EPA by preparing information that can be used to support the development of the final action, to include language that can be used in a regulation, guidance or policy, as appropriate. The language will be based on the comment response document, the public hearing, other analyses that may be needed to satisfy OMB requirements and other input from EPA.

SCHEDULE OF DELIVERABLES

Task Number and Deliverable	Schedule
Task 1: Prepare Work plan and cost estimate	Within 20 days of initiating WA
Task 2: Support for Public Hearing	
• Logistical and Organizational Support for Public Hearing	Public Hearing to occur on July 17, 2018, with preparatory work before and follow up work after
• Draft and Final Transcribed public comments for submission to docket	Draft transcribed public comments within 2 weeks of hearing and final within 3 weeks of hearing
Task 3: Comment Review, Organization and Templates	
• Draft Templates	Templates due within 25 days of initiating Task Order
• Draft Comment Response Document • Final Comment Response Document • Summary of Substantive Comments Report	Other deliverables due to the WAM based on the volume of comments received
Task 4: Support for Final Action	TBD, under the direction of the WAM

Message

From: Hawkins, CherylA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D917BEE23E774E0DBB05CE06D694985E-HAWKINS, CHERYLA]
Sent: 5/23/2018 3:39:31 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
CC: Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]; Anand Mudambi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a94638932b49af8a6cf581262d5059-Mudambi, Anand]
Subject: FW: More letters from CCU
Attachments: 18-000-7115.pdf; 18-000-7324.pdf; AX-18-000-7232.pdf; 18-000-7394.pdf; 18-000-7397.pdf; 18-000-7435.pdf; Regulatory Science.Controlled correspondence.Response letters and emails....docx

Hi Tom,

Attached are more items from CCU along with a file with response letters/emails for each.

Please pay special attention to AX-18-000-7232 and the response. That letter is from several Attorneys General and was sent out from the NY Attorney General's office. Since the NY attorney general who signed the letter is no longer there, I addressed the letter to all of the Attorneys General without specifying their names and have it addressed to be sent back to the NY office.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Cawiezell, Thomas
Sent: Monday, May 21, 2018 3:28 PM
To: Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Subject: More letters from CCU

Thomas Cawiezell
Office of the Science Advisor
ORAU for U.S. Environmental Protection Agency
Office ☎ 202-564-0221
Mobile ☎ 563-508-5861
✉ cawiezell.thomas@epa.gov

143 Forest St.
Arlington MA 02474

April 5, 2018

Secretary Scott Pruitt
Environmental Protection Agency,
Mail Code 1101A,
1200 Pennsylvania Avenue, N.W.,
Washington, DC 20460.

Dear Secretary Pruitt,

I am writing to ask that you reconsider a proposal to introduce a regulation that would only allow studies with public data to influence writing regulations. While this proposal sounds good, it would severely limit the pool of scientific research that the EPA uses to base its rules. For example, an insistence that data be "reproducible" will prevent the EPA from looking at data from events that are impossible or unethical to simulate—such as the BP oilspill or lead in children's drinking water. It seems to me that the EPA should cast a broad and wide net in looking to scientific data for information that impacts human health and safety and the health of our environment.

I trust the Union of Concerned Scientists, which opposes this regulation. Groups such as the oil and gas lobbyists, who are in favor of this regulation would appear to have a serious conflict of interest. The organization you oversee is the Environmental PROTECTION Agency. Please act accordingly.

I look forward to hearing from you.

Sincerely,

Judi Paradis

Ms. Judith M Paradis
143 Forest St
Arlington, MA 02474-8902

FCL 2113411

BOSTON MA 021
27 APR 2018 PM 7 L

USA

Secretary Scott Pruitt
Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave NW
Washington DC 20460

Response letter for Control Number AX-18-000-7115

Judi Paradis
143 Forest St.
Arlington, MA 02474

Dear Ms. Paradis,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response email for Control Number AX-18-000-7324

Dear Ms. Johnson,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science" available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,
Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7394

Keith L. Seitter
Executive Director
American Meteorological Society
45 Beacon St.
Boston, MA 02108-3693

Dear Mr. Seitter,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response email for Control Number AX-18-000-7397

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science" available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,
Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7435

Peter Wood
President
National Association of Scholars
12 East 46th St., 6th Floor
New York, NY 10017

Dear Mr. Wood,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7232

Office of the Attorney General
28 Liberty St.
New York, NY 10005

To the Attorneys General of NY, CA, DE, IA, MA, MN, PA, and DC,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

EPA has extended the comment period until August 16, 2018. In addition, a public hearing will be held on July 17, 2018. Should you wish to testify at the public hearing please register at https://www.epa.gov/osa/strengthening-transparency-regulatory-science. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/24/2018 8:18:37 PM
To: ORD-OSA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e137514eedb34419bde8f3580a120d88-ORD-OSA]
CC: Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]; Nelson, Daniel K. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9bd641d949d4a96b2d6c307be288afa-Nelson, Dan]
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

Folks – today Administrator Pruitt announced this proposed rule. Many of you have heard about this in the media. The proposal likely touches upon three aspects of OSA work – public access to EPA funded research, human subjects research protection, and scientific integrity. **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

I expect a high volume of emails and telephone calls coming into OSA. Tom Cawiezell's phone number is listed in the NPRM as is an STPC staff email. No doubt we will all have a lots of questions re this – but I wanted you to be aware of this and encourage you to read about it.

From: Orme-Zavaleta, Jennifer
Sent: Tuesday, April 24, 2018 4:01 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; ORD-Exec-Council-Directors <Execcouncildirectors@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/21/2018 12:32:00 PM
To: Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
CC: Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Kumar, Manisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497133a6697a45f9bea221a07f4359f6-Kumar, Mani]
Subject: RE: Request re BYU Professor Pope & Proposed EPA Transparency Rule

Cheryl – I agree with you. Let's keep a folder of incomings that we do not forward to the docket with an explanation of why.

In this instance, an individual (Dr. Enstrom) sent a personal email to several scientists he has been challenging for several years regarding their past studies on air pollutants. He copied the OSA email box as a bcc. His email does not indicate that this information was intended for the docket nor does it provide any comment about the proposed rule.

From: Hawkins, CherylA
Sent: Friday, May 18, 2018 3:01 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: RE: Request re BYU Professor Pope & Proposed EPA Transparency Rule

Now that I've read the email carefully, I don't believe we should respond nor send it to the docket. He is addressing other researchers and it isn't clear why it was sent to Staff_OSA, I assume we were a bcc.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Staff_OSA
Sent: Friday, May 18, 2018 2:52 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Subject: FW: Request re BYU Professor Pope & Proposed EPA Transparency Rule

Hi Tom,

We've received this email and would like your input on how to respond.

Best,

Cheryl & Manisha

From: James E. Enstrom [mailto:jenstrom@ucla.edu]
Sent: Thursday, May 17, 2018 1:00 PM
To: 'Michael R. Ransom' <ransom@byu.edu>
Cc: 'Brent W. Webb' <webb@byu.edu>; 'Barry R. Bickmore' <barry_bickmore@byu.edu>; 'Delbert J. Eatough' <delbert@eatough.net>; 'Benjamin D. Horne' <benjamin.horne@imail.org>; 'J. Brent Muhlestein' <brent.muhlestein@imail.org>; 'Kent E. Pinkerton' <kepinkerton@ucdavis.edu>; 'Susan M. Gapstur' <susan.gapstur@cancer.org>; 'Michael J. Thun' <michael.thun@cancer.org>; 'Jonathan M. Samet' <jon.samet@ucdenver.edu>; dgreenbaum@healtheffects.org
Subject: Request re BYU Professor Pope & Proposed EPA Transparency Rule

May 17, 2018

BYU President Kevin J. Worthen
BYU Professor Michael R. Ransom ransom@byu.edu
BYU Professor Brent W. Webb webb@byu.edu
BYU Professor Barry R. Bickmore barry_bickmore@byu.edu
BYU Professor Emeritus Delbert J. Eatough delbert@eatough.net
IMC Epidemiologist Benjamin D. Horne benjamin.horne@imail.org
U Utah Professor J. Brent Muhlestein brent.muhlestein@imail.org
UC Davis Professor Kent E. Pinkerton kepinkerton@ucdavis.edu
ACS VP Epidemiology Susan M. Gapstur susan.gapstur@cancer.org
ACS VP Epidemiology Emeritus Michael J. Thun michael.thun@cancer.org
Former EPA CASAC Chair Jonathan M. Samet jon.samet@ucdenver.edu
nobel laureate greenbaum dgreenbaum@healtheffects.org

Subject: Request re BYU Professor Pope and Proposed EPA Transparency Rule

Dear Colleagues of BYU Professor Clive Arden Pope III,

I am writing regarding the Proposed EPA Rule "Strengthening Transparency in Regulatory Science" (https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science). The Summary of this Rule is "This document proposes a regulation intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation."

This rule is necessary in large part because Professor Pope and the American Cancer Society (ACS) have conducted 'secret science' epidemiologic research on fine particulate matter (PM2.5) and mortality that has been used by EPA to establish and tighten the 1997 PM2.5 National Ambient Air Quality Standard (NAAQS). My March 28, 2017 *Dose-Response* article "Fine Particulate Matter and Total Mortality in the Cancer Prevention Study Cohort Reanalysis" (http://journals.sagepub.com/doi/full/10.1177/1559325817693345), based on my independent reanalysis of the 1982 ACS Cancer Prevention Study (CPS II) data, found that Professor Pope's research is seriously flawed and does not support a scientific and public health basis for the PM2.5 NAAQS. My reanalysis clearly demonstrates the importance of access to underlying data and shows the need for the EPA Transparency Rule.

Since you have been involved in some way with Professor Pope's PM2.5 health effects research, please email me as soon as possible your YES or NO answer to the following four questions:

1) Do you support the Proposed EPA Rule "Strengthening Transparency in Regulatory Science"?

2) Is there extensive valid evidence that contradicts Professor Pope's evidence relating PM2.5 to premature deaths?
3) Should Professor Pope be held fully accountable for the validity of his research relating PM2.5 to premature deaths?
4) Should Americans, particularly Californians, be relieved of PM2.5 regulations that are based on a scientifically invalid relationship of PM2.5 to premature deaths?

Please let me know if you need clarification of these questions or this request. Until you respond to the contrary, I will assume that your answers to all four questions are NO.

Thank you very much for your consideration of this important request.

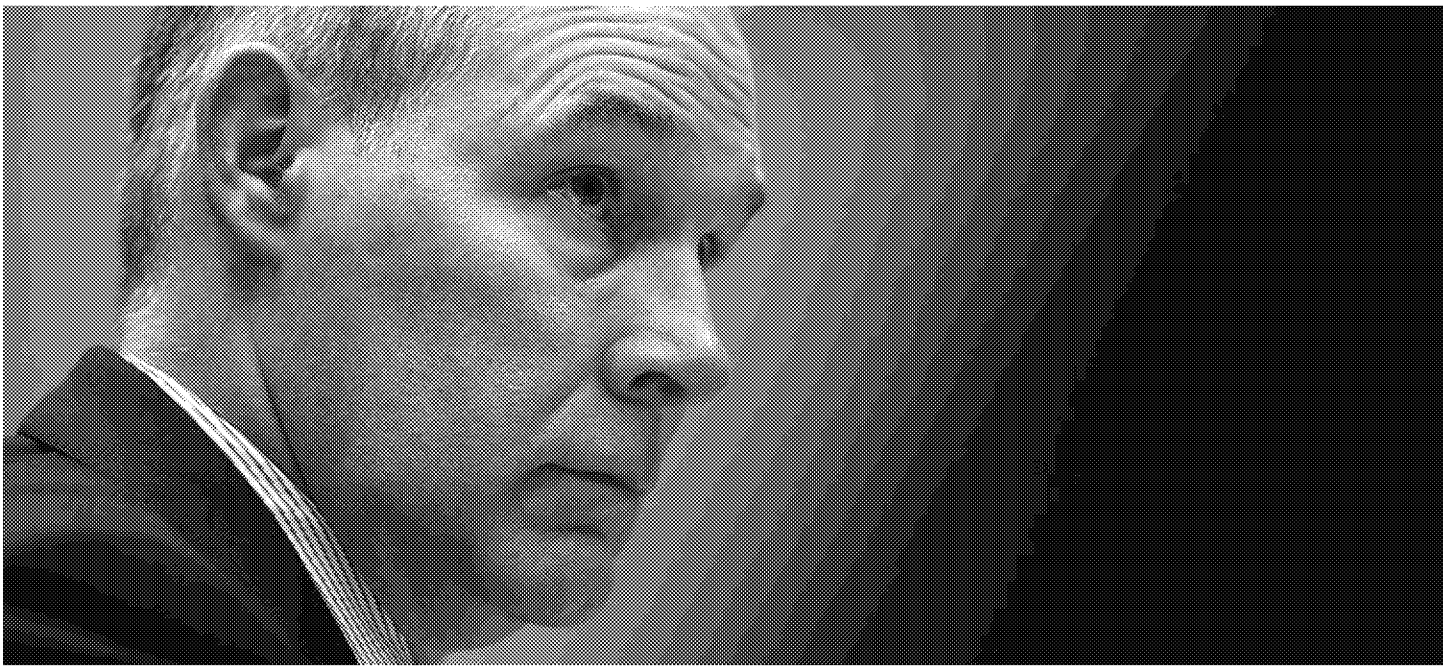
Sincerely yours,

James E. Enstrom, PhD, MPH, FFACE
UCLA and Scientific Integrity Institute
http://www.scientificintegrityinstitute.org/
jenstrom@ucla.edu
(310) 472-4274

Message

From: Benforado, Jay [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E3ADEEE7EFCE4889992919103F16E006-BENFORADO, JAY]
Sent: 4/30/2018 2:17:52 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: in case you hadn't seen this NEXTGOV article

Scott Pruitt's New Rule Could Completely Transform the EPA



Environmental Protection Agency Administrator Scott Pruitt ALEX BRANDON/AP

By ROBINSON MEYER,
The Atlantic
| April 27, 2018

It would not only undermine 30 years of clean-air regulations, but radically restrict what science the agency is allowed to use.

- In one sweeping move, the Trump administration may soon not only destabilize the last three decades of clean air and water rules, but also completely overhaul how the Environmental Protection Agency uses science in its work. If EPA administrator Scott Pruitt's recently-proposed rule gets enacted, it will spark a revolution in environmental regulation. But the question is—will it stand up in court?

Pruitt proposed the regulation on Tuesday, describing it as an effort to increase transparency. It would require the EPA to publish all the underlying scientific data used to support studies which guide clean-air and clean-water rules. It would forbid the use of studies that do not meet this standard, even if they have been peer-reviewed or replicated elsewhere.

Crucially, the proposed rule does not carve out an exemption for medical data, which is tightly regulated by federal law. As such, it could immediately disqualify many historic or long-running studies—especially those documenting the dangers of pesticides or air pollution—as the researchers who ran those studies never secured their subjects' permission to openly reveal their medical data. Under federal law, scientists can face criminal penalties if they publish confidential medical information about someone without first securing their permission.

Both environmental groups and anti-regulation activists said the rule would utterly transform the EPA's mission in ways that would outlast this administration. The proposal "may be the most consequential decision made by EPA since the

election of Donald Trump," said Joseph Bast, the director of the Heartland Institute, a conservative think tank that rejects the mainstream scientific consensus about climate change, in a statement.

"The science that we use is going to be transparent, it's going to be reproducible," Pruitt said after signing the proposal. "It's going to be able to be analyzed by those in the marketplace, and those that watch what we do can make informed decisions about whether we've drawn the proper conclusions or not."

"This is not a policy. This is not a memo. This is a proposed rule," he added, implying that future administrations will not be able to reverse the measure once it is finalized. Before it becomes a rule though, it's likely to become a lawsuit—numerous environmental groups have already promised to fight the rule in court. And the way its written, many say, makes it unlikely to stand up to such scrutiny.

To support the measure, the EPA cites a large, nonpartisan literature of recommendations about science in government. An agency statement bragged that the rule "is consistent with" two bipartisan reports in particular: one from the Administrative Conference of the United States, and one from the Bipartisan Policy Center.

Wendy Wagner, a law professor at the University of Texas, knows both of those reports well. In fact, she wrote them. Wagner was the sole author of the Administrative Conference report, and she served on the seven-author panel that produced the Bipartisan Policy Center's recommendations.

She said the proposed rule had nothing to do with her and her colleagues' work.

"I really don't know what the problem is that they think they're fixing," she said, adding that many of her co-authors "would laugh and hoot" at some of the scientific ideas expressed in the rule.

"They don't adopt any of our recommendations, and they go in a direction that's completely opposite, completely different," she told me after reading the rule. "They don't adopt any of the recommendations of any of the sources they cite. I'm not sure why they cited them."

Other legal scholars were unsparing in their criticism of the rule. "There's so many different issues with it that it's hard to know where to begin," said Sean Hecht, a professor of environmental law and policy at UCLA. "Reading the rule, it doesn't look like a proposal that has been strongly vetted by career lawyers."

"To anyone who's looked at a lot of EPA rules, this rulemaking is extraordinary in the lack of reference to any legal authority," he said.

Betsy Southerland, a former director in the EPA's Office of Water and a 30-year veteran of the agency, told me that the rule did not legally seem like a rule at all. At one point, the agency asks the public to comment on which Congressional laws give it the greatest authority to issue the rule. "That's a stunner," she said.

"The proposed rule is very sloppily drafted, to be sure," said Wagner. "It's very hard to know what they're talking about, why they're doing it, how they're doing it, why and where they see it applying —it's very mysterious. As a legal matter, that's not going to help."

The new rule also appears to invent entirely new terms in environmental law. One phrase—"pivotal regulatory science"—frequently appears throughout the proposed rule. The term seems to be completely novel: It does not appear anywhere else in the laws, rules, or court decisions that govern the EPA, Hecht said. According to Google, that exact phrase hasn't even appeared on the internet before.

"It's relatively rare for an agency to make up a term out of whole cloth and try to insert it into the law," said Hecht.

Wagner said she was "very, very confused" by that and other phrases in the law. Even though the rule is explicitly about "research data," the rule does not define that term, she said.

She worried that the rule was drafted ambiguously on purpose. "A sinister answer is that the ambiguity gives litigants more points to hold the agency up in court. Every single term is an attachment point," she said, meaning that a company suing the EPA can seize on the new phrase and attempt to get a court to define it.

Other aspects of the rule "seem to me to be efforts to allow rich stakeholders to 'data bomb' the agency," she said. They seemed designed to force the agency to surrender old data, she said, so that the fossil-fuel and chemical industry can run endless studies reanalyzing it, tweaking their models each time until they get the answers they want.

Just about everyone involved in the rule-making process agrees that the rule targets a specific and foundational piece of environmental science: the "Six Cities" study, from the Harvard School of Public Health. First published in 1993, the study found that Americans living in more air-polluted cities died earlier than Americans living in cleaner ones.

The killer was a specific type of air pollution: fine particulate matter smaller than 2.5 microns, which scientists call $PM_{2.5}$. Subsequent studies of human anatomy and biochemistry have backed up this finding: $PM_{2.5}$ appears to be so tiny that it can seep through the lungs and enter the bloodstream, where it weakens and inflames heart tissue, injures organ walls, and damages cell structures.

$PM_{2.5}$, in other words, appears to be exceedingly deadly. This makes it exceedingly expensive.

Every time the EPA adopts a new air or water rule, it must run a cost-benefit analysis, proving that the new rule's benefits to the public exceed its costs. Each time an American dies earlier than they otherwise would have, the EPA says their death costs the U.S. economy about $9.2 million. Since $PM_{2.5}$ kills hundreds of thousands of Americans every year, the costs of all these early deaths can quickly become overwhelming. The EPA has justified many air-pollution rules—including the Clean Power Plan, President Obama's landmark climate-change rule for the power sector—on the basis of the high cost of $PM_{2.5}$.

But it all comes back to the Six Cities study, say anti-regulation activists. While conducting the research in the 1970s and 1980s, Harvard scientists drew on hundreds of confidential medical records. These scientists say they cannot now release the underlying data to the public because doing so—even on an anonymized basis—would reveal the identity of individual patients.

But Harvard has turned over its data to third-parties and industry groups multiple times in the past. Each time, those scientists have reanalyzed the data and largely validated the results of the Six Cities study.

This isn't enough for Steven Milloy, a policy adviser at the Heartland Institute and a former coal executive. "If you have data that's really important for public health, then you ought to be willing to share it," he told me. "PM is the granddaddy of all this stuff. It's where the secret science came from."

He argues that the EPA must release the data from the Six Cities study, even though that data is controlled by Harvard University. Milloy has long fought for the HONEST Act, a law by Lamar Smith, a Republican congressman of Texas, that closely resembles the new rule.

"It's the biggest science fraud that has gone on in this country's history," he said of the Six Cities study and the larger effort to regulate $PM_{2.5}$.

He contests that $PM_{2.5}$ is not toxic at all. "I have challenged EPA for years and they have never produced a body," he said. "They've never been able to do that, not in China, not in India, not in the United States, not anywhere. China, for the last few years, has had these huge episodes of $PM_{2.5}$. No one's died."

The World Health Organization has found that ambient outdoor air pollution, including $PM_{2.5}$, killed 23 million people in China in 2012.

Milloy said that the new rule was "actually better than what I thought was coming."

"If it's actually implemented, it's going to be revolutionary for EPA science and regulatory science, period," he said. The new rule would force the agency to reshape rules on radiation, drinking water, pesticides, and air-quality issues, because much of the evidence supporting those rules is drawn from medical research using confidential patient data.

But first the rule must stand up in court. It's unclear how it will fare. On the one hand, the rule is inexactly written and disinterested in citing legal authority.

The rule also directly contradicts a 2002 ruling from the D.C. Circuit Court of Appeals. "We agree with EPA that requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary,'" the court decided in that case.

But the federal judiciary is being remade by the Trump administration. President Trump appointed 12 new appellate court judges in 2017, a record for a president's first year in office. These new, more conservative judges might find themselves more amenable to anti-regulatory arguments than their predecessors would have been.

It's possible that the rule, in any form, could outlast the EPA chief who signed it. Pruitt now faces the worst crisis of his 20-year political career: To describe him as scandal-plagued would be an understatement. He has set off a scandal pandemic. This weekend, The New York Times revealed that Pruitt personally met with a top energy lobbyist last year, even as Pruitt rented a $50-a-night condo from the lobbyist's wife. This follows revelations into alleged ethics lapses over staff pay, luxurious travel arrangements, and grift among his subordinates.

There are at least 10 different federal investigations into Pruitt's ethics scandals, including ones led by the White House and the Republican-led House Oversight Committee. Pruitt will testify before two House committees on Thursday.

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 3/19/2018 6:27:56 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: FYI - NIH policy re certificates of confidentiality

Not certain I shared this with you but it is also relevant to aspects of the HONEST ACT

Certificates of Confidentiality for NIH Funded Research

NIH awardees no longer have to apply for a CoC.

Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC. Compliance requirements are outlined in the NIH Grants Policy Statement, which is a term and condition of all NIH awards.

This policy applies to NIH funded:

- Grants
- Cooperative Agreements
- R&D Contracts
- Other Transaction Awards
- NIH's own intramural research

How do I know if my NIH funded research project is covered by a CoC?

Research in which identifiable, sensitive information is collected or used, including research that

- Meets the definition of human subjects research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that might identify a person

If your research meets any of the above criteria then your research data or information is automatically protected by a CoC from NIH.

What does having a CoC mean I need to do?

1. **Researchers with a CoC may ONLY disclose identifiable, sensitive information in the following circumstances:**
    - if required by other Federal, State, or local laws, such as for reporting of communicable diseases
    - if the subject consents; or
    - for the purposes of scientific research that is compliant with human subjects regulations
2. **AND you must ensure that anyone who is conducting research as a subawardee or receives a copy of identifiable sensitive information protected by the policy understand they are they are also subject to the disclosure restrictions, even if they are not funded directly by NIH.**

How do I document that I have a CoC for my NIH funded Research?

NIH will no longer issue a physical certificate. You may point to your Notice of Award and the NIH Grants Policy Statement as documentation of the CoC protection.

Will I ever need to extend or amend my CoC?

If your NIH-funding will or has ended but the collection of new data from research participants will continue without NIH-funding you will need to apply for a CoC for continuity of protections using the CoC application system. If your NIH funding will or has ended but your study has completed all enrollment and data collection, there is no need to extend the Certificate. Sensitive, identifiable research information maintained by investigators during any time a Certificate is in effect, is protected permanently.

Where can I learn more?

Read the 2017 NIH Certificates of Confidentiality Policy.

Have a CoC Question?

Please address your inquiries to: NIH Office of Extramural Research: NIH-CoC-Coordinator@mail.nih.gov

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Shoaff, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC16FB09CF2C44ADB34A7405DC331532-JSHOAFF]
Sent: 3/19/2018 6:15:36 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: RE: news article

Thanks Tom. Carl shared this as well:

https://www.scientificamerican.com/article/pruitt-expected-to-limit-science-used-to-make-epa-pollution-rules/

Deliberative Process / Ex. 5

John

JOHN SHOAFF | LEADER, POLICY SUPPORT GROUP
OFFICE OF AIR POLICY & PROGRAM SUPPORT (OAPPS)
OFFICE OF AIR & RADIATION | U.S. EPA | WJC NORTH 5442-B
1200 PENNSYLVANIA AVE. NW | MC 6103A | WASHINGTON, D.C. | 20460 | USA
Shoaff.john@epa.gov | 1-202-564-0531 DIRECT | 1-202-257-1755 MOBILE

From: Sinks, Tom
Sent: Monday, March 19, 2018 1:02 PM
To: Shoaff, John <Shoaff.John@epa.gov>
Subject: news article

Hi John – sharing this with you – **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

EPA: Pruitt is expected to restrict science. Here's what it means Climatewire

U.S. EPA chief Scott Pruitt is expected to roll out plans soon to restrict the agency's use of science in rulemakings, pitting him against critics who say it would threaten public health and environmental protections.

In a closed-door meeting at the Heritage Foundation on Monday, Pruitt told a group of conservatives that he has plans for additional science reform at the agency, according to multiple attendees. EPA hasn't formally shared details of the plan, but it's widely expected to resemble an effort that Republican lawmakers and conservative groups have been pushing for years. It's been met with staunch resistance from Democrats and many scientists.

The plan could come "sooner rather than later," said Steve Milloy, who served on Trump's EPA transition team and attended the meeting at the Heritage Foundation.

EPA did not respond to a request for comment. And Milloy cautioned that he did not know the specifics of the plan and said he was not authorized to discuss the meeting.

The initiative is expected to require EPA — when issuing rules — to rely only on scientific studies where the underlying data are made public. It's an idea that House Science, Space and Technology Chairman Lamar Smith (R-Texas) has been championing for years. He and others argue that EPA has been crafting regulations based on "secret science" to advance its regulatory agenda.

Smith, one of the leading opponents of mainstream climate science in Congress, has repeatedly accused federal climate scientists of engaging in a massive conspiracy to falsify climate data. And he has repeatedly introduced bills that would require EPA to publicize data it uses when crafting regulations.

Those efforts died when President Obama was in the White House, and Smith's newest legislative push doesn't appear to be moving even though Republicans control both chambers of Congress. The House passed a bill dubbed the "Honest and Open New EPA Science Treatment (HONEST) Act" — requiring that EPA rules be based on science for which

underlying data is publicly available and reproducible — last March. But the measure has gone nowhere since it was referred to the Senate Environment and Public Works Committee.

Smith has tried to push the idea elsewhere, too. In comments on the 2019 budget proposal, the GOP majority on the Science panel led by Smith suggested that EPA's funding should be contingent on the administrator's "requiring that all scientific and technical information and data relied on to support a risk, exposure, or hazard assessment; criteria document; standard; limitation; regulation; regulatory impact analysis; or guidance issued by the EPA is made publicly available."

Smith did not respond to a request for comment.

Critics on the left and in the scientific community see the effort as an attempt to hinder EPA from issuing rules.

"A lot of the data that EPA uses to protect public health and ensure that we have clean air and clean water relies on data that cannot be publicly released," said Yogin Kothari with the Union of Concerned Scientists.

Many scientific studies rely on data that can't be made public for reasons like patient privacy concerns or industry confidentiality.

"If EPA doesn't have data to move forward with a public protection for a safeguard, it doesn't have to do that at all," said Kothari. "It really hamstrings the ability of the EPA to do anything, to fulfill its mission."

Publishing raw data also opens scientists up to attacks from industry, which can twist or distort data to shape a deregulatory agenda, said Betsy Southerland, a former senior EPA official in the Office of Water who worked on a staff analysis of the "HONEST Act."

Southerland, who left EPA last summer, said the effort is deceptive and is not about transparency, but about sidelining peer-reviewed science that supports regulation of pollution. She said there are numerous examples of groundbreaking studies that are not replicable, such as human health studies after the dropping of atomic bombs in Hiroshima or the ecological effects of the BP PLC Gulf of Mexico oil spill. In many of the older studies, there are a plethora of people, including some who are dead, who could no longer be tracked down.

"This is just done to paralyze rulemaking," she said. "It's another obstacle that would make it so hard and so difficult to go forward with rulemaking that in the end, the only thing that would happen — in the best case you would greatly delay rulemaking; in the worst case you would just prevent it. It would be such an obstacle you couldn't overcome it."

Publicizing the data in some EPA actions, which often come after years of research, could be extensive. For example, risk assessments for certain chemicals sometimes cite hundreds or even thousands of studies, all of which would have to be tracked down for data collection, according to the EPA analysis of the "HONEST Act."

Requiring data transparency would cost hundreds of millions of dollars because it would require EPA staff to track down data from study authors and create an online management system to store and present those data, the analysis found. In addition, EPA staff would have to spend time redacting personally identifiable information in the studies, and study authors would likely require payments for preparing and sending their data.

EPA career staff estimated that Smith's legislation would add $250 million in costs annually for the first few years after it was implemented, Southerland said. That estimate was dismissed by senior EPA officials who said those costs were inflated and that the agency would not use many studies to which the rule would apply, but they did not provide evidence, she said. EPA's **analysis** of Smith's bill was published by the radio program "Marketplace."

Milloy, who has long pushed for EPA to stop issuing regulations unless the underlying scientific data are made public, said the science reform effort could be done through a directive, in the same way that Pruitt reshaped EPA's science advisory panels.

The overhaul of those committees is another area where Pruitt came through on one of Smith's longtime priorities.

In October, Smith was seated front and center at an event where Pruitt announced that he would reform the advisory panels to bar researchers who take government funding. Critics said that move skewed the advice EPA is getting by making it tough for researchers who rely on public funding to participate, but keeping industry-funded scientists on board.

Pruitt then appointed as science advisers a number of researchers whose work is funded by industry, energy lobbying groups and conservative think tanks, while forcing out academics from major research institutions.

"Pruitt did a great job in cleaning up the science advisory boards, and if he does that kind of work on this, that's fantastic," Milloy said of the expected science data reform effort. "My goal is to make sure EPA does not rely on scientific studies unless the data is made available for replication by somebody."

Kothari of the Union of Concerned Scientists called it "alarming" that the Trump administration's science agenda "is being run by the chairman of the Science Committee, given that he has continued to not care about how science informs policymaking."

"This is the second thing now that this administrator will be implementing based on legislation that was never enacted," Kothari said. "It's just another excuse for Pruitt's EPA to really abrogate EPA's responsibility to protect human health and the environment."

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/24/2018 6:28:42 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: Record - Honor Act NPRM

Personal Matters / Ex. 6

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 Personal Matters / Ex. 6
email: sinks.tom@epa.gov

Message

From: Hawkins, CherylA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D917BEE23E774E0DBB05CE06D694985E-HAWKINS, CHERYLA]
Sent: 5/18/2018 6:43:42 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
CC: Anand Mudambi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a94638932b49af8a6cf581262d5059-Mudambi, Anand]; Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]
Subject: Response letters and emails for CMS items
Attachments: Response letters and emails 05182018.docx; 18-000-6993.pdf; 18-000-7134.pdf; 18-000-7322.pdf; 18-000-7423_2.pdf; 18-000-7325.pdf; 18-000-7383.pdf; 18-000-7309.pdf; 18-000-7154.pdf; 18-000-7155.pdf; 18-000-7159.pdf

Hi Tom,

Attached is a file with the response letters and email for CMS items AX-18-000-7159, AX-18-000-7309, AX-18-000-7322, AX-18-000-7325, AX-18-000-7383, AX-18-000-6993, AX-18-000-7134, AX-18-000-7154, AX-18-000-7155, and AX-18-000-7423. I've also attached all of the CMS files in case you want to see them.

I believe the first letter in the file can be printed, signed by you and sent. All of the other letters and the emails should be held until the FRN for the public comment period extension and public hearing is posted since these CMS included requests for extension of the comment period and a public hearing. I will need to add the url for the new FRN to these letters once it is posted.

I ask that you take a quick look at the response letters and email file, let me know if he is okay with the additional language for the new FRN and then I'll work with Thomas to get the letters sent out.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

Response letter for Control Number AX-18-000-7159

Ms. Cynthia Winfield
4650 Chicken Road
Lebanon, TN 37090

Dear Ms. Winfield,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-6993

Robert Gropp, Ph.D.
Co-Executive Director
American Institute of Biological Sciences
1201 New York Avenue, NW
Suite 420
Washington, DC 20005

Dear Dr. Gropp,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public hearing will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7134

Harold Wimmer
National President and CEO
American Lung Association
1201 New York Avenue, NW
Suite 420
Washington, DC 20005

Dear Mr. Wimmer,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public hearing will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7154

Paul J. Miller
Deputy Director and Chief Scientist
NESCAUM
89 South Street, Suite 602
Boston, MA 02111

Dear Mr. Miller,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public hearing will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7155

Nat Mund
Director of Federal Affairs
Southern Environmental Law Center
601 West Rosemary Street, Suite 220
Chapel Hill, NC 27516-2356

Dear Mr. Mund,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public hearing will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response letter for Control Number AX-18-000-7423

Ruth Greenspan Bell and Michelle Roos
Environmental Protection Network
3100 Ellicott Street, NW
Washington, DC 20008

Dear Mses. Bell and Roos,

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science," available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been submitted to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public hearing will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Response email for Control Numbers AX-18-000-7309, AX-18-000-7322, AX-18-000-7325, AX-18-000-7383

Thank you for your comments regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science" available at https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science.

Your comments have been forwarded to Docket ID No. EPA-HQ-OA-2018-0259 at Regulations.gov. Please submit any future comments to https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

With regard to your request for an extension of the comment period and a public hearing, the comment period has been extended to July 30, 2018, and a public comment will be held on July 17, 2018. Further details can be found at (link to new FRN).

Sincerely,
Tom Sinks, Ph.D.
Director, Office of the Science Advisor

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/26/2018 4:10:21 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: Strengthening Transparency in Regulatory Scence.TSanalysis.04252018.docx
Attachments: Strengthening Transparency in Regulatory Scence.TSanalysis.04252018.docx

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/25/2018 5:41:53 PM
To: Maxfield, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=26348f1a495d4f149d8e3a3999f01dbb-Maxfield, Robert]
Subject: RE: SIGNED: Strengthening Transparency in Regulatory Science

Bob – the only thing I have to share is the rule which I received yesterday at 4pm.

From: Maxfield, Robert
Sent: Wednesday, April 25, 2018 9:09 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: RE: SIGNED: Strengthening Transparency in Regulatory Science

Tom –

I have a general understanding of the implications were this proposal to go forward. Do you have an analysis with some detail that you could share?

Rob Maxfield
Science Advisor
EPA new England

From: Sinks, Tom
Sent: Wednesday, April 25, 2018 8:10 AM
To: STPC Members <STPC_Members@epa.gov>; STPC_SSP <STPC_SSP@epa.gov>
Cc: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

Yesterday today Administrator Pruitt announced this proposed rule. The proposed rule touches upon three aspects of OSA work – public access to EPA funded research, human subjects research protection, and scientific integrity. It has highly significant implications for EPA programs and regions in defining how access to research data is used in rulemaking.

I presume it will be released in the Federal Register shortly. The proposed rule seeks comments and I suspect your state, local, academic, industry, and NGO partners will be interested. Please feel free to distribute it to them.

From: Orme-Zavaleta, Jennifer
Sent: Tuesday, April 24, 2018 4:01 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; ORD-Exec-Council-Directors <Execcouncildirectors@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan

<bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/25/2018 12:45:03 PM
To: Personal Email / Ex. 6
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: Public access to data and regulatory rulemaking
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

Hi Doug – I'm still waiting to get a + response from the CDC Vietnam office. My contact has moved on and the current director has not responded to me.

Meanwhile, I thought this might interest you. The Administrator released it yesterday. It is based on the House 2016 HONEST Act which the Senate would not take up. Don't know if you are interested in commenting or sharing with others but your expertise in causality and the underlying thesis that public access and reanalysis of a dataset = quality = causation is an interesting concept.

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Doa, Maria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99E502A905374B0B890DB9B22E18D92E-MDOA02]
Sent: 9/5/2018 3:24:02 PM
To: Shao, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36641c9d93784a1899d4e3640f8c6ac3-Shao, nicole]; Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Vallero, Dan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338898e9462940748baa103863a000c7-Vallero, Dan]; Wade, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cd67598ea624da8bfd1b53bdfb4e9d4-Wade, Timothy J.]; Nelson, Daniel K. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9bd641d949d4a96b2d6c307be288afa-Nelson, Dan]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Updike, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920571ed9264c93b7bc670b0a498d04-Updike, David]; Noel, Glenda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4b623a1613b46af874225422c979326-Noel, Glenda]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]
CC: Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]
Subject: RE: ORD Team on Strengthening Transparency in Regulatory Science
Attachments: Strengthening Transparency in Regulatory Science presentation v4.pptx

Hi All,

Thanks for participating on the call. Attached is the power point presentation I mentioned. I will follow-up with you all on the status once Jennifer is able to meet with the Acting Administrator on this rulemaking and I get some feedback on their discussion.

Thanks,
Maria

Maria J. Doa, Ph.D.
Office of Science Policy
Office of Research and Development
Environmental Protection Agency
Tel. 202.566.0718

-----Original Appointment-----
From: Doa, Maria
Sent: Wednesday, August 22, 2018 4:56 PM
To: Doa, Maria; Shao, Nicole; Flowers, Lynn; Bussard, David; Vallero, Dan; Wade, Tim; Nelson, Daniel K.; Sinks, Tom; Updike, David; Noel, Glenda; Vandenberg, John
Cc: Teichman, Kevin
Subject: ORD Team on Strengthening Transparency in Regulatory Science
When: Wednesday, September 05, 2018 10:15 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB51161

Personal Matters / Ex. 6

Message

From: Joanne O'Loughlin [joloughlin@scainc.com]
Sent: 8/29/2018 2:47:29 PM
To: Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
CC: Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]
Subject: Follow-Up Items From This AM Meeting (Strengthening Transparency Rule) - EDF Base Comment Letter Attached/FDMS Draft/Metadata Ready Comment Assessment
Attachments: EDF Primary Comment.pdf

As promised:

Follow-Up SC&A Action Items

EDF Base Letter:

Maria, I have attached the EDF base letter - without attachments. I have not assessed all "parts" or "attachments" (or even seen them), but this represents 193 pages of targeted comments.

FDMS Assessment:

Tom, I assessed "Draft" and "Metadata Ready" comments. Although the "received" date indicated a date after the August 16 deadline in many cases, when I open these letters, all of them pre-dated the deadline date (some were even from July-mailed (postmarked)/e-mailed)).

Regards,

Joanne O'Loughlin
Environmental Scientist
1414 Raleigh Road, Suite 450
Chapel Hill, North Carolina 27517
(984) 234-3970
joloughlin@scainc.com
www.scainc.com

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 8/22/2018 2:48:43 PM
To: Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: + selected comments
Attachments: Comment (1).pdf; ACC Comments on Strengthening Transparency in Regulatory Science Comment Final 2018 08 16.pdf; ASDWA Comments on Regulatory Transparency 08152018 Final.docx; Letter to EPA re proposed science rule.pdf; 2018.08.15 Comment Letter re Transparency in Science (FINAL FOR FILING).pdf; Coons_Comment_EPA_Transparency_Rule.pdf; Comment.pdf; Comment.pdf

Maria here are some additional selected comments you might consider posting on the share point site. I'm not adept enough with pdf to know how to rename them so they often have the title "comment" which isn't very helpful. But this is what they include listed in order …

Chlorine Institute
ACC
ASDWA
UCS
Landry et al (11 attorneys general letter – this one includes a lot of references related to the reproducibility crisis)
Senate letter
AWWA
Underwood et al (6 attorney generals letter – there is also a letter from a scientists who works for the NY state AG but I did not attach).

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/24/2018 3:17:10 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: FW: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Sent this message as a bcc to those who contacted me directly about the status of an extension. (Sean Reilly E&E news; Katie Foreman ACWA-us.org; Christina Franz – ACC; and Ray McAllister Crop Life)

From: Sinks, Tom
Sent: Thursday, May 24, 2018 11:12 AM
Cc: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

From: EPA Press Office [mailto:press=epa.gov@cmail20.com] **On Behalf Of** EPA Press Office
Sent: Thursday, May 24, 2018 8:00 AM
To: Kuhn, Kevin <Kuhn.Kevin@epa.gov>
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now

close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

Visit The EPA's Newsroom

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/15/2018 1:49:24 PM
To: Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: RE: Website Help for Public Hearing
Attachments: FRN extension and hearing 5.10.18_.docx; FR Notice_Strengthening Transparency extension and hearing example.docx

Deliberative Process / Ex. 5 Looks like the best day for the hearing will be July 24th

From: Hubbard, Carolyn
Sent: Tuesday, May 15, 2018 9:17 AM
To: Dearie, Jessica <Dearie.Jessica@epa.gov>; Kapuscinski, Jacques <Kapuscinski.Jacques@epa.gov>
Cc: Kumar, Manisha <Kumar.Manisha@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Subject: Website Help for Public Hearing

Hi Jessica and Jacques,

We are likely going to be holding a public hearing for the Strengthening Transparency in Regulatory Science rule, and we are going to need a webpage were people can go to sign up for time slots to speak at the hearing. We are going to need to get this set up pretty quickly. Jessica, I know you've helped us before with creating sign up forms online. I don't know if we would use Eventbrite or something else for registration, or if we can just do it via a webform.

Would the two of you be able to assist? I'm copying Manisha Kumar in OSA- she is the EIC for the webpage where this will live and can help get this posted. I'm also copying Fred and Tom and Susan who are all lucky members of this team. The webpage is here-

https://www.epa.gov/osa/strengthening-transparency-regulatory-science

Thanks!

Carolyn

Carolyn Hubbard
Communications Director
EPA Office of Research and Development
202-564-2189
202-379-6744

Message

From: Sean Reilly [sreilly@eenews.net]
Sent: 5/24/2018 3:00:46 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: RE: Reported extension of public comment period on proposed rule re "Strengthening Transparency in Regulatory Science"

Understood, Dr. Sinks; thanks for following up.

Sean

Sean Reilly
Reporter
E&E News
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EnergyWire, ClimateWire, E&E Daily, Greenwire, E&ENews PM

From: Sinks, Tom <Sinks.Tom@epa.gov>
Sent: Thursday, May 24, 2018 10:59 AM
To: Sean Reilly <sreilly@eenews.net>
Subject: RE: Reported extension of public comment period on proposed rule re "Strengthening Transparency in Regulatory Science"

Sean – I did not want to get ahead of the official announcement …

Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments

on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

From: Sean Reilly [mailto:sreilly@eenews.net]
Sent: Wednesday, May 23, 2018 1:15 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: Reported extension of public comment period on proposed rule re "Strengthening Transparency in Regulatory Science"

Dr. Sinks:

Just wanted to check on a report I've received that EPA will extend the comment period from May 30 to Aug. 16, accompanied by at least one public hearing. Is that correct? (I've reached out to EPA's press office, but have thus far gotten no response and am simply trying to confirm that this information is accurate.)
Thank you in advance for your assistance.

Regards,
Sean Reilly

Reporter
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Twitter: @SeanatGreenwire

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122 C Street, NW, Suite 722, Washington, DC 20001
www.eenews.net • www.eenews.tv
EnergyWire, ClimateWire, E&E Daily, Greenwire, E&ENews PM

Message

From: Hubbard, Carolyn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2A93CE3245494318B109E87F7D826284-HUBBARD, CAROLYN]
Sent: 5/24/2018 2:41:18 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: FW: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Carolyn Hubbard
Communications Director
EPA Office of Research and Development
Personal Matters / Ex. 6

From: Kuhn, Kevin
Sent: Thursday, May 24, 2018 8:25 AM
To: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Christian, Megan <Christian.Megan@epa.gov>
Subject: FW: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Press release is out.

Kevin Kuhn
ORD/EPA
(202) 564-4835
Mobile: Personal Matters / Ex. 6

From: EPA Press Office [mailto:press=epa.gov@cmail20.com] **On Behalf Of** EPA Press Office
Sent: Thursday, May 24, 2018 8:00 AM
To: Kuhn, Kevin <Kuhn.Kevin@epa.gov>
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

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While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

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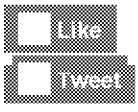

U.S. Environmental Protection Agency
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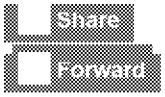
Washington, D.C. 20004



Message

From: Hawkins, CherylA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D917BEE23E774E0DBB05CE06D694985E-HAWKINS, CHERYLA]
Sent: 5/17/2018 8:45:54 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Kumar, Manisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497133a6697a45f9bea221a07f4359f6-Kumar, Mani]
CC: Sheppard, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63186a03f8e14015ba94b59c699363fc-Sheppard, Tracy]; Susanke, Greg [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fcc7f89d47a479abd2ac7cedc46a224-Susanke, Greg]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]; Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]
Subject: RE: new FRN and website registration
Attachments: FRL-9978-31-Science Transparency draft FRN extension and hearing.docx

Attached is the edited FRN.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Sinks, Tom
Sent: Thursday, May 17, 2018 4:43 PM
To: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Kumar, Manisha <Kumar.Manisha@epa.gov>
Cc: Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Susanke, Greg <Susanke.Greg@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>; Greene, Mary <greene.mary@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Cawiezell, Thomas <Cawiezell.Thomas@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: new FRN and website registration

We made the edits for the FRN that announces the public hearing on the rule. Cheryl will send Manisha and Carolyn the document tomorrow to help you complete the registration sign-up site.

FYI - Greg is coming in tomorrow to complete the package in ORD and send it to the FRN office. I assume they will get it tomorrow or Monday. Once it leaves EPA, I believe it takes 5 days to publish in the FRN. The registrations site will need to be ready to launch the day before the FRN is published and go live the morning of the publication.

Personal Matters / Ex. 6

Thanks everyone for the help ☺

Thomas Sinks, Ph.D.

Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 Personal Matters / Ex. 6
email: sinks.tom@epa.

Message

From: Staff_OSA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BE69B6688A614CA39759D52CA5716EF3-OSA]
Sent: 9/5/2018 1:45:50 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]
Subject: FW: Articles to Include in the Record for the "Strengthening Transparency in Regulatory Science" Proposed Rule
Attachments: Schwartz 2018 Transparency as Mask.pdf; Ref 1 - Curtis et al 2006 Spatial Confidentiality and GIS.pdf; Ref 3 - Sweeney et al 2017 Re-identification Risks in HIPAA Safe Harbor Data.pdf; Ref 4 - Pinault et al 2016 Risk Estimates of Mortality.pdf; Ref 5 - Vodonos et al 2018 Concentration-Response Between Long-term PM25 Exposure and Mortality.pdf

FYI

I'm going to forward the message to the docket manager and ask that it be included.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Tyler Smith [mailto:tsmith@earthjustice.org]
Sent: Tuesday, September 04, 2018 12:20 PM
To: Staff_OSA <Staff_OSA@epa.gov>
Cc: Carrie Apfel <capfel@earthjustice.org>
Subject: Articles to Include in the Record for the "Strengthening Transparency in Regulatory Science" Proposed Rule

Dear Dr. Sinks,

Attached please find an article on EPA's "Strengthening Transparency in Regulatory Science" proposed rule that was published in the New England Journal of Medicine (NEJM) on August 29, 2018, as well as several articles referenced by the first article. All of the attached documents should be included in the administrative record for the rulemaking.

We understand that the comment period on the proposed rule officially closed on August 16, 2018. As this article was published by the NEJM on August 29, however, it could not have been submitted before the comment period closed. Therefore, we are providing the article and the articles it references to the EPA now, less than three weeks after the comment period closed, which should provide a sufficient amount of time for the EPA to consider them as the Agency decides whether and how to move forward on this proposal.

Please confirm that the attached documents will be included in the record. I am happy to answer any questions.

Best regards,
Tyler Smith

Tyler Smith, MPH
Staff Scientist
Sustainable Food & Farming

48 Wall Street, 19th Floor
New York, New York 10005
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earthjustice.org

International Journal of Health Geographics

BioMed Central

Methodology

Open Access

Spatial confidentiality and GIS: re-engineering mortality locations from published maps about Hurricane Katrina

Andrew J Curtis*[1], Jacqueline W Mills[2] and Michael Leitner[1]

Address: [1]World Health Organization Collaborating Center for Remote Sensing and GIS for Public Health, Department of Geography and Anthropology, Louisiana State University, Baton Rouge, USA and [2]LSU GIS Clearinghouse Cooperative, Disaster Science Management Louisiana State University, Baton Rouge, USA

Email: Andrew J Curtis* - acurti1@lsu.edu; Jacqueline W Mills - jmills5@lsu.edu; Michael Leitner - mleitne@lsu.edu

* Corresponding author

Published: 10 October 2006

International Journal of Health Geographics 2006, **5**:44 doi:10.1186/1476-072X-5-44

Received: 16 August 2006
Accepted: 10 October 2006

This article is available from: http://www.ij-healthgeographics.com/content/5/1/44

Abstract

Background: Geographic Information Systems (GIS) can provide valuable insight into patterns of human activity. Online spatial display applications, such as Google Earth, can democratise this information by disseminating it to the general public. Although this is a generally positive advance for society, there is a legitimate concern involving the disclosure of confidential information through spatial display. Although guidelines exist for aggregated data, little has been written concerning the display of point level information. The concern is that a map containing points representing cases of cancer or an infectious disease, could be re-engineered back to identify an actual residence. This risk is investigated using point mortality locations from Hurricane Katrina re-engineered from a map published in the Baton Rouge Advocate newspaper, and a field team validating these residences using search and rescue building markings.

Results: We show that the residence of an individual, visualized as a generalized point covering approximately one and half city blocks on a map, can be re-engineered back to identify the actual house location, or at least a close neighbour, even if the map contains little spatial reference information. The degree of re-engineering success is also shown to depend on the urban characteristic of the neighborhood.

Conclusion: The results in this paper suggest a need to re-evaluate current guidelines for the display of point (address level) data. Examples of other point maps displaying health data extracted from the academic literature are presented where a similar re-engineering approach might cause concern with respect to violating confidentiality. More research is also needed into the role urban structure plays in the accuracy of re-engineering. We suggest that health and spatial scientists should be proactive and suggest a series of point level spatial confidentiality guidelines before governmental decisions are made which may be reactionary toward the threat of revealing confidential information, thereby imposing draconian limits on research using a GIS.

Background

Geospatial technologies and even Internet applications such as Google Earth are now frequently used in both social and biological sciences in the search for spatial patterns and processes (for recent commentaries and examples see [1-3]). Geospatial display on the internet, such as

Google Earth, not only provides a means to publicize the importance of "geography", but also acts as a dissemination tool for spatial results. This democratisation of spatial insight can have a dramatic impact on communities without the technical ability, hardware or software to use a Geographic Information System (GIS). At a recent symposium jointly hosted by the National Institute on Drug Abuse and the Association of American Geographers [4], in the concluding discussion session the universal appreciation of GIS was obvious. However, there was also a general concern expressed about preserving individual confidentiality within spatial displays. This concern is justified as map making, and the ability to deliver maps to a mass audience through the Internet becomes steadily easier [5-8].

Most health related maps are thematic involving data aggregated to a spatial unit, the most common map type being the graduated color or "choropleth" map. In an effort to protect individuals, the Health Insurance Portability and Accountability Act (HIPAA) provides guidelines to inform researchers as how to preserve confidentiality by employing minimum spatial denominator units on a map. According to the U.S. Department of Health and Human Services (HHS) health information can only be disclosed, if all zip codes with the same three initial digits exceed 20,000 people; otherwise the initial three digits are changed to 000 [9]. This guideline can be interpreted in another way. If we (conservatively) assume each building contains approximately 4 people, then health information should not be mapped at the residential level in areas containing less than five thousand buildings. It is unfortunate, however, that little exists explicitly for data display at this point (residential) level, even though many such maps exist in the academic literature. Examples of these health related point level maps which will be briefly discussed in this paper include, the spatial association between birth outcomes and disease (Toxoplasmosis) [10], birth outcomes and residential/work proximity to the World Trade Center [11], health effects of living close to heavily trafficked routes [12] and cases of an infectious disease[13].

Among the precautions that can be taken to preserve point level confidentiality include the masking or spatial manipulation of the location [14-17], the removal of other geographic reference layers, or the use of software agents [18]. In this last example the investigator never works with point level information. A software agent acting on behalf of the investigator, can access the data server where confidential data are stored, perform the required analysis functions, and return only useful aggregate results without any individual-identifiable details to the researcher [18].

If the researcher does have access to the original data, simply removing map detail, for example a road network, may not be enough to ensure that confidentiality is preserved [16]. For example, if a residential "point" appears in the middle of a map displaying only zip code boundaries, how could this display violate any individual's confidentiality, especially if all zip codes contain at least 20,000 individuals? The problem arises if the zip code boundaries can be used to re-engineer the map data back to smaller neighbourhoods, maybe even a street or single house, and in so doing dramatically change the size of the denominator. It is only prudent to test this assumption, and attempt to re-engineer information (also called inverse or reverse address matching) back to an individual residence from an apparently "detail free" map [16]. This is especially important given how easy it is to output GIS layers and display information to a large Internet audience through geospatial packages such as Google Earth, layers which as graphics can in turn be extracted and imported back into a GIS environment.

Contributing factors in the successful re-engineering of information from a cartographic display is the published map's scale, the size (and quality) of the published map, the projection used, and the accuracy (or error) in the initial mapping of the points. An error one would expect to find between the geocoded and re-engineered address is the positional error due to the address-matching procedure. This error occurs when a list of addresses is matched to a street network layer using a GIS. The extent of this error can be calculated by comparing the location of the gecoded addresses with a second measurement, usually generated with a Global Positioning System (GPS) satellite receiver or from an aerial image. As an example of such an investigation using a random sample of 200 addresses taken from a life history project of 3286 subjects, Bonner et al. (2003) found 79% of all distances between the gecoded and the GPS point to be within 100 m, the median distance being 38 m. [19]. The same study also found that urban addresses were slightly more accurate than non-urban, with 33% of addresses being within 25 meters. The accuracy of placement also varied according to the length of the road, with longer road segments, which again tend to be found in non-urban areas, being the least accurate [19].

When using a GIS to investigate geocoding error, the accuracy of the GPS measurement should also be taken into consideration. The positional accuracy of the GPS receiver can be tested using a National Geodetic Survey (NGS) point. GPS positions are recorded by holding the unit directly over the NGS point, for which the exact location is known. Usually, more than 100 positions are recorded for the same location at equal time intervals (for example, every second). The final coordinate is then calculated as

the spatial average of all recorded positions. Positional data can be used uncorrected or differentially corrected with data from a nearby base station. Differentially corrected positions have a higher accuracy compared to uncorrected positions. Listi, et al. (2007) tested the positional accuracy of the GeoExplorer® 3 Data Collection System (a hand-held GPS receiver in the mid-price range) from Trimble Navigation Limited for field mapping scattered human remains or other materials in forensic investigations. Using the spatial average of 206 positions and without any differential correction, the GPS unit produced an error of 3.523 meters (approx. 11.62 feet). In contrast, post-processed differential correction for the same spatial average of 206 positions produced an error of 0.424 meters (approx. 1.4 feet))[20]. Other considerations when using a GPS to confirm geocode accuracy include where the measurement was taken (for example the property line or front door), the position of the satellites, atmospheric conditions, and the line-of-sight to the satellites, which can be interrupted by tree cover, buildings or other structures.

As an alternative measure of geocode accuracy, Cayo and Talbot (2003) determined the positional error for 3,000 residential addresses using the distance between each geocoded point and its true location as determined with aerial imagery [21]. They found error increased as population density decreased and that the geocoding error substantially decreased, when property data are used instead of street network files. Both GPS and aerial imagery will be used in this paper to verify re-engineered addresses.

The question posed in this paper is to what degree can confidential information in the form of a person's home residence be extracted, or "re-engineered" from a map appearing in a journal article, book, newspaper or Internet site, especially if most traditional spatial reference layers, such as road networks, are removed from the map? In order to investigate this question two experiments could have been designed. The first would have been to fabricate data that are then geocoded, mapped, and printed before being given to a second team as a hard copy for re-engineering. First (fabricated) and second (re-engineered) addresses could be compared for separating distance (see [22]for an example). This is a valuable line of inquiry because of the insights it might provide not only in terms of the violation of confidentiality, but also in how the underlying population structure, street type, and building patterns impact the process of re-engineering. In his experiment Armstrong (2002) found that 68% of addresses could be re-engineered to the correct residence, 85% to the immediate neighbour, and 97% to the correct street segment [16]. He goes on to comment that errors in the geocode process would always leave an element of doubt in this type of exercise as the accuracy (was it the "correct" house) would be fuzzy. The second approach, and the one employed in this paper, is to take an actual published map of confidential residential information, and re-engineer these data back to actual addresses. This approach is the most appealing as it approximates the danger posed by spatially representing confidential information, and having a third party with no access to the actual data attempting to identify the residence of the "case". Although the second approach is most appealing, it is, by definition, almost impossible to investigate. If the data being mapped are confidential, how would the field researcher know if he/she had discovered the actual residence? However, Hurricane Katrina provided such an opportunity as a published map displayed point locations of deaths, and the search and rescue notations spray-painted on the houses allowed field teams to verify the accuracy of the re-engineering process. These markings also provide the means to identify the correct address missing in the Armstrong study. Figure 1 shows a field team member standing in front of a typical destroyed house using a GPS to mark the location. The search and rescue markings can be seen on both the roof and wall of the building. These markings can be deciphered as follows: the search team affiliation (left side of the X), the date of visit (top of the X), any "additional" information such as signs of looting or whether animals were present (right side of the X), and if any corpses were discovered (bottom of the X). It was therefore possible to identify those houses where fatalities had been discovered if a "1" or greater number was marked at the bottom of the "X". In addition, other markings are associated with mortalities, including comments such as "1 DB in back" or "Ken" which identifies the recovery team most frequently tasked to remove the body. In Figure 1 the first search and rescue team identified a dead body on September 11th ("1 dead" appears at the bottom of the X), and the body was removed on September 19th.

The Baton Rouge *Advocate* printed a map of mortality locations in Orleans and St Bernard Parishes on the 30th December 2005 (Fig 2). This map contained neighborhood areas of New Orleans (for example the Garden District, Lower Ninth Ward) and important features of the disaster, including the location of levee breaks, canals and floodwalls. The mortality locations were overlaid on a graduated color surface of poverty rate mapped by census tract. The map contained no roads or other references points, except for a generalized location of the University of New Orleans. Three neighborhoods heavily impacted by Hurricane Katrina, but of different urban character, were chosen for this study, these being the area around the London Canal levee break, New Orleans East, which suffered flooding directly from Lake Pontchartrain's surge, and the Lower Ninth Ward which flooded as a result of the Industrial Canal break. The specific goal of this investiga-

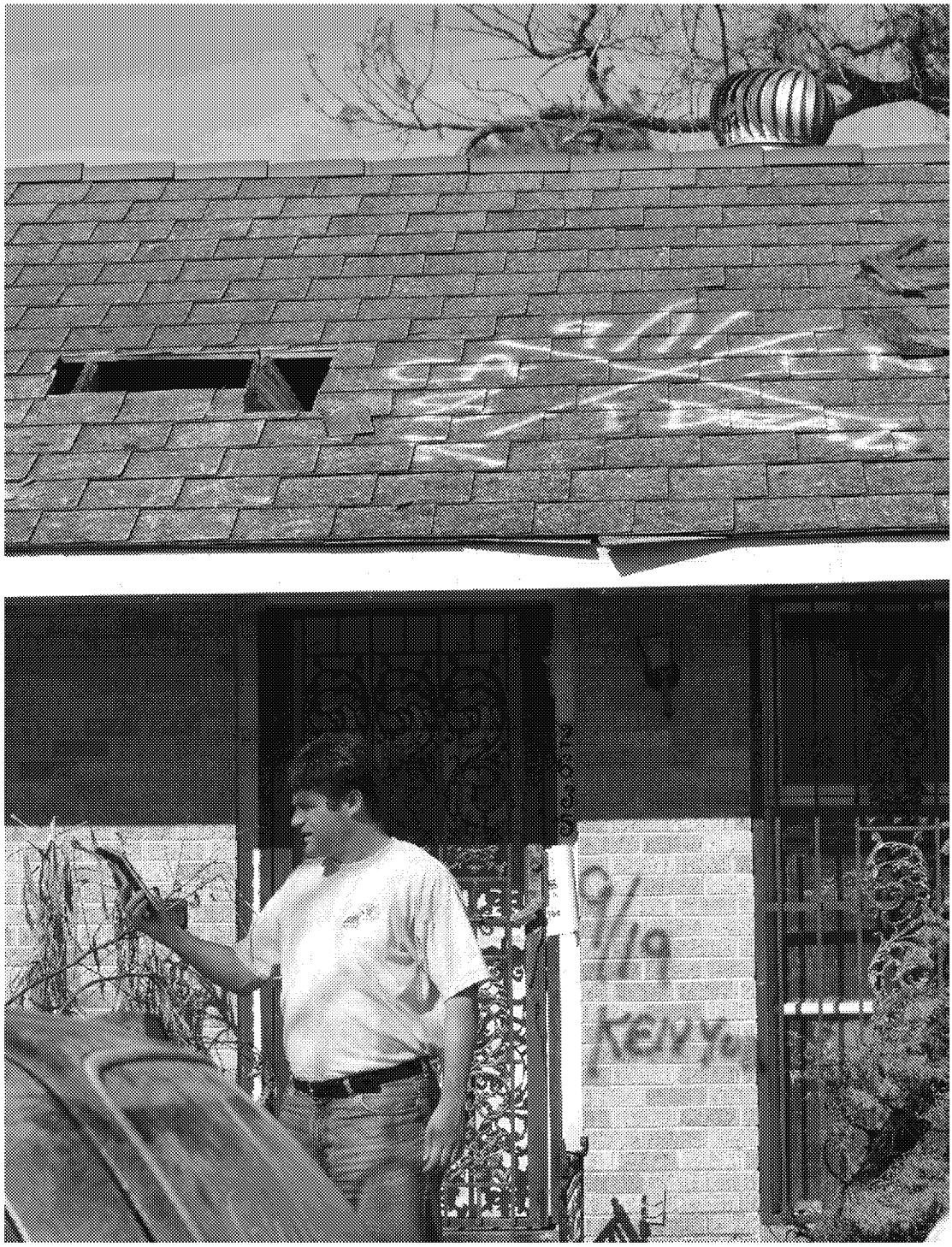

Figure 1
Hurricane Katrina search and rescue marking. This house displays the typical search and rescue "X". A California task force visited the house on September 11th and they found "1 dead". "Kenyon" removed the body on September 19th. The field team member is seen in front of the house marking its location with a GPS.

Figure 2
Deaths from Katrina map. The original map appearing in the Baton Rouge *Advocate* on December 30th. The red points are the mortality locations which have been digitised and overlaid on the original image.

tion was to use the *Advocate* map to guide field teams to the actual residence where a body was found. The larger concept was to investigate how a similar map displaying health outcomes could also be re-engineered to an actual residence. It can be argued that the *Advocate* map of mortalities does not represent a confidential surface as these data were mapped in the local paper, they are still "officially" considered such and have not been released to the authors of this paper for further validation purposes. However, this argument does not detract from the larger purpose of the study.

Results

Table One displays the distances from all mortalities re-engineered from the *Advocate* map to the closest street segment of the Orleans Parish street network. This was performed to assess the degree to which the underlying street pattern was preserved in the point locations on the map, remembering that actual streets had been removed. In total over 22% of all re-engineered mortalities were within 5 meters of a street segment. This percentage rose to over 45% when the distance from the mortality coordinate to the street was 10 meters or less. This result suggests that the original cartographer had employed a GIS based address matching approach and the underlying street pattern was still preserved within the mortality distribution. Of the three study neighborhoods investigated in this paper, the London Canal area had the greatest percentage of addresses within 5 meters (37.5%) of a road section. Although this might be indicative of the urban character of the neighborhood, with more tightly packed streets leading to a shorter distance to a road section by chance alone, the percentage of randomly generated points from 100 simulation runs in the same area within 5 meters was only 18%.

For all of Orleans Parish 18.4% of re-engineered mortalities were greater than 25 meters from a street centre line.

Table 1: Distance for re-engineered and randomly generated points to the closest road.

Distance from road (meters)	0 to 5	6 to 10	11 to 15	16 to 20	21 to 25	Above 25
New Orleans East						
Deaths From Map	16.7%	16.7%	8.3%	25.0%	8.3%	25.0%
Random Points	16.4%	12.5%	10.8%	9.4%	9.0%	42.0%
London Canal						
Deaths From Map	37.5%	4.2%	16.7%	25.0%	8.3%	4.2%
Random Points	18.0%	15.7%	13.0%	10.3%	11.0%	32.1%
Ninth Ward						
Deaths From Map	19.4%	27.8%	16.7%	11.1%	8.3%	16.7%
Random Points	19.6%	18.0%	14.9%	11.8%	10.0%	25.9%
All Deaths From Map (Orleans Parish)	22.5%	23.0%	14.1%	13.6%	8.4%	18.4%

Of the three study neighborhoods, the area with the highest percentage of (poorly) re-engineered mortalities falling in this 25-meter category was New Orleans East (25%), with the smallest percentage being the London Canal area (4.2%). When considering the randomly generated points falling into this greater than 25-meter category, all three neighborhoods registered higher percentages, ranging from 42% in New Orleans East to 25.9% in the Lower Ninth Ward. This shows how the underlying street pattern was still preserved in the mapped mortality surface.

Of the 24 mortalities re-engineered from the *Advocate* map in New Orleans East, 16 were identified to actual houses by the field team. Around these 16 houses a further eight residences were also sprayed with mortality markings. These additional residences were so close to the re-engineered location so as to fall within the "mortality circle" which covered approximately one-and-half-city blocks (Fig 3). The "mortality circle" is the white dot displaying the death location on the *Advocate* map. Of the 20 mortalities re-engineered from the *Advocate* map in the London Canal area, 14 were identified by the field team. Around these 14 houses a further two residences also could be identified with mortality markings. Of the 36 mortalities re-engineered from the *Advocate* map in the Lower Ninth Ward, 22 were identified by the field team. Around these 22 houses a further four residences could also be identified with mortality markings.

Table Two displays distances between the re-engineered mortalities and the closest field verified residences. The percentage of verified residences falling into each category of 5-meter increments is displayed. Of the three neighborhoods, New Orleans East produced the highest percentage of close distances between the re-engineered mortality and the actual residence "pairs" with almost 23% being within 10 meters, and over 40% being within 20 meters. By comparison, only 6% of the pairs for the London Canal, and 23% for the Lower Ninth Ward were within 20 meters.

As previously mentioned in this paper, there is an element of uncertainty concerning any exact distance measurement due to variations in both geocoding and GPS data collection. Therefore a second measure, the number of actual houses separating the re-engineered mortality and the field verified residence, as identified on the aerial imagery, was recorded. In three instances for New Orleans East both the re-engineered mortality and the field verified residence fell on the same house. In addition, three further pairs were separated only by the distance of the

Table 2: Distance between re-engineered and field verified residences.

Distance in meters	0 to 5	6 to 10	11 to 15	16 to 20	21 to 25	Above 25
New Orleans East						
Percentage of matched	4.5	18.2	13.6	4.5	4.5	54.5
London Canal						
Percentage of matched	0	6.3	0	0	6.3	87.5
Ninth Ward						
Percentage of matched	0	0	19.2	3.8	7.7	69.2

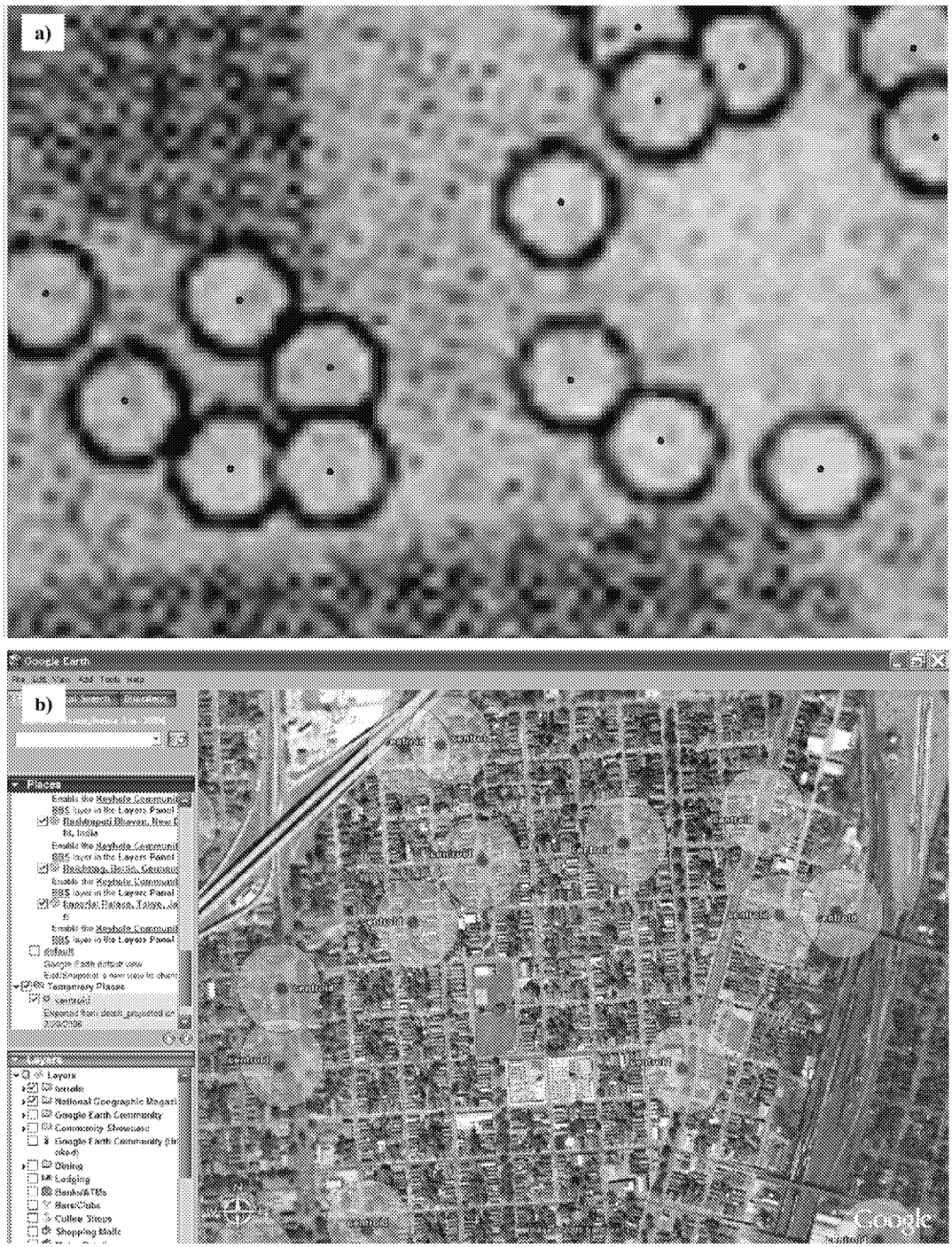

Figure 3
Digitised mortality locations. Mortality locations have been digitised from the newspaper map and are shown in terms of the coarseness of the original map image (a), and on a Google Earth display using the kmler tool in ArcMap (b). Each circle covers approximately 1.5 city blocks.

Figure 4
Distances between re-engineered mortalities and verified locations. The two locations in the detail from New Orleans East are separated by half a street width (a). In the London Canal Area, both locations fall on the same house (b). In the Lower Ninth Ward the two locations are found on either side of the same street (c).

house to the middle of the road. Five locations were next door, and three more had only two intervening residences. The greatest intervening distance was six residences. For the London Canal area, one of the re-engineered mortalities fell on the same field-verified residence, three were separated only by the distance to the middle of the road or the house on the opposite side of the street, and two houses were immediate neighbours to the re-engineered location. The greatest separating distance was nine houses. The extent of damage in the Lower Ninth Ward made this form of measurement impossible due to the amount of residential destruction with many houses having floated from their original foundation. Figures 4a–c display details for all three neighborhoods, with the red dot marking the re-engineered coordinate, and the yellow dot being the GPS measurement. Figure 4a (New Orleans East) shows an example of the separating measure between the pairs as being the middle of the road, figure 4b (London Canal) is an example of where both coordinates fall on the same residence, and 4c (Lower Ninth Ward) shows where the address is on the other side of the street.

A final step was to determine if the re-engineered coordinate actually guided the field team to the mortality location, or whether chance alone would have resulted in the same level of discovery. A series of random coordinates equalling the number of mortality residences were scattered throughout the study areas. This simulation was repeated 100 times generating a test distribution of mortalities. A 95% confidence level was determined if the distance between the actual re-engineered mortality and the field verified residence was smaller than in 95 of all simulated distances between a random coordinate and the same field verified residence. Meeting this 95% level were 73% of the New Orleans East pairs, 75% of the London Canal pairs, and 50% of the Lower Ninth Ward pairs. As an even more extreme comparison, for New Orleans East 9 of the 22 pairs were closer than in any of the simulation runs. Similarly, 3 of 16 pairs for the London Canal area, and 1 in the Lower Ninth Ward were closer than to any of the simulated coordinates.

Discussion

The success of this research should not be judged by the percentage of successfully re-engineered mortalities that can be verified back to an actual residence as other externalities could impact this process. These include: the body was recovered from a non-residence, such as a road median; the house has since been cleaned of all markings, or no distinguishable "mortality" marking was left on the residence; and the neighborhood could have suffered such extreme damage that mortality markings were not obvious, or the residence itself had disappeared or been moved. The success of re-engineering mortalities from the *Advocate* map should rather be judged if *any* residence could be verified. The fact that many of the re-engineered coordinates could be used to identify an actual address, or an address within the immediate vicinity, should sound a note of caution for academics publishing maps displaying human cases as points. In order to further impress on this point, and to show that similar cartographies have been employed to map health data, the following surfaces in the *American Journal of Public Health, American Journal of Tropical Medicine and Hygiene, Emerging Infectious Diseases, Environmental Health Perspectives,* and the *International Journal of Health Geographics* are briefly discussed.

Oyana et al. (2006) consider the proximity of asthma cases and controls to different pollution sources [12]. Their map contains an outer boundary shape of Buffalo, New York. The map contains additional "reference" material in terms of major roads. Cases (and controls) are displayed as a triangle or dot. The inner area of the study, the "West Side" is heavily populated making the potential re-engineering of addresses difficult. However, the re-engineering process would be easier to accomplish in the more sparsely populated areas (in terms of cases and controls), and especially if the residence falls close to locations useful for registering the image. For example, the area to the south of the map would be of particular concern with relatively few cases, and where several roads converge.

Lederman et al (2004), in their investigation of the effects of the World Trade Center disaster on birth outcomes, create a map showing work and home addresses as points [11]. Geographic features in the map that would allow for the georegistering of the image include the land/water boundary and major roads. Although the map on the journal page is relatively small, it is also possible to view a larger version of the figure at the journal's website.

Eng et al (1999) use three maps in their study of toxoplasmosis on Vancouver island, British Columbia, with residences being displayed as points [10]. The first map displays the geographic location of 94 acute cases of toxoplasmosis. The second and third maps display the location of women screened during pregnancy, who were either negative, or had non acute toxoplasmosis. These maps appear to be relatively safe as they contain few geographic references suitable for the georegistering of the image, beyond a detailed outer boundary of the map. As a larger version of the map is available on the journals website, it would still be interesting to see how close a re-engineered coordinate would be to the actual address.

Huhn et al (2005), in their investigation of the 2002 West Nile virus epidemic of Illinois, use a map displaying West Nile virus cases in Cook County. A solid cross is used to

mark the addresses of 536 cases. Although the overlap of crosses in the more case clustered areas would make the re-engineering of individual residences difficult, there are several sections of the map where relative geographic isolation of cases occurs [13]. In a second publication investigating the same outbreak, cases are overlaid onto a raster image of elevation [23]. This raises another issue, how would the re-engineering process be improved if a commonly available grid of data is used as backdrop? A second map in the same article is the most obvious candidate for a successful re-engineering as human cases are displayed as crosses on a map of census tracts. This map contains a greater georegistration potential than the *Advocate* New Orleans map used in this paper.

In none of these examples is mention made of any masking procedure applied to the point placement of human cases on the map. This suggests that the cases (usually shown as points) should mirror the underlying street network, and are therefore vulnerable to re-engineering. These comments are not meant to be criticisms of the academics involved in each study as the danger of re-engineering information from a map is a relatively new concern, though warnings have previously been sounded about mapping unmodified geocoded data [16,24]. There are, however, other more proactive studies that should be applauded for addressing confidentiality in their display.

Rothenberg et al. (2005) map the social and geographic interconnections for a subgroup of HIV infected individuals in their Colorado Springs study using a spider plot (nodes being connected with lines, with color being added to indicate the strength of connection). The authors comment that "...the map has insufficient detail to read the exact placement of nodes." [26] However, in order to preserve confidentiality each node was randomly moved by 1600 m. The authors further state that this "masking" allows for easier map interpretation while preserving the geographic relationship between nodes and links. Although the authors were mistaken in that the map does contain sufficient detail to allow re-engineering (census block boundaries are included), the random displacement of the nodes makes this a mute point.

Previous research has shown that urban density, urban/non-urban, and even length of street segment impact the success of geocoding [19], and similarly this paper has revealed how urban neighborhood structure plays a marked role in the success of re-engineering residential information. This is largely a result of two factors: the housing pattern on a street, which can affect address-matching results, and the amount of neighborhood detail allowing for more accurate georegistering of the image.

For example, the London Canal area has the highest percentage of mortalities (37.5) being close (within 5 meters) to a street section (Table 1). This area also has the lowest percentage (4.2%) of locations falling in the greatest distance away from a street category (above 25 m). If we look at the original georeferenced map, the London Canal area has the greater number of adjoining Census tracts of the three neighborhoods, resulting in more geographic detail, which in turn allows for more accurate georegistering of that part of the image. Although these coordinates are close to the street network, this does not reflect the accurate placement of geocoded points along a street, which in turn would have an impact in terms of the distance between mortality coordinate and verified residence. New Orleans East was the most successful in terms of this measure with just over 22% of the pairs within 10 meters. This suggests that house spacing within this area allows for a more accurate geocode. Most address matches are calculated with the house number being proportionally placed within the range of addresses on a street segment. More accurate address placement tends to occur in homogenous neighborhoods, such as in the suburbs, or in newer housing developments such as in New Orleans East. The worst neighborhood for geocode accuracy is the Lower Ninth Ward, with no pairs being within 10 meters. This can be explained by the considerable heterogeneity of housing structure, both in terms of size and lot placement. However, even in this neighborhood, a high proportion of the re-engineered mortalities were found, and 50% of these were closer than to any simulated "address" in 95 out of 100 simulation runs.

Conclusion

This paper has shown that any map containing point data, even when little secondary spatial information is presented, is vulnerable to being re-engineered to reveal the actual addresses associated with the points. It is therefore vital that some masking occurs of the original point data. Although HIPAA regulations state that health information can only be disclosed, if all zip codes with the same three initial digits exceed 20,000 people it is still feasible that a point displayed on a Parish boundary with no political subdivisions, meaning the cartographer is not violating any HIPAA regulation in terms of an apparent minimum denominator, could still be re-engineered if enough detail is present in the boundary shape. The question needing further discussion is how we should determine minimum denominators. If such a re-engineering process places a residence within a denominator area of 50 houses, this is a violation of the spirit of HIPAA.

Further research should concentrate on the degree of masking required in relation to urban structure, what could be considered safe amounts of map detail, and an appropriate minimum denominator of "alternative" resi-

dences. The suggestion should also be that until such research has been conducted, are maps really necessary in publications? Why not chose an abstract space on which to display spatial patterns [25]. The reader of the paper may need a graphic to understand the described relationship between geographic features, but it is unlikely he/she needs the actual geographic space. It is better to err on the side of caution than to make a mistake that might lead to a breach in patient privacy and further restrict the access spatial researchers have to confidential data

Methods

A map from the Front Page of the December 30, 2005 Baton Rouge *Advocate*, entitled "Deaths from Katrina hit both rich, poor", displayed a total of 412 mortality locations, though only 369 fell inside Orleans Parish which contains New Orleans. This map was scanned and georegistered using ArcMap 9.1. The process of georegistration, also called registering or rectifying an image, converts a representation of the earth into its real-world location by assigning coordinates to the image. After scanning the map, the image was added to an ESRI ArcMap 9.1 view already containing a shapefile of Census 2000 tract boundaries. On the *Advocate* map the point pattern of death locations is displayed on a choropleth map of poverty by census tract. Poverty is classified into four categories graded by colours from light yellow to dark brown (Figure 2). Due to the lack of streets or other geographic references that could be used in the georegistration of the map, only the Census tract layer was used as a source for control points assigned to the image.

Georegistration

The 2000 Census tract boundary file provides intersections that are recognizable throughout the map and thus were the primary source for assigning geographic coordinates to the graphic. The accuracy of matching the image to its real-world location is dependent on assigning control points evenly throughout the map. In this case, due to reliance on recognizable tract boundaries, some areas were assigned more control points than others. Also, in the *Advocate* map, when contiguous Census tracts fall into the same poverty classification the boundary between them is no longer visible, thus degrading ability to use these areas for control points. Even with these potential sources of inaccuracy, the resulting overlay of paper map and digital tract boundary left little error.

Digitizing death locations

Each mortality was heads-up digitized, meaning the mortality circle was added into the GIS by being drawn around its circumference using the mouse. Both this outer circle and the centroid, the circle's center point, were captured as digital layer files. The outer circle, once exported to Google Earth covered approximately one-and-a-half city blocks (Fig 2b). Each centroid was mapped onto a street map of New Orleans. Figure 2 shows the digitised centroids as red points on the original *Advocate* map.

Employing digitized death locations in field analysis

From Arc 9.1, 8.5 × 11 size maps were generated for each neighborhood showing streets, street names and the digitised centroids. These maps were used by the field team who systematically went to each coordinate point on the map, estimating exactly where they should find the residence along the street section, including on which side of the road it should fall. The field team did not search for the mortality residence beyond the immediate vicinity of the dot on the map, unless the location was situated inside a city block with no indication as to which street section the residence fell. Those houses in which a mortality was marked by a search and rescue team were photographed, the address recorded, and a GPS coordinate captured, using a Trimble GeoExplorer 3 hand-held GPS receiver.

Comparing field data with re-engineered death locations

The latitude and longitude coordinates of the re-engineered mortality and the verified address were displayed on high-resolution imagery (1 foot resolution post-Katrina imagery that originated with the Army Corps of Engineers and was flown by 3001 Inc.) of New Orleans using ESRI ArcMap 9.1. In order to determine how close the re-engineered coordinates were to the Orleans Parish road network, the distance between each coordinate and the closest street section was recorded using the spatial join feature in ArcMap 9.1. The distance was also calculated between each pair of re-engineered coordinates and the field verified address. A second distance measure was also employed for these pairs being the number of separating houses between the re-engineered coordinate and the actual address. This count was easily achieved by using the high-resolution imagery.

In order to determine if the re-engineered mortalities had guided field teams to the verified residences or whether the discovery was by chance alone, one hundred simulation surfaces were created for each neighborhood. These simulation surfaces were comprised of randomly located residences, where the "n" for each neighborhood equalled the number of re-engineered mortalities extracted from the *Advocate* map (24 for New Orleans East, 20 for the London Canal area, and 36 for the Lower Ninth Ward). The simulation surface was created using Hawth's Analysis Tools for ArcGIS which provide additional functions to ESRI's ArcGIS program. The Generate Random Points tool was used to randomly distribute points across the polygon layer of Census tracts. In order to see how dissimilar a geocoded surface was to a randomly generated point surface in terms of mirroring the underlying street network,

the distance between each randomly generated point and its closest street section was recorded using the spatial join tool in Arc 9.1. Similarly, to see how frequently a randomly generated point would fall closer to a field verified address than a mortality coordinate, the distance between the address and its closest randomly generated point was recorded using the spatial join tool in Arc 9.1. By recording this distance for 100 simulation runs, a test distribution of mortalities was created against which the distances of the mortality coordinate and field verified address pairs could be compared.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

AC JM and ML collected all field data. JM performed the re-engineering of mortality locations from the *Advocate* map. AC conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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Re-identification Risks in HIPAA Safe Harbor Data: A study of data from one environmental health study

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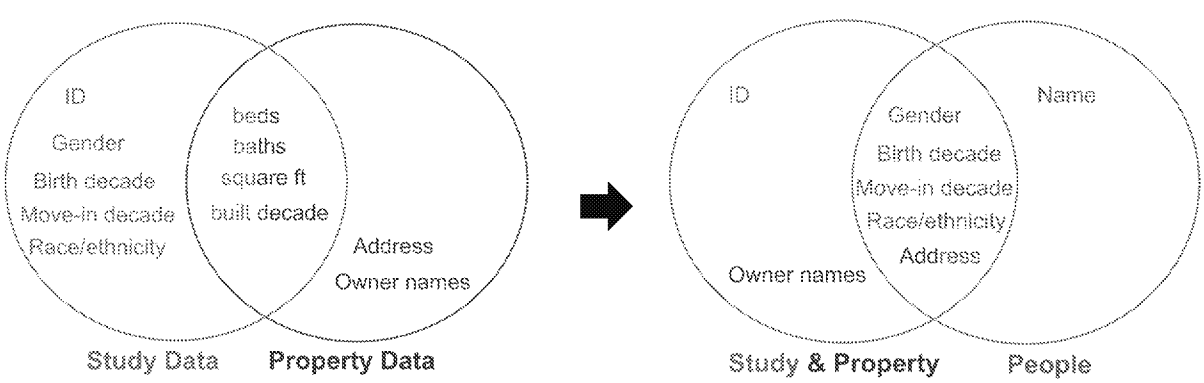
Highlights

- The HIPAA Safe Harbor is not sufficient to protect data against re-identification
- We found correct re-identifications for ~25% of records in a subset of a HIPAA-compliant environmental health dataset
- We used demographic and non-demographic fields to link a HIPAA-compliant dataset with external data sources
- Group re-identifications can extend potential harms to all individuals associated with the same record



(a) Phase 1 (b) Phase 2

Re-identification strategy to associate an ID in the Study Data with an Address and Name of a participant in the study

Abstract

Researchers are increasingly asked to share research data as part of publication and funding processes and to maximize the benefits of publicly funded research. The Safe Harbor provision of the U.S. Health Information Portability and Accountability Act (HIPAA) offers guidance to researchers by prescribing how to redact data for public sharing. For example, the provision requires removing explicit identifiers (such as name, address and other personally identifiable information), reporting dates in years, and reducing some or all digits of a postal (or ZIP) code. Is this sufficient? Can research participants still be re-identified in research data that adhere to the HIPAA Safe Harbor standard? In 2006, researchers collected air and dust samples and interviewed residents of 50 homes from Bolinas and Richmond (Atchison Village and Liberty Village), California, to analyze the residents' exposure to pollutants. The study, known as the Northern California Household Exposure Study [1], led to publications that have been cited hundreds of times. We conducted experiments with separate "attacker" and "scorer" teams to see whether we could identify study participants from two versions of the data redacted beyond the HIPAA standard, one in which all dates were reported in ranges of 10 or 20 years and another in which a study participant's birth year was reported exactly. The attackers were blinded to the names and addresses of the participants, and the scorers were blinded to the strategy.

Results summary: We correctly distinguished the 10 records from Bolinas and 32 records from Atchison Village, and we presented 9 records that included the 8 correct records from Liberty Village. When the redacted data contained the exact birth year, as allowed by HIPAA Safe Harbor, we correctly identified 8 of 32 (25 percent) Atchison Village participants by name and 9 of 32 (28 percent) by address. In comparison, earlier studies found unique re-identification rates in data that adhered to the level prescribed by HIPAA Safe Harbor to be much lower, namely 0.013 percent [2] and 0.04 percent [3]. However, these earlier studies relied solely on demographic fields for re-identification. Our experiments used fields beyond demographics (e.g., housing characteristics), and by doing so, substantially increased re-identification risk in data compliant with HIPAA Safe Harbor. Even in more heavily redacted data showing participants' birth years in 10- or 20-year ranges, we uniquely and correctly identified 1 of 32 (3 percent) of the Atchison Village study participants by name and address and identified 4 of 32 (13 percent) participants as being one of fewer than five named choices. No correct results were found for Liberty Village or Bolinas under these conditions. These results suggest that the HIPAA Safe Harbor is not a sufficient privacy guard for environmental health data and bring into question the practice of using the HIPAA Safe Harbor standard as a general rule for "de-identifying" other datasets in today's data-rich, networked environment.

Introduction

The Privacy Rule of the Health Information Portability and Accountability Act (HIPAA) is the U.S. federal regulation that governs the sharing of patient medical information by doctors,

hospitals, and others involved in direct patient care or in the billing for that care [4]. Improper handling of patient information can result in civil and criminal penalties. For example, an incidental data breach could cost $50,000, and patient information knowingly disclosed could result in a criminal penalty of $250,000 and ten years of imprisonment [5].

On the other hand, if the data are redacted as prescribed by the Safe Harbor provision within HIPAA, then the redacted version can be shared freely without concern for civil or criminal penalties [6]. HIPAA Safe Harbor requires eliminating 16 kinds of patient identifiers (e.g., patient name, Social Security number, email address, and telephone, account, and all other record numbers) and generalizing date and geography information: dates must be reported as years, and the smallest reportable geographic subdivision is the first 3 digits of the ZIP (postal) code (unless the three-digit ZIP code contains fewer than 20,000 people, in which case it is reported as 000) [7]. Personal health information redacted in this format can be shared widely, online or offline, with no restrictions and without a data use agreement. Promulgated on August 14, 2002, the HIPAA Privacy Rule remains in effect today. Although it formally applies to patient health records, HIPAA Safe Harbor is sometimes proposed as a benchmark in other contexts, such as Institutional Review Board oversight of research [8].

The HIPAA Safe Harbor standard uses a traditional pillar of data privacy known as de-identification – the removal of explicit identifiers from data to make the result sufficiently anonymous. The rationale behind de-identification is simple. If an individual cannot be distinctly identified in data, then no individual's privacy interests are affected, so the data can be shared widely for many worthy purposes.

HIPAA Safe Harbor is convenient. A researcher can easily comply by merely making the appropriate data redactions. No special computer programs, statistical modeling, or advanced analysis is necessary. But does the HIPAA Safe Harbor adequately protect privacy?

Re-identification

When sharing personal data widely, the biggest privacy threat to "de-identified" data is "re-identification" – the ability for an interested adversary to use reasonable effort to match details in the de-identified dataset to distinct persons sufficiently to contact them. We use the term "named person" to refer to having sufficient information to identify a person by name and "named location" to refer to having sufficient information to identify a physical place having few people. An example of a named location is the residential address of a family. If specific records in a de-identified dataset can be associated with one or few named people or named locations, then we say in this writing that the dataset is re-identified (regardless of whether the associated records contain the true identity). Harm from a re-identification may result if sensitive information contained in the data becomes known about named persons or named locations. For example, when Sweeney re-identified hospital discharge data released by Washington state, her re-identification exposed records that included sensitive

information such as "references to venereal diseases, drug dependency, alcohol use, [and] tobacco use" [9].

A "unique re-identification" occurs when a record in the data matches exactly one named person or location. A "group re-identification" occurs when one or a few records in the dataset match a small number of named people or locations. Both unique and group re-identifications raise privacy concerns. For example, if a de-identified dataset does not include names or home addresses, but does include age in months, gender, and 5-digit ZIP codes, it is possible to use publicly available websites to deduce the identity and home addresses of many individuals in the database, as was demonstrated by the recent re-identification of de-identified medical records from Washington state [9]. A one-to-few match can be just as damaging as a one-to-one match. For example, showing that a record in a de-identified dataset of lead poisoning cases belongs to one of few named locations could cause all the real estate properties in the group to suffer adverse consequences, even though only one of the named locations actually has the lead poisoning risk. As another example, a group re-identification of de-identified medical records showing that 6 of 7 named people have a genetic disposition toward cancer would leave the impression that each individual was equally likely (6 in 7) to have that condition, including the individual without the condition. It is well recognized that one-to-few and few-to-few re-identifications pose privacy risks similar to unique re-identification [10].

Rarely is zero risk of re-identification required in publicly shared datasets, and HIPAA is no exception. In 2011 El Emam et al. conducted a review of 14 published re-identification attacks [11]. Of the 14 examples, the authors dismiss 11 as being conducted by researchers solely to demonstrate or evaluate the existence of a risk of re-identification, not necessarily knowing whether the re-identification was correct. They classify the work of Narayanan and Shmatikov [12] in this category. Narayanan and Shmatikov demonstrated the possibility of re-identifying published Netflix rental histories from the (identified) movie reviews submitted by Netflix customers.

More generally, Sweeney used 1990 Census data to estimate that 0.04 percent of the United States population was uniquely identified by the basic demographic fields allowed by the HIPAA Safe Harbor – namely, year of birth, gender, and first 3 digits of ZIP [3]. Both the study by Kwok and Lafky and the study by Sweeney examined only demographic fields, and both found low likelihoods for unique re-identifications. Are we failing to consider other possible risks of re-identification by only studying those addressed by HIPAA Safe Harbor? What about small group re-identifications? What about matching on fields other than demographics?

Answers to these questions are critical as researchers seek to share research data widely. Many academic publications now require authors to submit a version of the data on which results are reported as a condition of publication (for examples, see [13, 14]). Also, federal, state and city governments increasingly make their datasets publicly available as part of

open data initiatives (e.g., [15]). Sharing research data freely is important for science because it allows other researchers to verify published findings and can lower research costs through data reuse. U.S. regulations for data sharing are sector–specific, and most kinds of research data are not subject to any federal data sharing standards. In cases where the data are not subject to HIPAA, researchers and Institutional Review Boards that approve data sharing for research often wonder whether the HIPAA Safe Harbor's prescriptive solution will suffice [8]. In what cases does the HIPAA Safe Harbor provide sufficient privacy protections for sharing research data?

Background

In 2006, researchers (including this paper's authors Brody, Perovich, and Brown) from the Silent Spring Institute, Northeastern University, and the University of California, Berkeley, with funding from the National Institute of Environmental Health Sciences, collected air and dust samples and interviewed residents in 40 homes in two neighborhoods in Richmond, California, and 10 homes in Bolinas, California. This project, known as the Northern California Household Exposure Study (HES), aimed to improve scientific understanding of indoor exposures to pollutants [1]. The two communities of Atchison and Liberty Villages in Richmond were chosen for the study because they were industrial communities within a few miles of the Chevron Richmond Refinery, major transportation corridors, and a marine port [14]. Bolinas was chosen on the advice of the community advisory council to provide a rural comparison within the same region. The researchers published findings in leading journals with summary statistics that describe the demographics of the research participants and detailed analysis of chemical pollutants found in the participants' homes and outdoor air [1, 16, 17, 18, 19].

In addition, the researchers wanted to share the study data widely for further analysis by others. For example, the US Environmental Protection Agency requested access to the HES data to estimate human exposures from consumer products. However, the researchers sought to honor the privacy statement made to research participants when sharing data. The informed consent for the study states:

HOW WILL THE DATA BE KEPT CONFIDENTIAL?
All information that could identify you will remain confidential to the full extent of the law. The samples from your home will be identified with a number rather than your name when they are sent to the laboratory for tests. Any record that includes your name or personal identifying information will be kept in locked file cabinets and access to these records will be restricted to researchers involved in this study.

In research studies like these, the risk of re-identification is a matter not only of privacy protections required by the IRB and described to participants when they first consented to the study, but also of researchers' broader responsibilities to avoid harms to participants. For

example, if participants' names or addresses can be matched to the research data, the information about certain pollutants in their homes could adversely impact the value of their properties. If participants were renters, identification might lead landlords to terminate or refuse to renew leases in the belief that the renters may have exposed them to economic problems by participating in research.

Knowledge from an attempt to re-identify a HIPAA Safe Harbor–compliant version of the HES research data can inform data-sharing practices, informed-consent documents, and the development of new strategies to protect study participants.

HES researchers did not collect the data as part of patient medical care, so it was not subject to HIPAA. Still, they faced decisions about data redaction and wondered what protection a HIPAA Safe Harbor version would offer.

In the next sections, we report on our attempt to match names and addresses of research participants to a HIPAA Safe Harbor–compliant version of the demographic and house information collected as part of the exposure study. The HES researchers have never shared the data publicly, so this experiment reports on risks of data that would result if the data were shared in compliance with HIPAA Safe Harbor.

About Re-identification

A "re-identification strategy" in this writing is a means to assign identifying information to entities (e.g., people or addresses) whose information is believed to appear in de-identified records. Approaches typically include a stepwise process applied to various datasets, where one of the datasets is the de-identified dataset itself.

The relevant outcome of a re-identification strategy is usually a set of sufficiently small group re-identifications. The total "number of re-identifications" is the number of records re-identified, regardless of whether the correct identification is included. If only unique re-identifications are of interest, then the number of re-identifications is the number of one-to-one associations found. When larger-sized groups are relevant, then the number of re-identifications of records in the dataset is the number of groups. For example, consider a re-identification having 4 groups, with 2 named people in each group. One person in each of the two person groups is believed to be the correct person, but the re-identification strategy does not distinguish which of the two named people that person might be. Therefore, the number of re-identifications is 4, one person from each group.

A re-identification does not necessarily need to be correct to be harmful. If a sufficiently reliable re-identification strategy strongly associates a record to a person, then that person will likely suffer the same harm whether they are named correctly or incorrectly. We use the term "correct re-identification" to distinguish instances when re-identification identifies the

true person. Consistent with data privacy literature, both re-identifications and correct re-identifications are important.

In prior work, Sweeney introduced the notion of a "binsize" as the number of entities (people or addresses) that matches one or more de-identified records indistinguishably [9, 20, 21]. Unique re-identifications have a binsize of 1, denoting a single one-to-one matchup, uniquely identifying the person or address. A binsize of k lists k possible matches to a single person or address.

The number of unique re-identifications is the value at binsize 1 (we write k=1). Past government data-sharing policies required suppression of data that could lead to re-identifications for binsizes less than 5 (k<5) (e.g., [22]). Recent government data-sharing policies proscribes re-identifications for binsizes less than 11 (k<11) (e.g., [23]). Guidelines for defamation cases have focused on expecting no re-identifications for binsizes less than 20 (k<20) (e.g., [24]) or 25 (e.g., [25, 26]). Therefore, for generalizability, we report the number of re-identifications having thresholds at k=1, k<5, k<11, and k<20.

A re-identification strategy identifies a "risk pool" for groups 1 to k [27], comprising all distinct entities named in the re-identified groups from size 1 to k. Risk pools are important because they identify which other entities may be harmed indiscriminately. In the prior example in which the results of a re-identification strategy was 4 groups with two named people for each group, then 8 named people are in the risk pool and the total number of re-identifications is 4. Notice that the risk pool, as defined here, relates to a re-identification strategy. Another re-identification strategy operating on the same de-identified dataset may generate a different risk pool.

Methods

We split ourselves into two separate teams, the "Scorers" and the "Attackers," to conduct an experiment in which the names and addresses of study participants, held by the Scorers, were kept private from the Attackers, and re-identification strategies, developed and conducted by the Attackers, were kept private from the Scorers until the experiment's conclusion. Although we met to organize ourselves, actual names, addresses and re-identification strategies were not shared during these discussions. The Attackers attempted to put names and addresses to records in a HIPAA Safe Harbor–compliant dataset and then submitted batched matches to the Scorers. The Scorers consisted of co-authors Brody, Perovich, Boronow, and Brown. The Attackers consisted of co-authors Sweeney and Yoo. The Attackers performed two preliminary iterations with the Scorers before establishing the more succinct version of the re-identification strategy described here.

A re-identification experiment requires registers containing named people and locations to match to the de-identified records. Because the HES is a study of air and dust samples from homes, we used property tax registers for Atchison Village and Bolinas, California, where

most homes were owned by residents. Liberty Village is rental housing, so an address register had to be constructed. HES participants lived in the homes tested, so registers were constructed of the names and addresses of adult residents in those communities during the study period. Below is a description of materials, subjects, and our 7-step approach.

Materials

The "HES Study Dataset" refers to the original data collected in the Northern California Household Exposure Study (HES) [1]. These data include demographic information about participants such as race, gender, birthdate, education level, the year they moved into their residence, and whether they owned the home. Information about residences includes room descriptions and dimensions, use of carpet per room, year the house was built, heating and cooking options, and numerous details about appliances, cleaning choices, pesticide use, pets, and lawn care. The HES Study Dataset also includes extensive one-time air and dust measurements taken at each home. The original dataset was redacted and modified to comply with HIPAA prior to re-identification (see Detailed Approach).

"HES Publications" refers to the set of papers previously published about the study (including [1, 16, 17, 18, 19, 28, 29]).

The "Atchison Village Property Register" is a copy of the 2006 tax assessor data for Atchison Village purchased from the County of Contra Costa Assessor's Office for $35 [29]. For each homeowner in Atchison Village, these data include the names of the property owners, the address of the property, the number of rooms, baths and bedrooms, the date the house was built, whether a garage is present, and the total land area.

The "Bolinas Tax Data" is a copy of the 2006 tax assessor data for Bolinas, California purchased for $112 from the Marin County Assessor's office [40]. Unlike the Atchison Village Property Register, the Bolinas tax data do not include any of the specific housing characteristics, such as the number of rooms, baths and bedrooms, the date the house was built, whether a garage is present, and the total land area. The data do include the names of the owners, the address of the property, and various tax parameters.

An online subscription to a "data broker" website allows searches that associate the names and biographical information of people to known addresses, and vice versa, and therefore provided the ability for the Attackers to construct a register of people who live in a particular geographical area. Hundreds of data brokers sell personal information on Americans, including names, telephone numbers, birthdates, and current and historical addresses [31, 32, 33]. Some data brokers list the dates at which the person was known to reside at an address. Many data broker websites allow searches by any field – e.g., by name or historic or current address. Subscription costs typically range from $12.95 per month to $99 per month for an unlimited number of searches or $1 to $5 per search.

Internet tools include a web browser and the use of Google Earth and Google Street View images [34]. Additional data include the Census data on the popularity of occurrences of first names by gender ("Gender Names") [35] and of last names by race and ethnicity, specifically Black, White, Asian, Native American, and Hispanic surnames ("Race Names") [36]. Computational tools include a spreadsheet program, a text editor program, and the Python programming language [37] running on off-the-shelf laptops.

Subjects

The subjects of the re-identification experiment were the 50 adult participants in the HES study, 10 of whom resided in Bolinas, California, and 40 of whom resided in the Atchison Village or Liberty Village communities of Richmond, California.

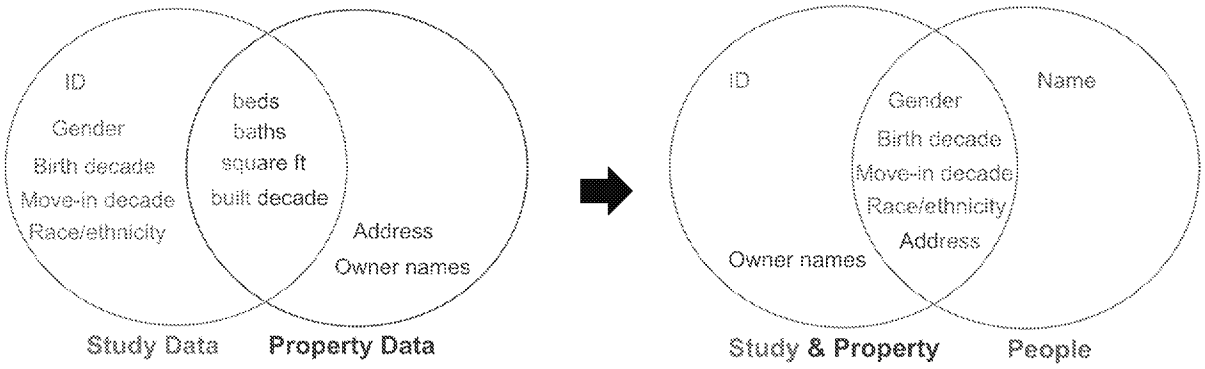
Approach

The Attackers crafted a re-identification strategy that involves matching HES data to community real estate and people registers. "Property registers," drawn from real estate data, contain the same kind of housing characteristics – namely, the number of beds and baths, total living area, and when the house was built – that the HES data contain. The real estate data additionally include the address of the property and the names of the homeowners. A "people register" is a list of people in a community relevant to the re-identification. For example, a local voter list is a people register of all registered voters in a community and might be useful for re-identifications involving a geographically bounded group of adults. People registers tend to include the names, addresses and demographics of the people in the community. The study was conducted in 2006, so the Attackers sought to construct registers of property as it was in 2006 and of people who lived in these communities in 2006.

The Attackers' approach unfolds in two phases; see Figure 1. In the first phase, the Attackers match HES data to real estate data on housing characteristics (see the left side of Figure 1). Any matches found will associate named property owners and home addresses to the demographics of participants in the HES who reside at a home having those characteristics. If unique matches result, then re-identifications would likely be done for those HES records. However, houses in these communities tend to have similar number and types of rooms, and most were built at the same time. Therefore, multiple matches are likely for each HES record and so further matching is necessary.

In the second phase, the Attackers match the results from the first stage to a people register on race, gender, age, address, and move-in date, in order to associate names of people residing at those residences. See the right side of Figure 1. Matches associate the name of someone known to live at the address in the people register with an HES participant living in a similar house and having those demographics. Further, if the homeowner name is the same

as the name from the match in the people register, and the HES data states the person is a homeowner, then the match is further confirmed.



(a) Phase 1 (b) Phase 2

Figure 1. Re-identification strategy to associate an ID in the Study Data with an Address and Name of a participant in the study. (a) First, match records in the HES study data (green) to real estate property data (brown) on beds, baths, square feet of living area, and decade group in which the house was built (mixed green and brown lettering) to put an address to an ID. Then, (b) match the joined information (green and brown) from (a) on gender, decade group of birth, move-in decade group, race and ethnicity, and address (mixed green, orange, and brown lettering) to a people register (orange) to put a name to the ID. The name of a known resident at the address in the people register may or may not be the same as the name of the owners in the real estate property data. A re-identification results when a name or address is associated with an ID. "Decade" refers to dates grouped in ranges of 10 to 90 years.

The Attackers assess the re-identification strategy by identifying risk pools and computing the number of re-identifications for k<5, 11, and 20. These re-identifications are believed to contain the correct match, but they do not necessarily contain the correct match. Therefore, each experiment concludes when the Scorers report, by binsize, how many of the proposed groupings include the correct named person or the correct address. Re-identifications of addresses rely on the same matches of resident demographics, but are evaluated separately because addresses themselves are important personal information, as described earlier.

Finally, Attackers also explore variations of the approach based on human matching versus automated matching. Computers can process more records quickly, but humans tend to use heuristics that may provide improved results.

The next subsection provides a stepwise description of the approach for replication and detailed study. The general reader can advance to the Results section without loss of understanding.

Detailed Approach

To test their re-identification strategy, the Attackers acquire and construct appropriate property and people registers and then match records, as described in the 7 steps below.

Step 1. The Scorers construct dataset that satisfies more than the minimum HIPAA Safe Harbor requirements. Starting with the original HES Dataset, the Scorers redact names, addresses, and other personally identifiable information and identifiers (e.g., number of dogs in the home, information on IV treatments, individual room dimensions). All dates (e.g., birth year, year house built, year moved in) are converted to decade and aggregated, so that they are reported in ranges of 10 or more years. Decades were aggregated so that each reported range contained at least 5 records. One field was constructed (total square feet of living area in aggregated ranges) because the Scorers considered individual room dimensions or exact square footage as potentially uniquely identifiable data. We refer to the resulting data as the "HIPAA Dataset".

Step 2. The Attackers attempt to distinguish Richmond from Bolinas records and, among the Richmond records, Atchison Village from Liberty Village, in order to improve re-identification accuracy. Using information in the HES Publications, the Attackers identify characteristics in the HIPAA Dataset that are specific to homes in Atchison Village, Liberty Village, and Bolinas and then subdivide the records of the HIPAA Dataset into those records likely to be specific to those communities. The Scorers report the accuracy of the Richmond-Bolinas and Liberty Village-Atchison Village subdivisions at the end of the study, even though the Attackers may use these partitions in intermediate steps.

Step 3. The Attackers construct a dataset to use for re-identification. They compute new fields that are convenient for re-identification and eliminate fields that are not relevant to the re-identification strategy. We refer to the result as the "De-ID Dataset." The De-ID Dataset remains HIPAA Safe Harbor–compliant because it is a subset of the HIPAA Dataset. All re-identification attempts are on the De-ID Dataset.

Step 4. The Attackers construct a property register for the rental units in Liberty Village. The tax assessor data list the Liberty Village complex as one large real estate block. So the Attackers use Google Earth images and rental property websites to infer the addresses, number of baths, and number of bedrooms for each unit. We refer to the result as the "Liberty Village Property Register."

Step 5. The Attackers construct a property register for Bolinas, California. Unlike the tax assessor data for Atchison Village, the acquired 2006 tax assessor data for Bolinas does not contain any housing details [38]. Instead, the data for each home include the names of the owners, address, a unique parcel identifier, and various tax values. However, the tax assessor additionally hosts a website on which searches by a parcel identifier yield detailed housing characteristics, such as the number of rooms, baths, and bedrooms for the parcel [39]. The Attackers use the parcel identifiers from the acquired property tax data to construct a "Bolinas Property Register" with the same fields as the Atchison Village Property Register.

Step 6. The Attackers construct registers of people known to have lived in Atchison Village, Liberty Village, and Bolinas in 2006. Many HES participants in Atchison Village and Bolinas are homeowners, but reliance solely on the names found in the property registers may be misleading and limiting, so the Attackers construct registers of people known to be associated with the addresses in these communities. Using information from a data broker, the Attackers search the addresses from the Atchison Village Property Register to identify named people who lived at an Atchison address in 2006, from the Bolinas Property Register to identify those who lived at a Bolinas address in 2006, and from the Liberty Village Property Register to identify those who lived in a Liberty Village unit in 2006. We refer to the resulting registers as the Atchison People Register, the Bolinas People Register, and the Liberty People Register, respectively.

Step 7. The Attackers execute re-identification strategies, and the Scorers report results. There are four sub-steps.

In Step 7a, the Attackers associate records in the De-ID Dataset with known addresses by matching housing characteristics, such as number of baths and bedrooms, in the De-ID Dataset to those in the property registers. Rather than matching against all records in the De-ID Dataset, the Attackers use the partitions derived in Step 3 to match those records in the De-ID considered most relevant to a community. The result is an association of named locations to specific records in the De-ID Dataset.

In Step 7b, the Attackers put names from the people registers to specific records in the De-ID Dataset by matching the combined property and addresses linkages from the results of Step 7a to records in the people register on personal demographics, such as age, gender, and race/ethnicity. The Attackers visually determine gender from the person's first name and Hispanic ethnicity from the person's last name and perform matching manually using a spreadsheet program. The result is an association of named people and locations to specific records in the De-ID Dataset.

In Step 7c, the Attackers repeat Step 7b using a computer program to associate race and gender to last and first names based on statistical occurrences of those names in U.S. Census data and to match records automatically based on personal demographics, such as age, gender, and race/ethnicity. The result is another association of named people and locations to specific records in the De-ID Dataset.

Finally, in Step 7d, the Scorers report on the correctness of the associations (or matchups) separately by community. Scorers report the number of HES participants found in each people register and the number of addresses of HES participants found in each address register. Matchups (or re-identifications) of one or more named people or named locations to a specific study record are given to the Scorers, who report the number correct per binsize group.

When scoring results, the Scorers apply the following rules:

- Names must match exactly, except in the following cases:
  - Shortened versions of names (e.g., Jon for Jonathan)
  - Commonly accepted nicknames (e.g., Bill for William)
  - Hyphenated last names, where at least one name overlaps (e.g., Jon Smith and Jon Smith-Jones will match)
  - Participant last name is listed as a middle name with a different last name (e.g., maiden name adopted as middle name following marriage)
  - Excepting the above case, middle names and initials will not be considered for matching. Note: if the Attackers re-identified "Katherine Jones" as an HES subject, but the HES Dataset listed "Katherine Smith," the Scorers would not consider the Attackers successful. However, the scorers would accept Katherine Smith Jones as a match to HES participant Katherine Smith.
  - Obvious misspellings, including non-alphanumeric characters, spacing, and capitalization
- Addresses much match exactly, except in the following cases:
  - Street suffix abbreviations (e.g., St for Street)
  - Street suffix omissions
  - Prefixes used to designate unit may differ, but unit number must match (e.g., Unit 1 and Apt 1 will be accepted as a match, but Unit 1 and Apt 2, or Unit 1 and Unit 2, will not)
  - Word order changes
  - Obvious misspellings

Step 8. The Scorers construct a dataset with exact birth years, which satisfies the minimum HIPAA Safe Harbor requirements. A second version of the HIPAA Dataset, provided after re-identification on the first version, included exact birth year. We refer to this as the "HIPAA Exact Dataset". The Attackers then repeat the relevant parts of Step 7 using the HIPAA Exact Dataset.

Results

This section walks through the work performed. In the first subsections, the Attackers establish a dataset redacted beyond the HIPAA Safe Harbor standard that provides the basis for re-identification. The Attackers also explain the means used for distinguishing between Atchison Village, Liberty Village, and Bolinas records in the dataset.

The next consecutive subsections report on the construction of property registers for Atchison Village, Liberty Village, and Bolinas. Afterwards, subsections detail the assembly of people registers for each community and report on demographic statistics for each population.

The remaining subsections report on matches of records in the dataset to people and addresses in the registers made after assembly of all the components – the dataset, the property registers and the population registers – and itemize which matches were correct. These results appear in consecutive subsections, one for each of the communities, Atchison Village, Liberty Village, and then Bolinas.

The final subsection repeats the matching experiment having year of birth information in the records of the dataset. The section ends with a comparison of results between data redacted beyond the HIPAA standard to data redacted at a level permissible by the HIPAA standard. The paper ends in the following section with a discussion of the findings.

Results for Step 1. HIPAA Dataset

The Scorers produced the "HIPAA Dataset" from the original HES Study Dataset that goes beyond the minimum HIPAA Safe Harbor requirements. The HES dataset consists of three files, divided into survey data, air measurements, and dust measurements. Appendix A provides a complete list of field descriptions for the files.

The Survey file contained 50 rows, one row for each house sampled. There were 256 fields, including demographic data about the research participants such as race, gender, birth decade group, education level, decade group participant moved into the residence, whether participant owns the home, square footage of living area, number and types of rooms, decade group house was built, and details about the home and the use of various appliances and pesticides.

Dates in the Survey file appeared in decade groups of at least 10 years. Specifically, values for birth were: 1920-1939, 1940-1949, 1950-69, or 1970-1989. Values for move-in date were: 1970-1989, 1990-1999, or 2000-2009. Values for house built date were: 1840-1949 or 1950-1989.

Values for total square footage were: 450-500, 500-650, 650-700, 700-1000, or 1000-2000.

There was no ZIP (or postal code) or other explicit geographical designation in the Survey file.

The Air and Dust files described the compounds found. The Air file had 12,767 indoor and outdoor measurements, and the dust file had 3,871 measurements for the 50 homes.

Results for Step 2. Records for each neighborhood

The Attackers reviewed HES Publications, found the following description of participant demographics, and reviewed online information about the communities.

The study was done 10 years earlier in 2006. Table S1, available as a supplement to the online version of the article [1], provides the following demographic summary.

Participants were 85 percent female and 15 percent male from Richmond and 60 percent female and 40 percent male from Bolinas. In Richmond, 5 percent were less than 26 years in age, 15 were between 26 to 40 years, 43 percent were between 41 and 60 years, and 37 percent were more than 60 years in age. In Bolinas, 10 percent were less than 26 years in age, 20 percent were between 41 and 60 years, and 37 percent were more than 60 years in age.

In Richmond, 41 percent of the participants self-identified as Hispanic, 54 percent self-identified as White, and 11 percent selected another race/ethnicity (3 percent Black, 5 percent Native American, and 3 percent Asian). Participants could self-identify as more than one race. Sixty-two percent were interviewed in English and 38 percent in Spanish. In Bolinas, none of the participants were Hispanic, 89 percent were White, and 44 percent selected another race/ethnicity (11 percent Black, 22 percent Native American, and 11 percent Asian); all were interviewed in English. The racial composition of Bolinas reflects a correction provided by the Scorers due to one person missing race information in Bolinas that was not noted in the original Table S1 [1].

Highest educational attainment in Richmond was as follows: 37 percent had a college education or higher, 26 percent had some college or post-high school training, 5 percent were high school graduates, and 32 percent had completed 11th grade or less. In comparison, 100 percent of Bolinas participants had at least a college degree.

Finally, in Richmond, 79 percent were homeowners compared to 70 percent in Bolinas.

From these characteristics, the Attackers computed the following invariants about the 10 records of Bolinas participants:

- All 10 Bolinas participants spoke English
- 4 were male, 6 were female
- 0 Hispanic, 1 Asian, 1 Black, 2 Native American
- More than one race per person reported
- 3 were renters, 7 were homeowners
- All 10 have a college education or better
- Year of birth groups:
    - 1 was born 1970-1989
    - 2 or fewer were born 1950-1969
    - 9 or fewer were born 1940-1049
    - 7 or fewer were born 1920-1939

None of the 50 records indicated a garage. Forty of the properties were built between 1840 and 1949, five between 1950 and 1989, and five were missing built year.

Based on these findings, the Attackers sought to identify which 40 of the 50 records in the De-ID Dataset belonged to Richmond participants and which 10 records belonged to Bolinas

participants by using published information about the study and values that appeared in the 50 records. The three geographical areas had a combined population of about 3,000 adults at the time of the study.

The attackers wrote a computer program to search all possible combinations of 10 of the 50 records that satisfied the demographic constraints. The computer identified 3 combinations of 12 records that satisfied all the demographic constraints for Bolinas. The remaining records would be the 40 for Richmond.

Another published table (reprinted in Appendix B) showed differences between outdoor air samples for homes in Bolinas and those in Richmond [17]. Attackers reviewed the publication for any chemical differences that might distinguish Bolinas and Richmond homes and learned that fluoranthene values for 33 Richmond homes reportedly ranged from 0.41 to 2.7 ng/m^3. For Bolinas, 8 homes did not have detectable levels of fluoranthene, one home had the maximum of 3.8 ng/m^3, and one home had an unknown level.

The Attackers manually examined the outdoor fluoranthene measures for the 43 homes and found that there were exactly 33 records in the 0.41 to 2.7 ng/m^3 range and 10 others that conformed to the summary statistics for Bolinas. Therefore, the Attackers believed the 10 records to be the Bolinas records and all others to be Richmond (including those for which no outdoor fluoranthene measurement was available). This configuration also agreed with one of the combinations found by the computer, which further supported the finding.

The Attackers submitted 40 PrivacyIDs as belonging to Richmond participants and 10 PrivacyIDs as belonging to Bolinas participants. The Scorers reported (after the experiment concluded) that the record designations were 100 percent correct. Therefore, the Attackers were able to use previously published results from the study to identify which records belonged to which community (Bolinas or Richmond).

The researchers reported that 40 of the records came from Richmond but did not distinguish how the 40 records split between Atchison Village and Liberty Village. The Attackers examined the 40 Richmond records and found 8 were for renters, 31 were for homeowners and one was unknown. Liberty Village is a rental complex, so all Liberty Village participants should be renters. Atchison Village is a housing cooperative. A "homeowner" in Atchison Village owns a share of the cooperative, and the cooperative decides who lives where. Cooperatives often have specific rules that impose limitations on renting. Therefore, the Attackers concluded that the 31 homeowners were from Atchison Village, the 8 renters were from Liberty Village, and the one unknown could belong to either neighborhood. In summary, the Attackers split the 40 Richmond records into 32 records for Atchison Village and 9 records for Liberty Village, a total of 41 records because one record appears in both groups. The Attackers then used these groupings for re-identifications involving Atchison Village and Liberty Village.

The Scorers reported (after the experiment concluded) that the 32 records for Atchison Village were correct and 8 of the 9 records for Liberty Village were correct. Therefore, the Attackers were able to reasonably ascertain which records belonged to Atchison Village and which to Liberty Village.

Results for Step 3. De-ID Dataset

Based on the Attacker's approach (see Figure 1), the data observations noted, and derivations above, the Attackers identified 15 fields in the HIPAA Dataset and 3 computed fields (the number of rooms and the numbers of bedrooms and bathrooms) as the subject of re-identification. The result is the De-ID Dataset, which contains 50 data rows and 18 fields. The fields include participants' race, gender, decade group of birth, education level, decade group for when they moved into their study residence, and whether they owned the home. Information about a residence includes square footage, room counts, and multi-decade grouping in which the house was built (i.e., 1840-1949 and 1950-1989). Fluoranthene level in outdoor air was also included. Figure 2 provides a summary of the fields in the De-ID Dataset.

Field name	Field Description: Possible Values
PrivacyID	From HIPAA Dataset: Unique ID created for scoring
birth_yr	From HIPAA Dataset: Year born in: reported as decade group
school	From HIPAA Dataset: Highest grade in school completed: <= 8th grade, …
own_home	From HIPAA Dataset: Owns own home: Yes or No
gender	From HIPAA Dataset: Gender of respondent: Male or Female
movein	From HIPAA Dataset: Year moved to this house: as decade group
housebuilt	From HIPAA Dataset: Year house was built: reported as decade group
SurveyLanguage	From HIPAA Dataset: Survey language: English or Spanish
totalsquareft	From HIPAA Dataset: Total square feet of living area in ranges
race_asian	From HIPAA Dataset: Asian or NA
race_white	From HIPAA Dataset: White or NA
race_black	From HIPAA Dataset: Black or NA
race_his	From HIPAA Dataset: Hispanic or NA
race_nam	From HIPAA Dataset: Native American or NA
fluoranthene	Copied from air data (Fluoranthene) in HIPAA Dataset
totalrooms	Computed from room1,…,room9 fields in HIPAA Dataset
numberBaths	Computed from room1,…,room9 fields in HIPAA Dataset
numberBeds	Computed from room1,…,room9 fields in HIPAA Dataset

Figure 2. Fields of the De-ID Dataset, as selected and computed from fields in the HIPAA Dataset listed in Appendix A. These 18 fields are the basis for re-identification. Possible values for birth_yr: 1920-1939, 1940-1949, 1950-69, or 1970-1989; for move-in: 1970-1989, 1990-1999,

or 2000-2009; housebuilt: 1840-1949 or 1950-1989; and for totalsquareft: 450-500, 500-650, 650-700, 700-1000, or 1000-2000.

Results for Step 4. Atchison Village and Liberty Village Property Registers

Atchison Village Property Register

As described earlier, the Attackers purchased the 2006 tax assessor data for Atchison Village from the County of Contra Costa Assessor's Office [29]. The Atchison Village Property Register had 124 fields and 450 data rows. The fields included the names of the owners, the address of the property, the numbers of bedrooms and baths, the total number of rooms, the year the house was built, and the total living area. The Attackers identified these 8 (of the 124 fields) fields as being relevant to re-identification; see Figure 3a.

All 450 properties had one living unit built in 1942. Most had two bedrooms, one bathroom, and a total of 4 rooms in a living area of 781 square feet (179 of 450 houses or 40 percent). Figure 3b displays the counts of bedrooms, bathrooms, total rooms, and living area in combination.

Field name	Field Description (original field names in tax assessor data)
owner1	Name of primary owner of property (P_OWNR_NM)
owner2	Name of secondary owner of property (OWN_NM_2ND)
address	Address of property (concatenate S_STR_NBR, S_STR_NM, S_STR_SUF)
numberBeds	Number of bedrooms (BEDS)
numberBaths	Number of bathrooms (BATHS)
totalrooms	Total number of rooms (TOT_ROOMS)
housebuilt	Year house built (YR_HS_BLT)
totalsquareft	Total living area (TLA)

Figure 3a. Fields of the Atchison Village Property Register, which are a subset of fields selected from the 2006 tax assessor data for Atchison Village, as acquired from the County of Contra Costa Assessor's Office [29].

Beds	Baths	Total Rooms	Living Area	Number of Units	Percent
1	1	3	554	68	15%
1	1	3	851	1	0%
2	1	4	672	47	10%
2	1	4	781	179	40%
2	1	4	787	36	8%
2	1	4	799	1	0%

Beds	Baths	Total Rooms	Living Area	Number of Units	Percent
2	1	4	799	2	0%
2	1	4	851	2	0%
2	1	4	865	1	0%
2	1	4	922	2	0%
2	1	5	1003	1	0%
2	1	5	1081	1	0%
2	1	5	736	1	0%
2	1	5	792	1	0%
2	1	5	851	2	0%
2	1.5	4	907	1	0%
2	1.5	4	925	1	0%
2	2	4	937	1	0%
3	1	5	851	47	10%
3	1	5	865	48	11%
3	1	6	1007	1	0%
3	1	6	885	1	0%
3	1	6	977	1	0%
3	1	7	1234	1	0%
3	1.5	6	971	1	0%
3	2	6	1188	1	0%
4	1	5	985	1	0%

Figure 3b. The number and percent of units in Atchison Village having specific combinations of bedrooms, bathrooms, total rooms, and total living area. There are a total of 450 units. The typical unit has 2 bedrooms and 1 bath (179 of 450 units or 40 percent).

Because the tax assessor data should be a complete record of all properties in Atchison Village, a list of the addresses from the Atchison Village Property Register should contain all the addresses of HES participants from Atchison Village. So the Attackers submitted the list of 450 addresses. At the end of the experiment, the Scorers reported that 32 of the addresses from HES participants appeared on the list, further suggesting that the remaining eight Richmond addresses are from Liberty Village.

Liberty Village Property Register

At the time of these experiments, Liberty Village was a 100-unit rental complex consisting of 50 duplexes comprised of one-, two- and three-bedroom single-story units that ranged from 528 square feet to 816 square feet [40]. The units were grouped into courtyards with a front and back yard for each residence, were carpeted, and had gas stoves and heating. There was also a clubhouse and a swimming pool. The one-bedroom units were 528 square feet, the two

bedroom units were 624 square feet, and the three bedroom units were 816 square feet [41]. All units had one kitchen, living room, and bathroom. The complex was built in 1942.

The Attackers used aerial Google images [34] to determine the bedroom count for each unit as follows. First, the Attackers measured the length of each roofline to determine the number of bedrooms in a unit. Then, they used parking spot numbers to estimate approximate street numbers for the addresses. Finally, the Attackers associated the addresses with the number of bedrooms for each unit. Below is a walk-through of the approach.

Figure 4 shows a Google image of Liberty Village. The buildings with the brown roofs are Liberty Village. From the image, each building has two pathways leading to the building, implying each building houses two rental units, with the possible exception of the clubhouse area.

The Attackers measured the lengths of the rooflines in a printed image and found that each roof was one of three measurements: 1.9 cm, 2.1 cm, or 2.6 cm. The roofline lengths and the fact that each building had two pathways led to the following inferences: each of the smallest buildings houses two one-bedroom units; each of the middle-sized building houses two of the two-bedroom units; and, each of the largest buildings houses two of the three-bedroom units. The 4 small buildings (red lines in Figure 5) identified 8 one-bedroom units. The 34 middle-sized buildings (green lines in Figure 5) identified 64 two-bedroom units. Finally, the 12 large buildings (blue lines in Figure 5) identified 24 three-bedroom units. In total, the Attackers graphically identified 100 units, which was the correct total number of units in Liberty Village.

The aerial Google images name streets. The Attackers used parking spot numbers to infer the street numbers of the units, as practical (yellow circles in Figure 6). The Google Earth interface allowed a user to identify some addresses by hovering over rooftops. The Attackers refined these addresses based on the parking spaces and unit address patterns (rectangles in Figure 6). The result was 111 addresses for the 100 units because of ambiguity with some addresses. The final street addresses were from 7 to 168 Chanslor Circle, from 6 to 30 Chanslor Row, from 14 to 24 Circle Court, from 118 to 217 Chanslor Avenue, and from 115 to 348 West Chanslor Avenue.

The 111 addresses identified as being in Liberty Village had 3 configurations based on the number of bedrooms. The most commonly occurring home had two bedrooms, one bathroom, a living room, and a kitchen, for a total of 6 rooms in a living area of 624 square feet. Figure 7 lists the counts of the three configurations.

The final result was the Liberty Village Property Register, which listed the address, number of bedrooms and baths, total rooms, year house built, and square footage for each of the 100 Liberty Village units at 111 addresses. See Figure 7.

Figure 4. Original Google aerial image of Liberty Village. The brown-roofed buildings comprise Liberty Village [34].

Figure 5. Measurements of the rooflines of the buildings in Liberty Village. Three measurements found: red was 1.9 cm, green was 2.1 cm, and blue was 2.6 cm. Red lines show duplexes with 2 one-bedroom units. Green lines show duplexes with 2 two-bedroom units. Blue lines show duplexes with 2 three-bedroom units. In total, there are 100 units.

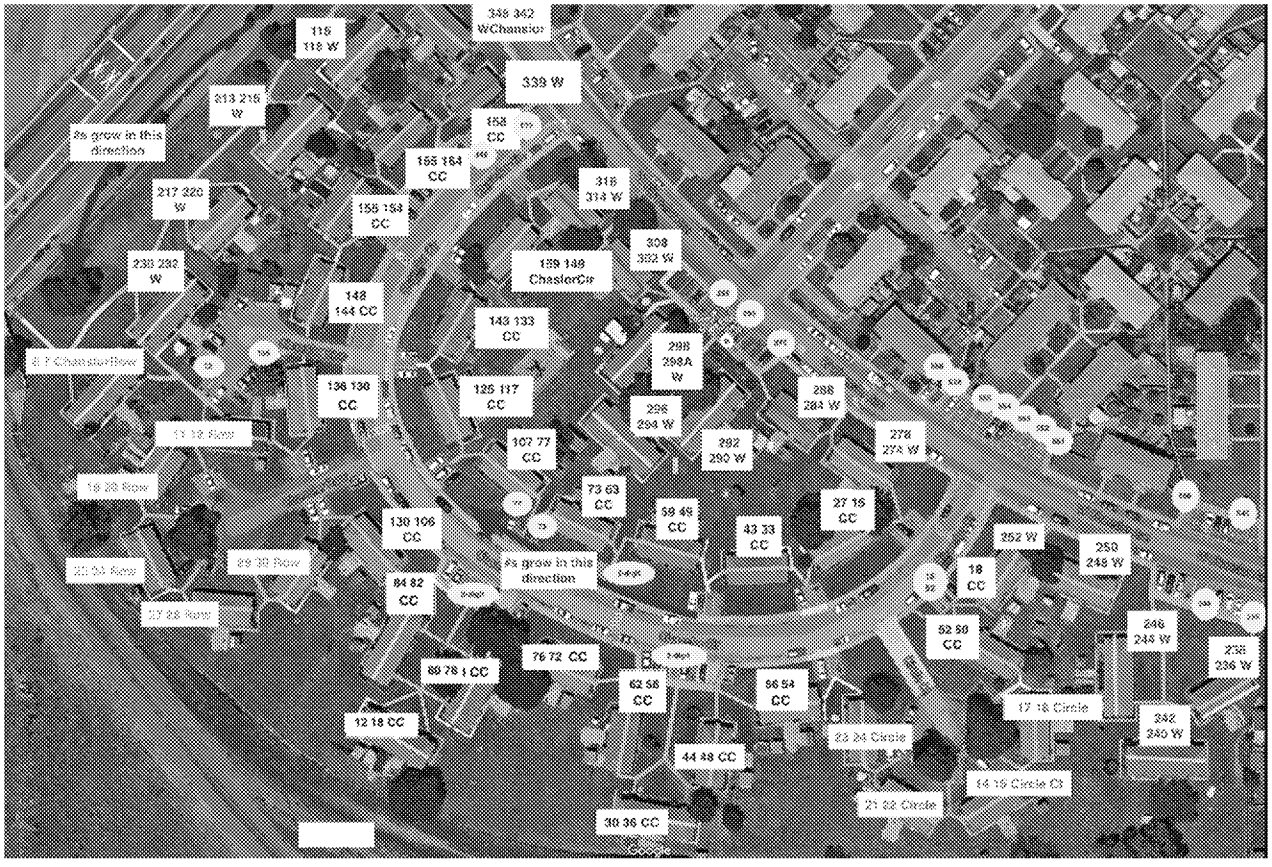


Figure 6. Addresses of the 100 units in Liberty Village (rectangles) and the parking spot numbers (yellow circles) as inferred by the Attackers. Streets are Chanslor Circle (CC), Chanslor Row (Row), Circle Court (Circle Ct), and West Chanslor Avenue (W).

Beds	Baths	Total Rooms	Living Area	Number	Percent
1	1	4	528	8	7%
2	1	5	624	75	67%
3	1	6	816	29	26%

Figure 7. The number and percentage of units in Liberty Village having specific combinations of bedrooms, bathrooms, total rooms, and total living area. A total of 100 units were found with 111 possible addresses. The typical unit has 2 bedrooms and 1 bath (75 of 111 units or 68 percent).

Field name	Field Description: and possible values
address	Address on: Circle Ct, W Chanslor Ave, or Chanslor Cir, Row, or Ave
numberBeds	Number of bedrooms: 1, 2, or 3
numberBaths	Number of bathrooms: 1
totalrooms	Total number of rooms: 4, 5, or 6
housebuilt	Year house built: 1942
totalsquareft	Total living area: 528 sq ft, 624 sq ft, or 816 sq ft

Figure 8. Fields of the Liberty Village Property Register constructed by the Attackers using aerial images and published facts about the rental community.

The Attackers sent a list of the 111 addresses from the Liberty Village Property Register to the Scorers. The Scorers reported, at the end of the experiment, that 5 of the addresses from HES participants appeared on the list. Together with the Atchison Property Register, the Attackers identified 37 out of 40 Richmond addresses. The HES researchers never disclosed the number of Liberty Village versus Atchison participants in their publication.

Results for Step 5. Bolinas Property Register

As described earlier, the Attackers purchased the 2006 Bolinas Tax Data [38]. Unlike the tax data for Atchison Village, the Bolinas tax data did not contain housing characteristics; specifically, it did not contain the number of rooms, bedrooms, baths, or total living area. Instead, the tax data for Bolinas included the address and owners of the property, the number of units on the property used for living, and then various fields related to the tax computations, such as land value. There were 26 fields and 1,583 data records. However, only 626 of the data records were properties that had units for living; the other records concerned land that apparently had no property on which people lived. Of the 626 real estate properties where people lived, only 610 had addresses listed. Most of the 610 addresses had single-family dwellings (572 of 610 or 94 percent). The median and average were homes with one living unit, and the standard deviation was 0.4. One property had the maximum of 6 units in which people lived.

The Attackers constructed a table with these fields: property id, the number of units on the property in which people live, the names of the owners, and the address for each property that had living units. We term this the "Bolinas Tax Data table."

The Marin County Tax Assessor's office had a website that displayed the number of bedrooms and baths and other housing characteristics for a property once a "property id" is given [39, 42]. Figure 9 steps through the pages of the website to display housing characteristics for the randomly selected residence having property id 188-100-05.

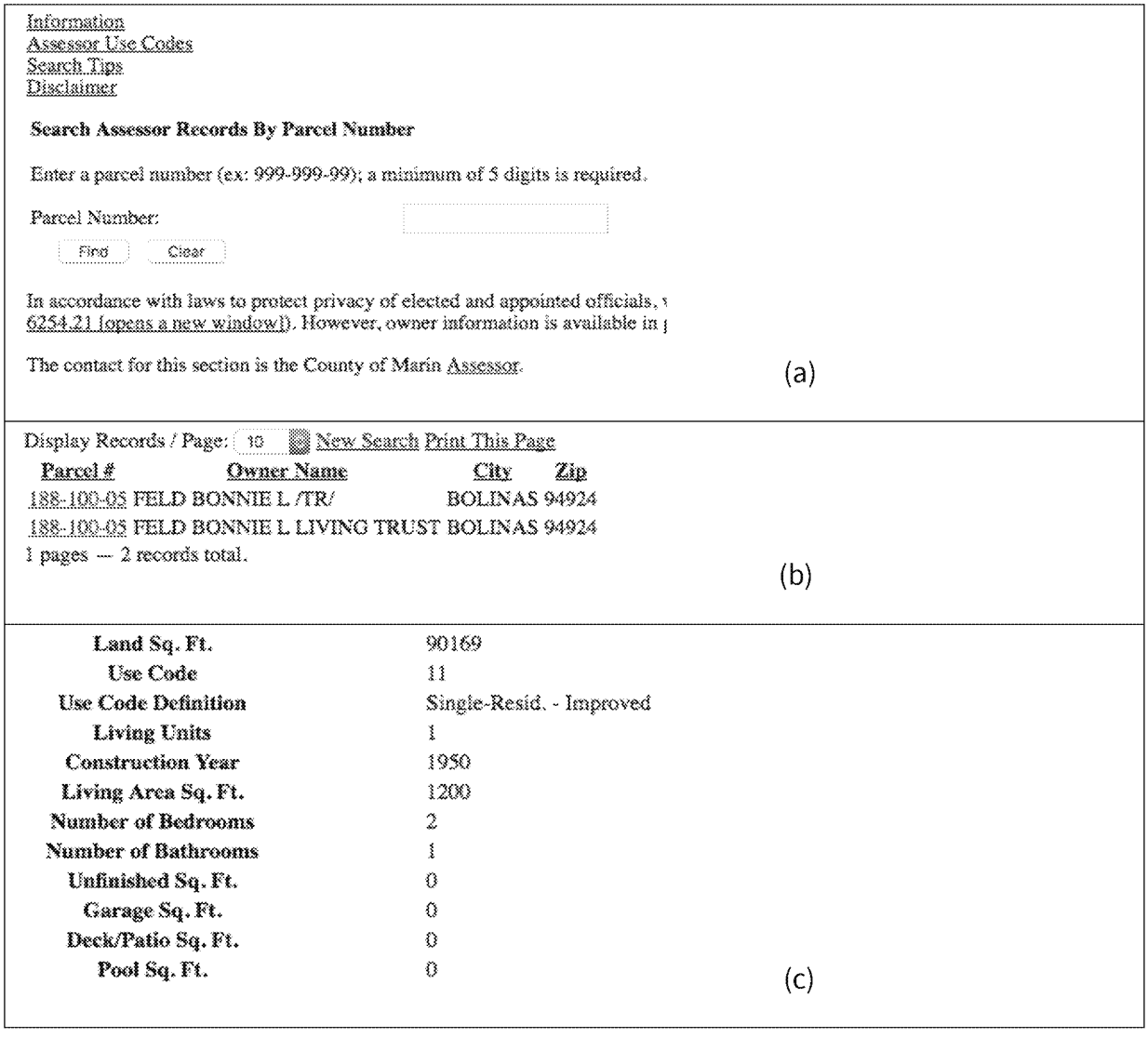


Figure 9. A walk-through of the Marin County Tax Assessor website [42] to learn the housing characteristics for a Bolinas property: (a) The initial screen requires a parcel number, which appears as the property id in the Bolinas Tax Data. (b) Search results for the property id (or parcel) 188-100-05. (c) Selection of a search result gives housing characteristics for the property id, in this case a single residential home constructed in 1950 having 2 bedrooms and 1 bath in a living area of 1,200 square feet.

Using the website added uncertainty, because the identity of the homeowners was from 2006 tax data but the housing characteristics were mined from the website in 2013 (and replicated in 2017). An HES participant from Bolinas could have made home renovations that changed the number of bedrooms or bathrooms during this time, and if so, the recorded information would not match the 2006 information.

Regardless, the Attackers automated the process shown in Figure 8 by writing a Python program that used the property (parcel) ids from the Bolinas Tax Data to walk through the website in the same way a human would to retrieve the housing characteristics for each of the 610 Bolinas residences. If an error was encountered, the Attackers then searched for properties having the same first groups of digits on the parcel number and the same owner that did not otherwise appear on the list. In these cases, the parcel numbers may have changed between the date of the tax data (2006) and the web searches of housing characteristics (2013 and replicated in 2107), so this was a means of locating the new property id to fetch the housing characteristics. The website provided housing characteristics for 533 of the 610 parcels. Searches for the remaining 77 parcels gave an error, and no other parcel id was found for the property.

Of the 533 parcels found on the assessor's website, 3 were built after 2006, so they were dropped. The final result was housing, address, and ownership information for 530 of 610 (or 87 percent) of the Bolinas residential properties. Of these 530 addresses, 105 (20 percent) had parcel changes since 2006, most of which were subdivisions. An unknown number of parcels may have further changed, and likely increased, the number of bedrooms or baths since 2006.

The Attackers constructed a file that associated the owner names and property addresses from the Bolinas Tax Data with the housing characteristics retrieved from the website for the same property; this is the "Bolinas Property Register." It had 8 fields and 530 data rows. Figure 11 lists its fields.

The Bolinas Property Register is similar to the Atchison and Liberty property registers, except it does not include the total number of rooms. It does include the names of owners, whereas the Liberty Property Register includes no names. The Bolinas Property Register additionally includes the square footage of the garage.

The Bolinas properties were far less homogeneous than the Atchison Village and Liberty Village properties. Of the 530 properties in the Bolinas Property Register, 477 (or 90 percent) had a unique combination of bedrooms, baths, and living area, with the variability being greatest in the amount of living area. For example, the largest number of residences having the same combination of bedrooms, baths, and living area was 7 for homes having 2 bedrooms and one bathroom and 768 square feet. Even though 158 (or 30 percent) of the 530 homes had 2 bedrooms and one bathroom, the possible living areas ranged from 465 to 2,338 square feet, with a median of 968 square feet, an average of 1,057 and a standard deviation of 361. Figure 10 shows descriptive statistics for each housing characteristic separately.

Bedrooms	Total	Percent
0	3	1%
1	93	18%
2	232	44%
3	131	25%
4	46	9%
5	15	3%
6	5	1%
7	3	1%
8	1	0%
9	1	0%
Baths	**Total**	**Percent**
0	2	0%
1	281	53%
1.5	33	6%
2	137	26%
2.5	27	5%
3	28	5%
3.5	8	2%
4	9	2%
5	3	1%
5.5	2	0%
Total Living Area	**Square ft.**	
Smallest	274	
Largest	8,093	
Median	1,311	
Average	1,496	
Standard Deviation	815	
Year House Built		
Earliest	1879	
Latest	2005	
Median	1959	
Average	1929	
Standard Deviation	208	
Value not known	6	
Total Units	**530**	

Figure 10. Number and percentage of bedrooms and baths, and statistics about the living space and year houses were built in Bolinas, based on a total of 530 addresses having descriptive tax assessor data [38, 39, 42].

Field name	Field Description (original field names in tax assessor data)
owner1	Name of primary owner of property
owner2	Name of secondary owner of property
address	Address of property
numberBeds	Number of bedrooms
numberBaths	Number of bathrooms
housebuilt	Year house built
totalsquareft	Total living area
garagesqft	Total square feet of garage

Figure 11. Fields of the Bolinas Property Register. Addresses and ownership based on 2006 tax assessor data, as acquired from the Marin County Assessor's Office [38]. Housing characteristics from the Marin County Assessor's Website in 2013 [39, 42].

The Attackers sent a list of the 530 addresses that constitute the Bolinas Property Register to the Scorers. The Scorers reported, at the end of the experiment, that 9 of the 10 Bolinas addresses of HES participants (or 90 percent) appeared in the Bolinas Property Register.

Results for Step 6. People Registers

At this point, the Attackers had constructed three property registers, one each for Atchison Village, Liberty Village, and Bolinas. Later, the Attackers used these property registers in the first stage of the re-identification, as depicted on the left side of Figure 1. The second stage of the re-identification required the construction of people registers, which are lists of named people known to have lived at the addresses during the study period.

The names of homeowners from the Atchison Village property data were not used as a people register because the Atchison Village Cooperative accommodates relocations within Atchison Village. As a consequence, the tax data for an individual property may not reflect the true resident at the time of the study. The names of homeowners from the Bolinas property data were not used as a people register because some participants from Bolinas rented. So the Attackers constructed people registers for all 3 communities using the following 3 steps:

1. Start with a blank people register. The fields are: address, name, birth year, move-in and move-out years, gender, and race.
2. For each address in the property register:
   Search a public data broker's website [31, 32] for people who lived at the address during 2006 (the study period).

   a. For each person found:
      Add a record to the people register that contains the person's name, birth year, the earliest year they were known to live at the address, and the year they moved out, if provided.
3. For each name acquired in (2) above:
   a. Infer the person's gender, as possible, from the person's first name and append the information to the person's record in the people register.
   b. Infer the race or ethnicity of the person, as possible, from the person's last name (also known as the family or surname) and append the information to the person's record in the people register. Using last names to infer race is not a good predictor of Blacks because Whites and Blacks often share a last name. Therefore, some number of those identified as white may be black using last name inference.

The subsections below describe the demographics of the people register in more detail than is necessary to interpret the results. The reader can advance to the summary subsection, Summary of Property and People Registers, without loss of information sufficient to understand the results. Meanwhile, the reader seeking a deeper understanding of the communities involved in this study should proceed.

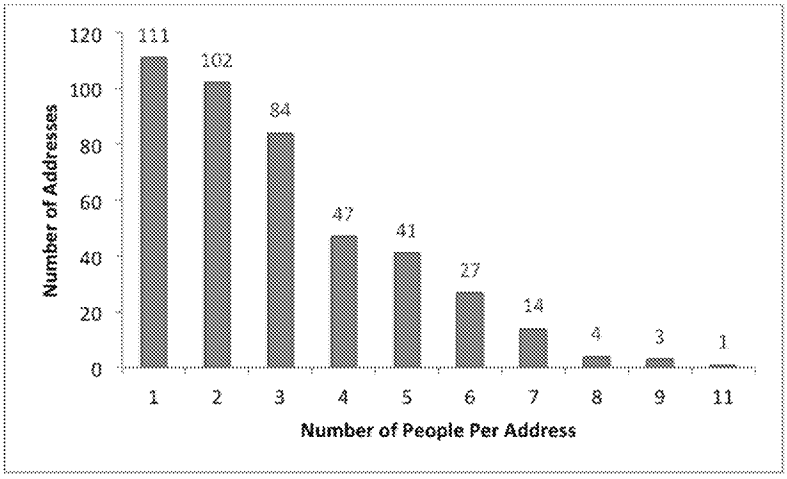
Atchison Village People Register

The Attackers searched each of the 450 addresses from the Atchison Village Property Register on the public data broker's website. Names and demographics for 1,290 adult residents were found for 434 (or 96 percent) of the addresses; 16 addresses reported no residents.

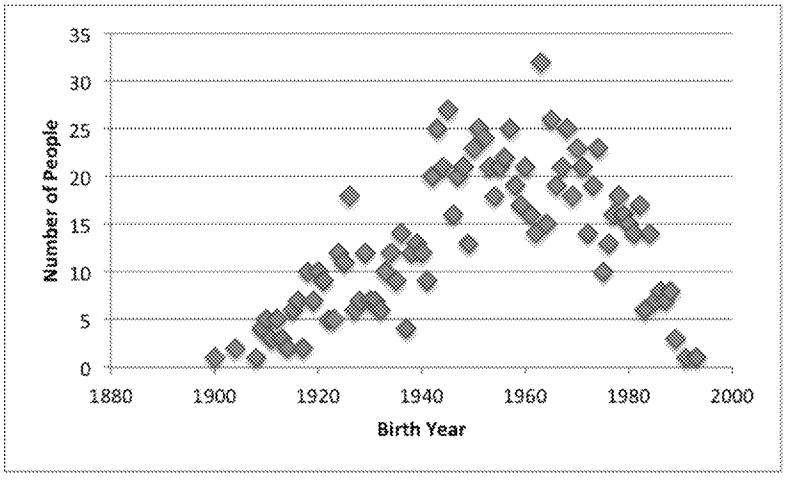
Almost half the addresses (213 of 434 or 49 percent) had 1 or 2 adult residents. Figure 12(a) shows the distribution of the number of adults per address: 1,127 of 1,290 (or 87 percent) of the people had a year of birth. Figure 12(b) shows the distribution of the birth years of the adults. The youngest people were born in 1993 and the oldest in 1900. The median year of birth was 1956 and the average was 1954 with a standard deviation of 19 for the 1,127 people having birth year information.

Figure 12(c) shows the distribution of move-in dates. The person living at their Atchison Village address the longest moved into the residence in 1970. The median year in which people moved to their Atchison address was 1998, and the average was 1997 with a standard deviation of 7 for the 1290 people.

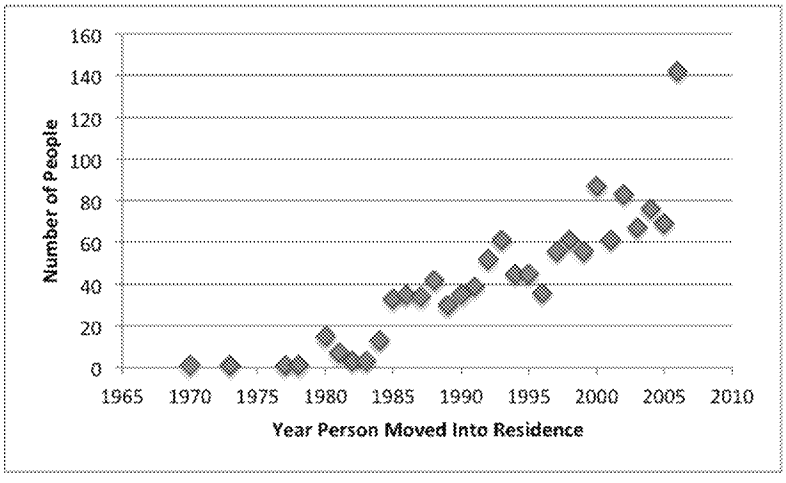
Many people (142 of 1,290 or 11 percent) moved into their Atchison residence during the year of the study, while 76 residents moved out during the study year of 2006.


Number of Addresses
120
100
80
60
40
20
0
111
102
84
47
41
27
14
4
3
1
1
2
3
4
5
6
7
8
9
11
Number of People Per Address

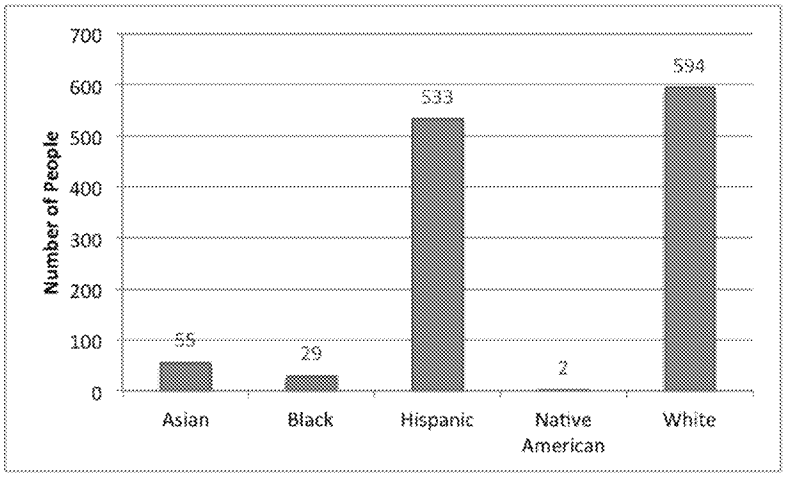
(a)


Number of People
35
30
25
20
15
10
5
0
1880
1900
1920
1940
1960
1980
2000
Birth Year

(b)


Number of People
160
140
120
100
80
60
40
20
0
1965
1970
1975
1980
1985
1990
1995
2000
2005
2010
Year Person Moved into Residence

(c)



(d)

Figure 12. Distributions of information about named people who lived in Atchison Village in 2006: (a) the number of people per address; (b) their birth years; (c) the year in which they moved into their residence; and, (d) residents' race or ethnicity inferred from last name by computer program. Using last names to infer race is not a good predictor of Blacks; some number of those identified as white may be black.

The Attackers wrote a Python program that used a list of the 1,645 most popular first names and their frequency of gender usage in the 1990 U.S. Census [35] to assign gender. Of the 1,290 names for residents identified in Atchison Village, 560 (43 percent) had first names more likely to be associated with males, and 582 (45 percent) had first names more likely to be associated with females. Gender was assigned to 1,142 of 1,290 (89 percent) of the names in the Atchison Village People Register.

The Attackers wrote a Python program that used a list of the 151,671 most popular last names and their frequency by race and ethnicity in the 2000 U.S. Census [36]. Of the 1,290 names found for residents in Atchison Village, 594 (46 percent) had last names more often associated with Whites, 533 (41 percent) had names more often associated with Hispanics, and 77 names (6 percent) could not be assigned an inferred race. Figure 12(d) shows the distribution by race and ethnicity. Values in the race field in the Atchison Village People Register were assigned accordingly.

The Attackers submitted the names of the 1,290 residents that they found as residents of Atchison Village in 2006. At the end of the experiment, the Scorers reported that 32 of the names from HES participants appeared on the list of 1,290 residents.

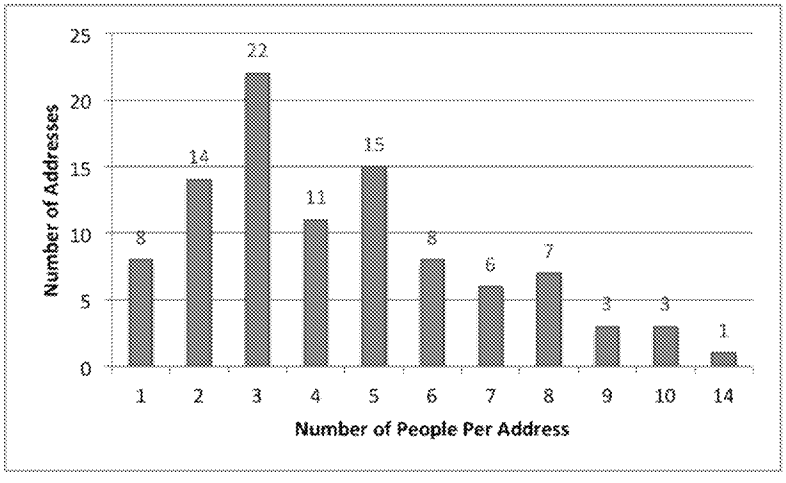
Liberty Village People Register

The Attackers searched each of the 111 addresses from the Liberty Village Property Register on the public data broker's website. Names and demographics for 438 adult residents were

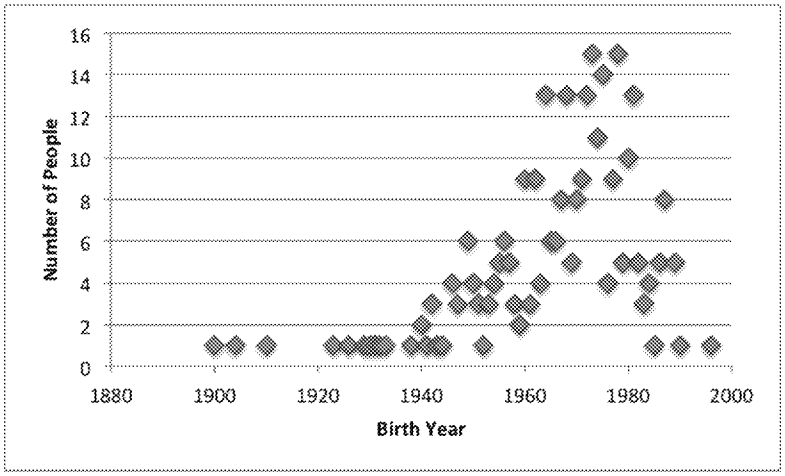
found for 98 addresses. Recall, Liberty Village actually had 100 units with 100 addresses, and the Attackers had derived 11 additional addresses. The data broker's website found some addresses defunct, yielding people for 98 of 100 (98 percent) units.

Almost half the addresses (44 of 98 or 45 percent) had 1, 2, or 3 adult residents; see Figure 13(a). Only 303 of 438 (or 69 percent) of the people had year of birth. Figure 13(b) shows the distribution of the birth years. The youngest person was born in 1996 and the oldest in 1900. The median year of birth was 1970, and the average was 1967 with a standard deviation of 14 for the 303 people. Figure 13(c) shows the distribution of move-in dates. The person living at their Liberty Village address the longest moved into the residence in 1980. The median year was 2004, and the average was 2003 with a standard deviation of 4 for the 438 people.

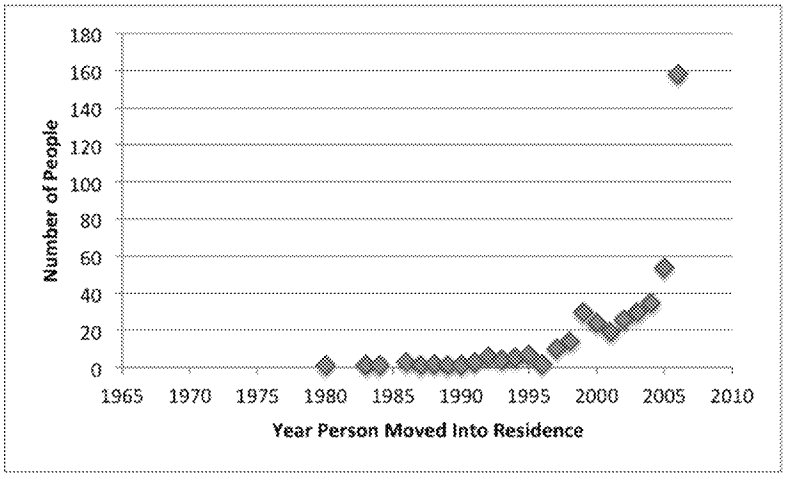
Many people (158 of 438 or 36 percent) moved into their Liberty Village residence during the year of the original study. Many people (112 of 438 or 26 percent) also moved out of their Liberty Village residence during the study year. The number of named residents that the Attackers found who neither moved in nor moved out of Liberty Village during 2006 was 244 (of 438 or 56 percent) of the residents, which is about half of all the Liberty Village residents that the Attackers identified.



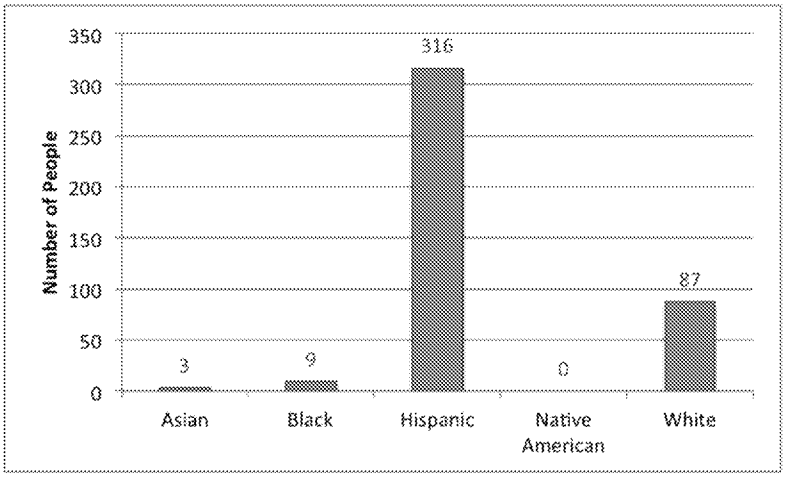
(a)



(b)



(c)



(d)

Figure 13. Distributions of information about named people who lived in Liberty Village in 2006: (a) the number of people per address; (b) their birth years; (c) the year in which they moved into their residence; and, (d) residents' race or ethnicity inferred from last name by

computer program. Using last names to infer race is not a good predictor of Blacks; some number of those identified as white may be black.

The Attackers used their Python program (described earlier) to assign gender to the names of the people identified as living in Liberty Village during the study year. Of the 438 names of residents identified in Liberty Village, 209 (48 percent) had first names more likely to be associated with males, and 161 (37 percent) had first names more likely to be associated with females. Gender was assigned to 370 of 438 (84 percent) of the names in the Liberty Village People Register.

The Attackers used their Python program (described earlier) to assign race and ethnicity to the names of the residents identified as living in Liberty Village during the study year. Of the 438 names found for residents in Liberty Village, 316 (72 percent) had last names more often associated with Hispanics, 87 (20 percent) had names more often associated with Whites, and 23 (5 percent) had no race or ethnicity assigned. Figure 13(d) shows the distribution. Overall, 415 of 438 (95 percent) of the surnames were assigned a race or ethnicity.

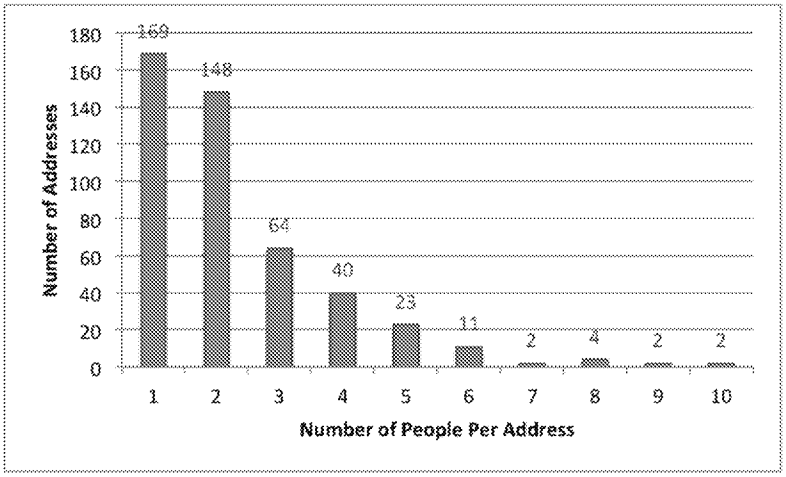
The Attackers submitted the names of the 438 residents that they found as residents of Liberty Village in 2006. At the end of the experiment, the Scorers reported that 3 of the names from HES participants appeared on the list of 438 residents.

Bolinas People Register

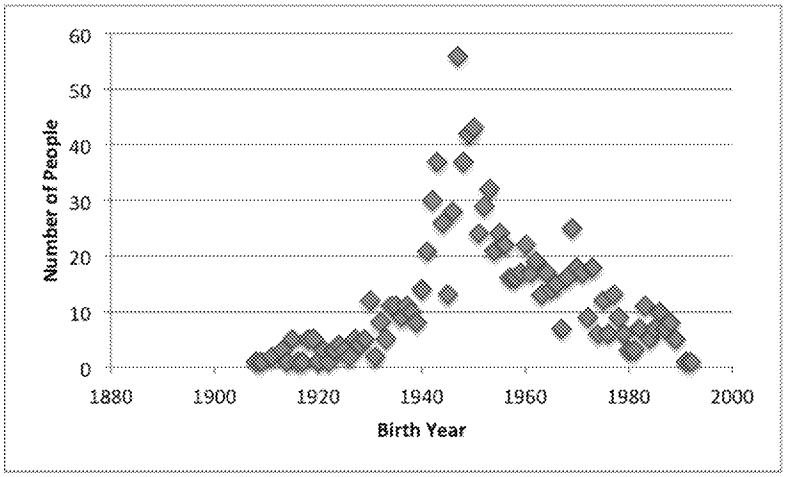
The Attackers searched each of the 530 addresses from the Bolinas Property Register on the public data broker's website. Names and demographics for 1,082 adult residents were found for 465 (87 percent) of the addresses; 67 addresses reported no residents.

More than half the addresses (317 of 465 or 68 percent) had 1 or 2 adult residents; see Figure 14(a). Most people, 1,038 of 1,082 (96 percent), had a year of birth; only 44 did not; see Figure 14(b). The youngest person was born in 1992 and the oldest in 1908. The median year was 1952, and the average was 1954 with a standard deviation of 16 for the 1,038 people. Figure 14(c) shows the distribution of move-in dates. The person living at their Bolinas address the longest moved into the residence in 1963. The median year was 1994, and the average was 1994 with a standard deviation of 8 for the 1,082 people.

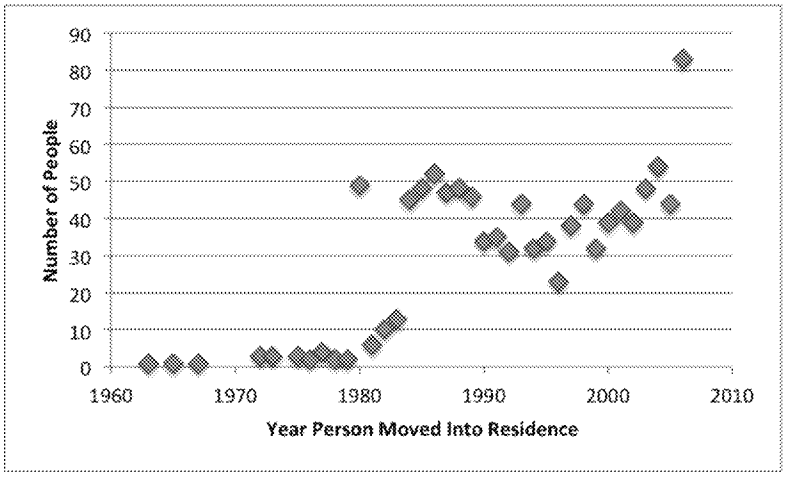
Some people (83 of 1,082 or 8 percent) moved into their Bolinas residence during the year of the study. Similarly, some Bolinas residents (90) moved out during the study year of 2006. The number of named residents that the Attackers found who neither moved in nor moved out of Bolinas during 2006 was 949 people.



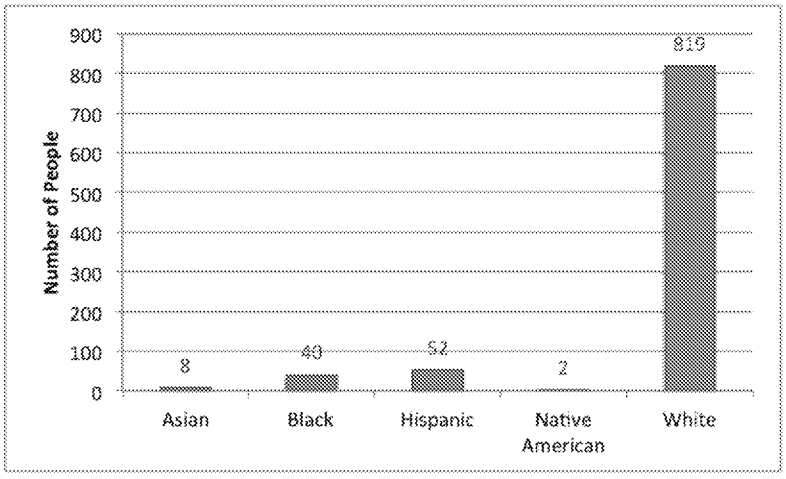
(a)



(b)



(c)



(d)

Figure 14. Distributions of information about named people who lived in Bolinas in 2006: (a) the number of people per address; (b) their birth years; (c) the year in which they moved into their residence; and, (d) residents' race or ethnicity inferred from last name by computer program. Using last names to infer race is not a good predictor of Blacks; some number of those identified as white may be black.

The Attackers used their Python program (described earlier) to assign gender to the names of the people identified as living in Bolinas during the study year. Of the 1,082 names of residents identified in Bolinas, 476 (44 percent) had first names more likely to be associated with males, and 495 (46 percent) had first names more likely to be associated with females. Gender was assigned to 971 of 1,082 (90 percent) of the names in the Bolinas People Register.

The Attackers used their Python program (described earlier) to assign race and ethnicity to the names of the residents identified as living in Bolinas during the study year. Of the 1,082 names found for residents in Bolinas: 52 (5 percent) had last names more often associated with Hispanics, 819 (76 percent) had names more often associated with Whites, and 161 (or 15 percent) had no assignment; see Figure 13(d). Overall, 921 (of 1082 or 85 percent) of the surnames were assigned a race or ethnicity.

The Attackers submitted the names of the 1082 residents that they found as residents of Bolinas in 2006. At the end of the experiment, the Scorers reported that 5 of 10 (or 50 percent) of the names from HES participants appeared on the list of 1,082 residents.

Summary of Property and People Registers

Each property register was produced in a distinct manner. The Atchison Village Property Register, containing 450 addresses, came directly from the tax assessor data, and therefore should contain all addresses in Atchison Village with their appropriate housing characteristics. Liberty Village was a rental community of 100 units. The Attackers constructed a property register by inferring 111 addresses and housing characteristics for the 100 units. The Bolinas Property Register started with tax information to identify addressed parcels having living units, but the Attackers mined the housing characteristics from a tax assessor website almost 10 years after the study for the list of 530 addresses. Therefore, the Atchison Village and Liberty Property Registers appear to be the most complete and Atchison the most accurate.

The communities differed in their property characteristics and homogeneity. Atchison Village and Bolinas were both communities of primarily homeowners, whereas Liberty Village was a rental complex. The housing characteristics – number of bedrooms and baths and living area – of Atchison Village and Liberty Village were homogeneous. Most homes had two bedrooms and one bathroom built in 1942.

Of the 530 properties in the Bolinas Property Register, 477 (90 percent) had a unique combination of beds, baths, and living area with the variability being greatest in the amount of living area. The houses were built between 1879 and 2005 with a median year of 1959. The largest number of residences having the same combination of bedrooms, baths and living area was only 7 homes, which had 2 bedrooms and one bathroom with a living area of 768 square feet.

The Attackers constructed population registers using information available from a data broker. While the information seemed reasonable and comprehensive, there was no guarantee that the data were accurate or complete.

The characteristics of residents differed among the communities. The residents found for Atchison Village had last names the computer program associated with Whites (46 percent) and Hispanics (41 percent). The names found for residents in Liberty Village were much more frequently associated by the computer program with Hispanics (72 percent) than Whites (20 percent). The computer program associated names of Bolinas residents predominantly with Whites (76 percent) with few Hispanics (5 percent).

Liberty Village experienced a lot of mobility during the study year (as reported earlier in Liberty Village People Register). A total of 76 of the 98 units (78 percent) changed occupancy during the year of the study. A third of the properties in Atchison Village changed occupants during the study year (150 of the 450 or 33 percent). However, few of the Bolinas residences changed occupancy during the same year (40 of the 530 or 8 percent of the addresses).

The characteristics described above about these people registers place important limits on re-identification attempts. Here is a summary based on a comparison of demographic homogeneity, the number of adults per residence, mobility, and data quality.

The more homogeneous a community, the more difficult it is to acquire correct small group re-identifications because many different people and homes share the same features indistinguishably. All three groups are homogeneous, but there is a noticeable difference in racial homogeneity. The Liberty Village People Register is almost all Hispanic, and the Bolinas People Register is almost all White. Only the Atchison Village People Register has substantive variability in race (about half Hispanic), so we might expect more matches from Atchison Village than the other two. Liberty Village had the most homogeneous property register.

A population having more adults per residence will likely make larger groups in matches of people by name based on housing. The Liberty Village People Register has many more people on average per household than does Atchison Village or Bolinas, so we might expect Liberty Village to have fewer small group re-identifications.

The greater the number of people moving in and out of a residence during the year of the study, the more difficult it is to match a person to a residence because the register and the data may show different residents for the same year. Liberty Village had the greatest mobility during the study period.

Finally, using Bolinas housing characteristics that are 10 years newer than the study data would be expected to limit correct matchups of Bolinas data.

Results for Step 7. Re-identifications

Matching Characteristics

Matches between the property data and the HES records in the De-ID Dataset should have no garage, the same number of bedrooms and baths, and, in the case of Richmond homes, be built in 1942.

At least 32 of the 50 properties (64 percent) in the De-ID Dataset were from Atchison Village, yet the property square footages did not match those listed in the De-ID Dataset even accounting for smaller units at Liberty Village. The Attackers modeled the records in the De-ID Dataset as a random sample drawn from the three different communities and then compared the distributions of their square footages for living units. The Attackers assumed the distributions in the De-ID dataset were representative of the population, so normalizing the distributions allowed the Attackers to associate values in the De-ID dataset with likely equivalents in the property data based on the following cut-offs used for all three communities.

totalsquareft in De-ID Dataset	Total Living Area in Property Data
400-450	<= 750
450-500	>=700 and <=790
500-650	>=736 and <=890
650-700	>=840 and <=910
700-1,000	>=875 and <=1,125
1,000-2,000	>= 1,080

A record in a people register matches a record in the De-ID Dataset if the person's birth year, move-in date, gender, and race or ethnicity assignment agrees. A person's year of birth would match to one the following ranges: 1920-1939, 1940-1949, 1950-1969, and 1970-1989. Similarly, a person's move-in year in a people register matches one of the following ranges found in records in the De-ID Dataset: 1970-1989, 1990-1999, or 2000-2009. Gender is Male or Female and race is one or more of: Black, White, Hispanic, Asian, or Native American.

Two sets of matches exist based on whether a computer or human assigned gender and race. The computer-assigned set also includes whether matches to missing values for gender or race in the people register are used or not. The set whose values for race and gender were tagged manually matches only to non-blank results. Below we report on the most relevant results.

The subsections below describe details of matchups and the scoring of matchups in detail by community. A summary of results starts the Discussion section.

Atchison Village Re-Identifications

The Attackers matched the records in the Richmond records of the De-ID Dataset to those in the Atchison Village Property Register based on housing characteristics using a computer program written by the Attackers; see Figure 1(a). The program matched records having the same number of bedrooms and baths, having been built in 1942, and having living areas consistent with the ranges described earlier.

The result was 3,813 matches for 32 of 40 (or 80 percent) of the Richmond records. These matches agreed with the 32 records the Attackers considered to be Atchison Village records. The Attackers continued their analysis with these 32 possible Atchison Village records.

Two records in the De-ID Dataset each matched to only one record in the Atchison Village Property Register. In terms of the maximum number of matches, 3 records in the De-ID Dataset matched to 223 different records in the Atchison Village Property Register. The same record in the Atchison Village Property Register may match to more than one record in the De-ID Dataset. Figure 15 shows the cumulative number of Richmond records in the De-ID Dataset matched to records in Atchison Village Property Register by binsize.

This matching result combines the Atchison Village Property Data to the De-ID dataset. Subsequent steps use this combined dataset.

Number of Property Records in a Match (Binsize)	Cumulative Number of Matches
1	2
3	3
5	4
7	6
48	7
68	11
96	20
215	29
223	32

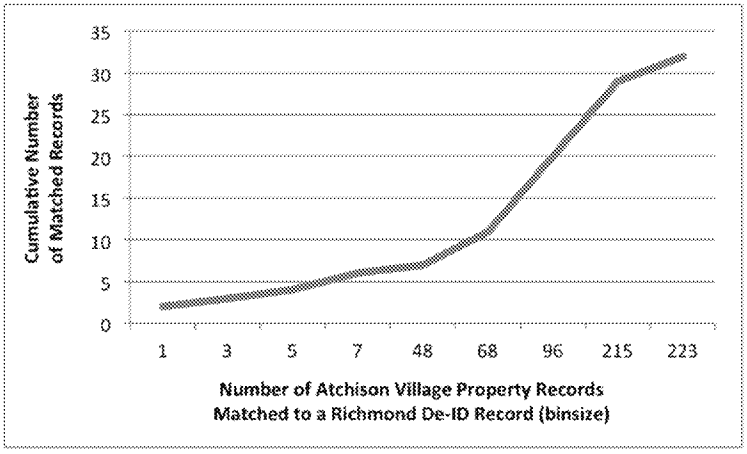


Figure 15. Matches of records in the Atchison Village Property Register to 32 records in the De-ID Dataset based on housing characteristics alone. The binsize is the number of property records matched to the same De-ID Dataset record. Two records matched uniquely. Three records in the De-ID Dataset each matched to 223 records in the Atchison Village Property Register. The same record in the Atchison Village Property Register may match to more than one record in the De-ID Dataset.

Atchison Village Re-Identifications: Named People with Hand Labels

The Attackers matched the combined Atchison Village property and De-ID data to records in the Atchison Village People Register using a Python program that the Attackers wrote. The program matched records based on birth year and move-in year information; see Figure 1(b). Gender and race were not used. The Attackers then manually assigned race and ethnicity and gender to the matching records and concluded the matching manually using information from HES Publications and a spreadsheet program.

The Attackers found a total of 121 matches of people from the Atchison People Register to records in the combined Atchison Village De-ID and property data for 17 of 32 (53 percent) of the Atchison records having a small group (k<20) re-identification. Five matches were unique re-identifications. For k<5, the risk pool was 9 people for 7 re-identifications. For k<11, the risk pool was 40 people for 12 re-identifications. For k<20 the risk pool was 109 people for 17 re-identifications. Some people appear in more than one group. Figure 16 shows the accounting of binsizes for the matches.

Number of Named People Matched to Same De-ID Record (Binsize)	Number of Binsized Groups
1	5
2	1
3	1
6	1
7	1
8	2
10	1
11	1
14	2
15	1
18	1

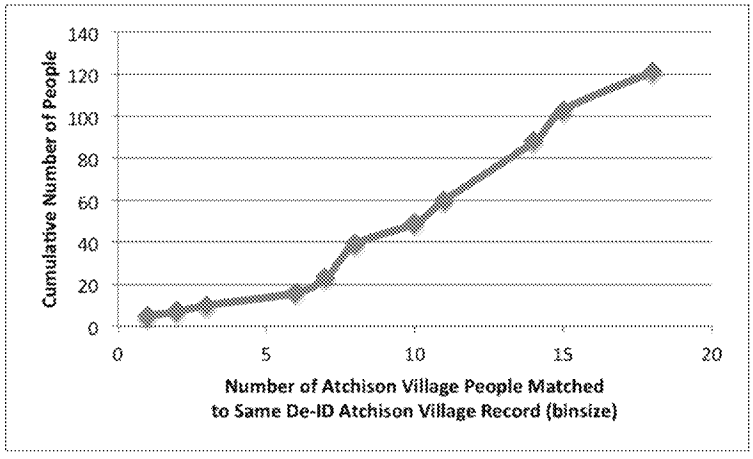


Figure 16. Small group re-identification (*k*<20) of named Atchison Village people based on housing characteristics and personal demographics with human-assigned values for gender and race. Matching records in the combined Atchison Village property and De-ID Dataset were further matched to records in the Atchison Village People Register; see Figure 1(b). Binsize is the number of named people matched to combined De-ID and property records. A total of 121 matches to named people appeared for 17 of 32 (or 53 percent) of the De-ID Dataset records for Atchison Village having small group (*k*<20) re-identifications.

Atchison Village Re-Identifications: Addresses with Hand Labels

The Attackers also examined the re-identification of addresses from the same Atchison Village People Register in which the Attackers manually assigned gender and race. The Attackers found a total of 135 matches of addresses from the Atchison Village People Register to records in the combined Richmond De-ID and Atchison Village property data for 18 of 32 (56 percent) of the Atchison Village records having a small group (*k*<20) re-identification. As had been the case with matches to named people, 5 were unique re-identifications. For *k<5*, the risk pool was 9 addresses for 7 re-identifications. For *k<11*, the risk pool was 39 addresses for 12 re-identifications. And, for *k<20* the risk pool was 109 addresses for 18 re-identifications. Some addresses appear in more than one group. Figure 17 shows the accounting of binsizes for the matches.

Number of Addresses Matched to Same De-ID Record (Binsize)	Number of Binsized Groups
1	5
2	1
3	1
6	1
7	3
10	1
11	1
14	3
16	1
19	1

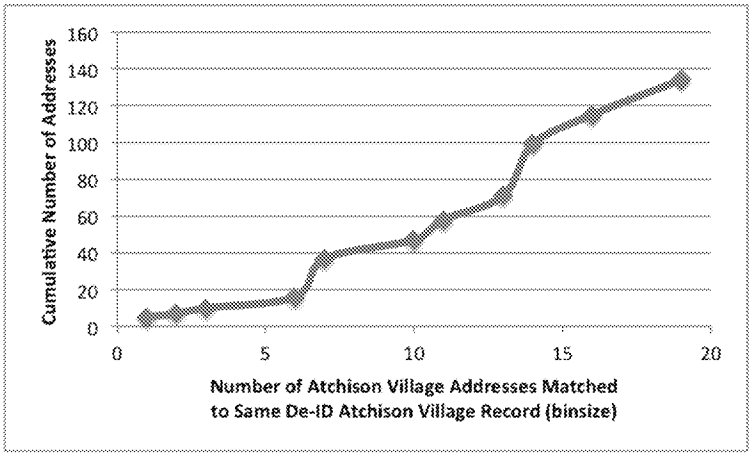


Figure 17. Small group re-identifications (*k*<20) of Atchison Village addresses based on housing characteristics and personal demographics with human-assigned values for gender and race. Matching records in the combined Atchison Village property and De-ID Dataset were further matched to records in the Atchison Village People Register; see Figure 1(b). Binsize is the number of addresses matched to combined De-ID and property records. A total of 135 small group (*k*<20) matches to addresses appeared for 18 of 32 (56 percent) of the De-ID Dataset records for Atchison Village.

Atchison Village Re-Identifications: People with Computer-Assigned Labels

The Attackers then matched the combined Atchison Village property and De-ID data to records in the Atchison Village People Register using a Python program that the Attackers wrote that included matches on the computer assignment of values for gender and race. Matches were based on birth year, move-in date, race and ethnicity, and gender. Blank entries were not matched.

The computer program found a total of 162 matches of people from the Atchison Village People Register to records in the combined Atchison Village De-ID and property data for 21 of 32 (66 percent) of the Atchison Village records having small group (*k*<20) re-identifications. Two matches were unique re-identifications. For *k<5*, the risk pool was 15 people for 7 re-identifications. For *k<11*, the risk pool was 58 people for 14 re-identifications. And, for *k<20* the risk pool was 124 people for 21 re-identifications. Some people appear in more than one group. Figure 18 shows the accounting of binsizes for these matches.

Number of Named People Matched to Same De-ID Record (Binsize)	Number of Binsized Groups
1	2
3	3
4	2
5	1
6	1
7	2
8	2
10	1
11	1
12	3
14	2
17	1

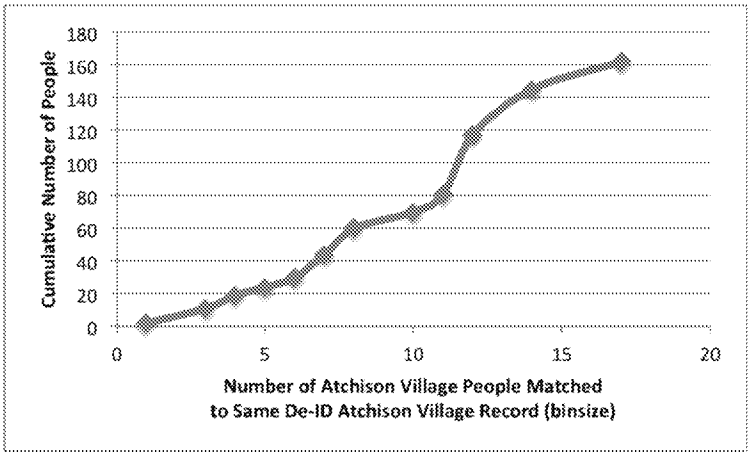


Figure 18. Small group re-identifications (*k*<20) of named Atchison Village people based on housing characteristics and personal demographics with computer-assigned values for gender and race. Matching records in the combined Atchison Village property and De-ID Dataset were further matched to records in the Atchison Village People Register; see Figure 1(b). Binsize is the number of named people matched to the combined De-ID and property records. A total of 162 small group (*k*<20) matches of named people appeared for 21 of 32 (66 percent) of the De-ID Dataset records for Atchison Village.

Atchison Village Re-Identifications: Addresses with Computer Assigned Labels

The Attackers also examined the re-identification of Atchison Village addresses from the same data in which a computer program assigned gender and race. The Attackers found a total of 159 matches of addresses from the Atchison Village People Register to records in the combined Atchison Village De-ID and property data for 21 of 32 (66 percent) of the Atchison Village records having a small group (*k*<20) re-identification. There were 2 unique re-identifications. For *k<5*, the risk pool was 16 addresses for 7 re-identifications. For *k<11*, the risk pool was 57 addresses for 14 re-identifications. And, for *k<20* the risk pool was 108 addresses for 21 re-identifications. Figure 19 shows the accounting of binsizes for the matches.

Number of Addresses Matched to Same De-ID Record (Binsize)	Number of Binsized Groups
1	2
3	3
4	2
5	2
7	2
8	2
10	1
11	3
12	1
14	2
17	1

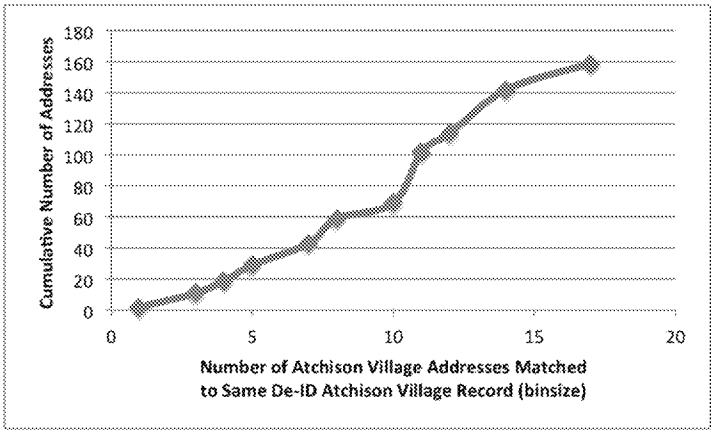


Figure 19. Small group re-identifications (*k*<20) of Atchison Village addresses based on housing characteristics and personal demographics with computer-assigned values for gender and race. Matching records in the combined Atchison Village property and De-ID Dataset were further matched to records in the Atchison Village People Register; see Figure 1(b). Binsize is the number of addresses matched to combined De-ID and property records. A total of 159 matches of addresses appeared for 21 of 32 (66 percent) of the De-ID Dataset records for Atchison Village having small group (*k*<20) re-identifications.

Atchison Village Re-Identifications: Results

The Attackers sent small group results for addresses and named people for Atchison Village re-identifications to the Scorers to identify which, if any, of the groups sized $k<20$ had a correct match. Figure 20 provides a summary of the results sent to the Scorers. Of the hand-labeled groups, 7 of the 17 (41 percent) named people groups contained the correct person, and 10 of 18 (56 percent) address groups contained the correct address. The computer labeled matches scored better. One of the 2 unique re-identifications was correct for the named person and the address, 16 of the 21 (76 percent) of the named people groups $k<20$ contained the correct person, and 16 of 21 (76 percent) of the address groups $k<20$ contained the correct address. Figure 21 and Figure 22 show the detailed results.

Overall, the Attackers correctly identified the 32 records from Atchison Village and correctly and uniquely identified 1 of 32 (3 percent) by name and address.

Atchison Village Re-Identification Strategy	k=1	k<5		k<11		k<20	
		Pool size	# of groups	Pool size	# of groups	Pool size	# of groups
People: Hand-Label Gender, Race	5	9	7	40	12	109	17
Address: Hand-Label Gender, Race	5	9	7	39	12	109	18
People: Computer-Assign Gender, Race	2	15	7	58	14	124	21
Address: Computer-Assign Gender, Race	2	16	7	57	14	108	21

Figure 20. Summary of Atchison Village re-identification pools and number of re-identification groups for named people and addresses using people registers having hand labeled and computer labeled values for gender and race/ethnicity. The size of the re-identification pool and the number of re-identification groups appear for binsizes of *k*=1 (unique re-identifications), *k*<5, *k*<11, and *k*<20.

Atchison Village People Re-identification Scores					
Hand-Label Gender, Race			Computer-Assign Gender, Race		
Group size	Total no. of groups	No. of groups having a correct match name	Group size	Total no. of groups	No. of groups having a correct match name
1	5	0	1	2	1
2	1	0	3	3	2
3	1	1	4	2	1
6	1	1	5	1	0
7	1	0	6	1	1
8	2	1	7	2	2
10	1	1	8	2	2
11	1	0	10	1	1
14	2	2	11	1	1
15	1	1	12	3	2
18	1	0	14	2	2
TOTAL	**17**	**7**	17	1	1
			TOTAL	**21**	**16**

Figure 21. Scored results for Atchison Village people re-identifications for binsizes less than 20. Left side reports results for data having manually labeled gender and race, in which 7 of 17 or 41 percent of the groups included the correct person. Right side reports results for data having computer-assigned labels for gender and race, in which 16 of 21 or 76 percent of the groups included the correct address.

Atchison Village Address Re-identification Scores					
Hand-Label Gender, Race			Computer-Assign Gender, Race		
Group size	Total no. of groups	No. of groups having a correct match address	Group size	Total no. of groups	No. of groups having a correct match address
1	5	0	1	2	1
2	1	0	3	3	2
3	1	1	4	2	1
6	1	1	5	2	1
7	3	2	7	2	2
10	1	1	8	2	2
11	1	0	10	1	1
14	3	3	11	3	2
16	1	1	12	1	1
19	1	1	14	2	2
TOTAL	**18**	**10**	17	1	1
			TOTAL	**21**	**16**

Figure 22. Scored results for Atchison Village address re-identifications for binsizes less than 20. Left side reports results for data having manually labeled gender and race, in which 10 of 18 or 56 percent of the groups included the correct address. Right side reports results for data having computer-assigned labels for gender and race, in which 16 of 21 or 76 percent of the groups included the correct address.

Liberty Village Re-Identifications

The Attackers associated 9 records in the Richmond subset of the De-ID Dataset to Liberty Village (8 renters and 1 whose home ownership was not known), and then matched those 9 records to records in the Liberty Village Property Register based on housing characteristics using a computer program written by the Attackers; see Figure 1(a). Matches had the same number of bedrooms and baths, were built in 1942, and had living areas consistent with the ranges described earlier.

The result was 623 matches for the 9 records. None of the matches was unique, and there were no small group matches, a result reflecting the homogeneity of the rental units. Figure 23 (left) lists the cumulative number of records in the Liberty Village Property Register matching to the Richmond records in the De-ID Dataset. Figure 23 (right) shows the cumulative number of Richmond records known to be renters in the De-ID Dataset matched to records in the Liberty Village Property Register by binsize. Subsequent steps use this combined dataset.

Number of Property Records in a Match (binsize)	Cumulative Number of Matches
29	2
75	3
83	9

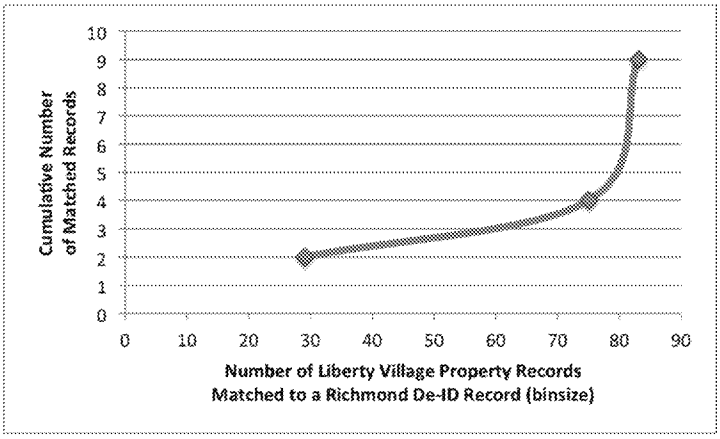


Figure 23. Matches of records in the Liberty Village Property Register to records in the De-ID Dataset based on housing characteristics alone. The binsize is the number of property records matched to the same De-ID Dataset record. There were no unique or small group matches. The same record in the Liberty Village Property Register may match to more than one record in the De-ID Dataset.

Liberty Village Re-Identifications: Hand Labels

Just as was done with Atchison Village, the Attackers matched the combined Liberty Village property and De-ID data to records in the Liberty Village People Register using a Python program that the Attackers wrote, notwithstanding concerns mentioned earlier – i.e., homogeneity of the population and property, and the greater number of residents per household. Gender and race were not used. The Attackers then manually assigned race/ethnicity and gender to the matching records and concluded the matching manually using a spreadsheet program.

The Attackers found a total of 76 matches of people from the Liberty People Register to records in the combined De-ID and property data. The matches were for 7 of the 9 records that the Attackers believed were from Liberty Village. For $k=1$ and $k<5$, the risk pool was 1 person for 1 re-identification. For $k<11$, the risk pool was 8 people for 4 re-identifications. And, for $k<20$ the risk pool was 26 people for 7 re-identifications.

Similarly, the Attackers found a total of 70 matches of addresses from the Liberty Village People Register to records in the combined Richmond De-ID and Liberty Village property data. The matches were for 7 of the records believed to be from Liberty Village. For $k=1$ and $k<5$, the risk pool was 1 person for 1 re-identification. For $k<11$, the risk pool was 7 addresses for 4 re-identifications. And, for $k<20$ the risk pool was 24 addresses for 7 re-identifications.

Liberty Village Re-Identifications: Computer Assigned Labels

Just as was done with Atchison Village, the Attackers then matched the combined Liberty Village property and Richmond De-ID data to records in the Liberty Village People Register using a Python program that the Attackers wrote that included matches on the computer assignment of values for gender and race. Matches were based on birth year, move-in date, race and ethnicity, and gender.

When matches were restricted to records in the Liberty Village People Register that had complete values – i.e., no missing move-in or birth year information, no small group re-identifications resulted. Therefore, computer matches were insufficient with complete information and possible but speculative with missing information.

Liberty Village Re-Identifications: Results

The Attackers sent the hand-labeled results for addresses and named people for Liberty Village re-identifications to the Scorers to identify which, if any, of the groups had a correct match. The Scorers reported that 1 of 7 named people groups contained the correct person and 2 of 7 address groups contained the correct address (Figure 24).

Liberty Village People Re-identification Scores					
Hand-Label Gender, Race			Hand-Label Gender, Race		
Group size	Total no. of groups	No. of groups having a correct match name	Group size	Total no. of groups	No. of groups having a correct match address
1	1	0	1	1	0
7	3	0	6	3	1
18	3	1	17	3	1
TOTAL	**7**	**1**	**TOTAL**	**7**	**2**

Figure 24. Scored results for Liberty Village People Re-identifications for binsizes of 20 or less. The data have manually labeled gender and race. One of 7 of the groups included the correct person by name (left), and 2 of 7 of the groups included the correct address (right).

Overall, the Attackers believed 9 records were from Liberty Village, and 8 of those records were actually from Liberty Village. Regardless, the Attackers did not correctly identify any small group re-identifications (k<5).

Bolinas Re-Identifications

Just as was done with the other communities, the Attackers matched the records in the Bolinas records of the De-ID Dataset to those in the Bolinas Property Register based on housing characteristics using a computer program written by the Attackers; see Figure 1(a). The program matched records having the same number of bedrooms and baths, being built in the same time period, and having living areas consistent with the ranges described earlier.

The result was 200 matches for 10 of 10 (100 percent) of the Bolinas records. None of the records in the De-ID Dataset matched uniquely. Figure 25 shows the cumulative number of Bolinas records in the De-ID Dataset matched to records in Bolinas Property Register by binsize. This curve is more similar to that for Atchison Village (Figure 18) than for Liberty Village (Figure 23), suggesting that there exists sufficient variability for matching. However, concerns about the quality of the matches remain because of the property data are from 2017 and the HES data are from 2006.

Number of Property Records in a Match (binsize)	Cumulative Number of Matches
4	2
9	4
12	5
21	6
24	8
28	9
65	10

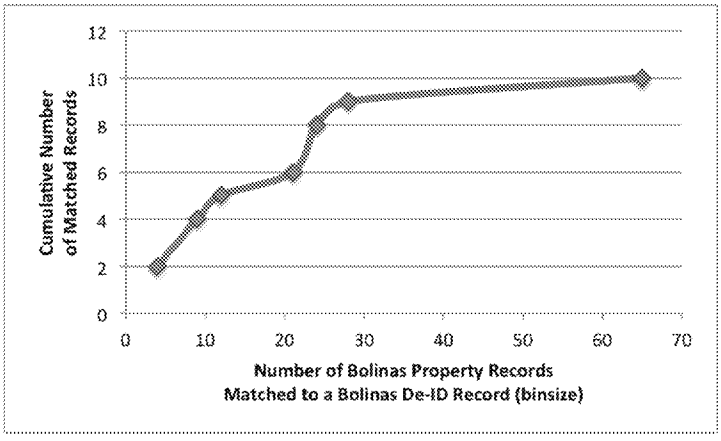


Figure 25. Matches of records in the Bolinas Property Register to records in the De-ID Dataset based on housing characteristics alone. The binsize is the number of Bolinas property records matched to the same Bolinas De-ID Dataset record. No records matched uniquely. A total of 163 Bolinas addresses matched to the 10 Bolinas De-ID records.

The Bolinas registers did not lend themselves to reliable manual matches. While some derivations were possible, the Attackers lacked confidence in the results because of the homogeneity of the people, small sampling fraction, and the lack of reliability in the housing data. Similar limitations existed for the matches using the computer-labeled data. For k<20, the risk pool was 18 people and addresses for 7 re-identifications. As we anticipated might be the case, none of the re-identifications was correct upon scoring.

At the HIPAA Safe Harbor

We repeated the experiments again using HES data that had exact year of birth (rather than decadized), which is permitted by HIPAA. Rather than reporting a study participant's age in bands of 10 or 20 years, we produced re-identifications using a De-ID Dataset that was the same as previously described except that the year of birth was provided. Information about the move-in date and when the house was built remained grouped in ranges of 10 or 20 years.

We matched records in the Atchison Village People Register to the combined Atchison Village property and De-ID records using a Python program that the Attackers wrote. Matches were based on birth year, move-in date, race and ethnicity, and gender. Blank entries were not

matched. The computer program found 11 unique re-identifications for named people and addresses. For *k<5*, *k<11* and *k<20*, the risk pool was the same 27 named people and addresses for 18 re-identifications. Figure 26 shows the accounting of binsizes for the matches.

The Attackers sent these results to the Scorers, who reported that 8 of the 11 (73 percent) unique re-identifications of named people were correct, and 9 of the 11 (82 percent) unique re-identifications of addresses were correct. For $k<5$ (same as for $k<20$), 15 of the 18 (83 percent) groups had a correct named person, and 16 of the 18 (89 percent) groups had a correct address. The Attackers uniquely ($k=1$) and correctly identified 8 of 32 (25 percent) Atchison Village records by name and 9 of 32 (28 percent) by address in the version of the HIPAA-compliant data having exact year of birth, compared to 1 of 32 (3 percent) by name or address in the version of the HIPAA-compliant data having year of birth grouped in 10- or 20 year ranges and using computer-assigned labels.

Similarly, for binsizes $k<5$, the Attackers correctly identified 15 of 32 (47 percent) Atchison Village records by name and 16 of 32 (50 percent) by address in the version of the HIPAA-compliant data having exact year of birth. The correct identifications dropped to 4 of 32 (13 percent) by name or address in data having year of birth grouped in 10- or 20-year ranges and using computer-assigned labels.

Even with the actual year of birth, no reliable re-identifications resulted for Liberty Village or Bolinas.

Atchison Village People Re-identification Scores					
Year of Birth			Year of Birth		
Group size	Total no. of groups	No. of groups having a correct match name	Group size	Total no. of groups	No. of groups having a correct match address
1	11	8	1	11	9
2	5	5	2	5	5
3	2	2	3	2	2
TOTAL	**18**	**15**	**TOTAL**	**18**	**16**

Figure 26. Scored results for Atchison Village People Re-identifications for binsizes of 20 or less using year of birth information. Left side reports results for named people, in which 15 of 18 or 83 percent of the groups included the correct person. Right side reports results for addresses, in which 16 of 18 or 89 percent of the groups included the correct address.

Discussion

We evaluated the potential for re-identifying 10 people and addresses from Bolinas, and 40 people and addresses from two communities in Richmond (32 from Atchison Village and 8 from Liberty Village), California, by matching a dataset redacted at and beyond the HIPAA

Safe Harbor standard with constructed people and property registers. Our results demonstrate that high rates of re-identification are sometimes possible even with heavily redacted data. When less-redacted data (including exact birth year) from Richmond were matched to Atchison Village registers with computer-inferred values for race and gender, we uniquely and correctly identified 8 of 32 (25 percent) by name and 9 of 32 (28 percent) by address. With year of birth grouped in periods of 10 or 20 years, we uniquely and correctly identified 1 of 32 (3 percent) by name and address, 4 of 32 (13 percent) as being one of fewer than 5 names or addresses, and 16 of 32 (50 percent) as being one of fewer than 20 names or addresses.

Anecdotal wisdom suggests that re-identification experiments on heavily redacted data should fail, and this was somewhat true for people and addresses in Liberty Village and completely true for Bolinas. The differences in re-identification rates between these three communities reflect differences in the demographic makeup of the communities and the quality and availability of property data.

All three communities had populations that were fairly homogeneous with respect to age and gender. Liberty Village was predominantly Hispanic and Bolinas predominantly white. Both Atchison Village and Liberty Village were constructed in 1942 and are comprised of a few types of living units repeated many times, but homes in Atchison Village have substantially greater variation in room count and living area. Additionally, accurate property data were available for purchase in Atchison Village, whereas property data had to be inferred for Liberty Village, which is a rental complex. Liberty Village, as a rental complex, also had much higher rates of mobility during the study year, thereby increasing the pool of possible adults living in each home compared to Atchison. These factors likely contributed to the higher rates of re-identification in Atchison Village compared to Liberty Village.

Bolinas differed from both Richmond communities in several important ways. Unlike Liberty and Atchison Villages, Bolinas is not a housing development, so there is much greater variation among homes. However, the quality of the housing data, obtained 10 years after the study with 20 percent of the records having parcel changes, potentially diminished re-identification capability. Bolinas, like Liberty Village, is substantially more racially homogeneous than is Atchison Village, and the sampling fraction was lower in Bolinas (approximately 0.6 percent versus 2 percent). These factors may have contributed to the lower rate of re-identification observed in Bolinas.

These findings suggest that there is something fundamentally flawed with ad hoc redactions of data. They fail to accurately account for the quality and nature of external information. Heavily redacted data may look anonymous, but it is not necessarily so.

The number of correct re-identifications found in the HIPAA Safe Harbor–compliant data having exact year of birth is remarkable (25 percent uniquely and correctly re-identified by name). HIPAA Safe Harbor does not purport to render data with no risk of re-identification.

Instead, the wording states that there exists a "minimal risk," but the regulation itself does not directly define what a minimal level of risk may be. Prior studies found far fewer re-identifications, less than 0.05 percent of unique re-identifications [2, 3], suggesting that the notion of minimal risk defined by the HIPAA Safe Harbor was that low. Correctly and uniquely re-identifying 25 percent of the people and 28 percent of the addresses is a substantial increase in demonstrated vulnerability.

Earlier studies about vulnerabilities in HIPAA Safe Harbor data narrowly relied on demographic fields (e.g., year of birth, gender and the first 3 digits of ZIP) as the basis for matching. Our study used those and other, non-demographic fields, such as the number of rooms and baths, to link to other data sources. These novel linkages increased the rate of re-identifications.

In fact, critical to our re-identifications was the use of property and people registers. The existence of registers is not unique to household studies. The preamble to the HIPAA Privacy Rule makes reference to Sweeney's earliest re-identification in which hospital data were matched to a voter list registry to re-identify the medical record of William Weld, then Governor of Massachusetts [44]. Sweeney's focus on demographics in that seminal example led to a focus on demographic fields in the HIPAA Privacy Rule itself. However, direct matching on demographic fields is not the only vulnerability. Instead, a series of registries can be used to link to other fields in the HIPAA Safe Harbor data before making the final link to a register of named individuals. In our study, the de-identified data were linked to real estate tax data to learn candidate addresses and then matched to the demographics of people associated with those addresses. While tax registries are not generally applicable to medical data, comparable registries in the medical data context today include prescriptions and disease-specific marketing data [45].

Extending HIPAA from healthcare to property data, as we did in these experiments, allowed us to match the HIPAA-compliant study data to identifiable property data using property fields that were present in both data. If all health data were covered by HIPAA, then it would be reasonable to believe that any other dataset containing the same medical fields would also be covered by HIPAA and therefore re-identification attempts would only be able to match medical fields to datasets that had the same redacted demographics, and no names or addresses. However, not all health data is covered by HIPAA, so following this same approach it is possible to link HIPAA-compliant health data with identifiable health data using medical fields. In prior work, Sweeney et al. surveyed flows of health data and found that about half of the more than 2,000 flows of health data they documented were not covered by HIPAA [46]. Among these, they found that 33 states collected and shared hospital discharge data publicly. Because these statewide datasets are not covered by HIPAA, 30 of the publicly available versions used standards weaker than HIPAA for redaction. In other work, Sweeney correctly re-identified records in one state's hospital discharge dataset by using details from newspaper stories to associate names to records [47]. Once re-identified, the records could

theoretically be further matched to HIPAA-compliant data on medical and demographic fields, and thus be used to re-identify the HIPAA-compliant data.

There are many other forms of health data that could also be used to re-identify HIPAA compliant health data. Disease specific marketing lists, for example, include patient names, addresses, and diseases [45]. In a survey of mobile apps, Zang et al. found that personal health monitoring and assistance apps often collect disease specifics, including the date of onset and severity of symptoms, along with the person's name and phone number [48]. A medication refill reminder app contains medication information, from which diagnoses—and even severity of the disease—can be inferred. Datasets of subscribers to health websites and disease discussion lists may include disease information along with names and email addresses. There are many possible sources of health data that include names and contact information as well as medical information, and any of these can be used to re-identify related HIPAA-compliant data.

Our study used three geographical areas whose total population was about 3,000 adults. The HIPAA prescription for reporting geography is the same for data having 3,000 people as it is for populations having up to 20,000 people. No ZIP codes appear. Still, knowing that the data came from three known communities narrowed consideration to a 2 percent sample drawn from 3,000 people.

More generally, there may be a false belief that the HIPAA Safe Harbor only applies to large, datatsets. However, the regulation is silent about the size and attribution of the dataset, which may contain revealing information. For example, if a small rural hospital releases a HIPAA-compliant dataset containing patient-level information, then recipients of the dataset may make inferences about the patients' residences (e.g., ZIP code) based on the nae and location of the hospital. If most of the patients reside in the same ZIP code, then even with no or a redacted ZIP code, a recipient of the data can still infer the full ZIP code for most patients. Similarly, while the regulation requires dates to be reported in years, more specific temporal information can sometimes be inferred. If a hospital releases a dataset daily about its emergency room visits from the day before, then exact visit date can be inferred even though only year is reported .

We use the HIPAA Safe Harbor standard to de-identify data that are not health records. Similar to how IRBs use clinical ethics to deal with all other scientific research ethics, researchers often assume that complying with HIPAA Safe Harbor requirements automatically ensures re-identification protection for their subjects and adds legal protection for themselves (by having chosen to adhere to HIPAA).

Earlier studies about vulnerabilities in HIPAA Safe Harbor data only reported unique identifications, and in so doing did not help develop scientific intuition about re-identification risks more generally. A static value, such as the number of unique re-identifications, describes how well one re-identification strategy performed on one set of

data. But how do we generalize the experience? Was it a fluke, or is it indicative of serious problems? A single number is not as useful as knowing the trajectory of small group re-identifications. How many people were re-identified as one of 2 possible named people, as one of 3 possible named people, and so on? As the number of small group re-identifications grows, so may the robustness of the re-identification risk grow.

In this study, we used the robustness of small group re-identifications to determine whether the re-identifications, even the unique ones, were likely to be correct. In Liberty Village and Bolinas, unique and small-group re-identifications resulted, but we discounted them because of the nature of the small-group re-identifications. For example, unique re-identifications and no other small group re-identifications resulted from Liberty Village data that had birth years in 10- and 20-year ranges and computer-assigned gender and race. Matching records to a homogeneous community foretells the existence of many small group re-identifications. Because none appeared, the Attackers did not believe the isolated unique re-identifications to be correct, and those re-identifications were confirmed not to be correct. Group re-identifications can be a useful aid in understanding re-identification risks.

On the other hand, re-identifications of the same kind of data for Bolinas yielded many small group re-identifications, as expected when matching records for a homogeneous community; however, the poor data quality foretells many noisy matches. Therefore, the Attackers did not believe those re-identifications were reliable, and again, the re-identifications were confirmed not to be correct.

Our results are not necessarily the worst case for re-identifying the data. Many fields in the HIPAA Safe Harbor–compliant data were unused in our experiment. Prior publications referenced chemical distinctions between the communities that were less obviously useful to the Attackers, as non-experts in environmental health. A re-identification expert may often lack domain-specific expertise that limits performance.

However, the opposite is true too: a re-identification expert may know much more than our Attackers. Data analytic companies are one of the top acquirers of publicly available hospital data [49]. Health, environmental, or legal data analytics companies whose data products benefit from re-identifying the de-identified dataset may be highly motivated and very knowledgeable about the de-identified data and therefore able to perform more re-identifications.

Our efforts did not use link analysis, deep learning or statistical matching algorithms, which are commonly used by data analytic companies to construct personal data profiles from disparate data sources [50]. Instead, we used manual and simple matching approaches. We acknowledge that more robust re-identifications may be possible using our same data and re-identification strategy with more sophisticated linking techniques.

Overall, there may exist other re-identification strategies and other data sources that may yield even more re-identifications than we demonstrated. Despite these limitations, we can state that the re-identification rate is at least as high as demonstrated here.

The original data that were the subject of our study was collected more than 10 years ago, and our effort required finding or constructing registers relevant to 2006. If the subject data had been more contemporary, then additional readily available sources of data could have been used for re-identification. For example, the HES data contained information about pets, appliances, and lawn care. If the HES data were more recent, we could have used contemporary marketing lists (e.g., [51]). While similar kinds of marketing lists existed in 2006, we were unable to obtain them retrospectively. We could have also used lookups on Facebook and other social media profiles for our re-identifications.

The environmental health researchers who conducted the original study consider the results to demonstrate a rate of re-identification risk that raises ethical cautions about sharing similar data. In prior work, Brown et al. reported on the challenges of doing community based participatory research that involves biomonitoring and household exposure studies. They emphasized the critical role consent agreements play in informing participants of potential harms as well as the steps taken to prevent or mitigate those harms [52]. They also describe the trust relationship between researchers and participants as imposing ethical requirements on researchers to protect the rights, well-being, and autonomy of participants because the participants alone may shoulder the harm based on decisions made by the researchers [54]. These considerations should be extended to include consideration of risks in datasets that are anticipated to be widely or publicly shared.

Beyond the ethical promise of anonymity, participants may suffer economic harm from loss of privacy. The value of real estate may be adversely impacted, and knowledge of research results may also impose a legal duty on the participant to inform government officials, landlords, tenants, and future homebuyers [54, 55]. This legal obligation may also result in financial costs. While all properties in a community may be impacted by outdoor air quality measures, measurements of indoor air or dust have the potential to pose greater costs to individual residents.

Environmental health studies often inform laws and regulations about industrial pollutants, which can cost companies billions of dollars (e.g., [56]). With so much money involved, protecting the identity and addresses of study participants is a critical shield from retaliatory action.

Of course, protecting privacy is not limited to cases of demonstrable economic harms. The protection of personal privacy has different goals and purposes, including upholding social values. Economic harms are often among the most dramatic examples of the consequences of loss of privacy, but other devastating consequences can be social, legal, political, and personal.

Our results show that the current HIPAA Safe Harbor cannot reliably anonymize data. How could data possibly be released with limited or virtually no risk of re-identification? To eliminate risk of re-identification, data must adhere to a formal property that provides a privacy guarantee. Computer scientists have introduced such models. The first formal protection model was *k*-anonymity, which guarantees that each record released will ambiguously map to at least *k* other records [20, 57]. Therefore, you cannot do better than guessing $1/k$ that any particular record belongs to a named person or location. If the HES data were *k*-anonymized, there would be no small group re-identifications less than *k* and each *k*-sized group would be indistinguishable. This guarantee would hold regardless of the amount of redaction.

The newest formal protection model is differential privacy, which uses additive noise or subsampling to enforce a mathematical guarantee of ambiguity or disassociation [58, 59]. Unlike *k*-anonymity, where the actual records of the data are changed to satisfy the *k* requirement, a differentially private approach to smaller datasets will often make a statistical model of the original data and then produce an alternative dataset that has the same statistical properties as the original data but none of the original records. New records are generated from the statistical model itself, thereby breaking the one-to-one correspondence between records in the original and anonymized datasets. While they differ from each other, both models make provable privacy guarantees. In comparison, HIPAA Safe Harbor makes no scientific privacy guarantee.

Fifteen years ago when the HIPAA Privacy Rule was promulgated, hundreds of data brokers, offering ever-increasing amounts of personal information on Americans, did not exist. Property data and other public information were not readily available electronically. Our findings suggest that the time is ripe to modernize HIPAA Safe Harbor, especially in the face of today's data rich networked society, and to so in a manner that encourages and adopts technological innovation. Formal protection models offer the privacy guarantees that patients, and research participants, deserve.

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Appendix

A. Data Fields in the HIPAA Dataset

The HIPAA Dataset is a version of the original study data from the Northern California Household Exposure Study (HES) [1] that was redacted beyond the minimum requirements of

the Safe Harbor provision of the Privacy Rule in the Health Information Portability and Accountability Act (HIPAA). Dates are reported within 10 or more year ranges as decades or decade groups, and all explicit geography, such as address, city and ZIP code, has been removed.

Survey File

The Survey File is a spreadsheet with 255 fields as columns and 50 data rows. Below is a description of each field. Date fields that were reported as decades are highlighted in orange

Field name	**Field Description: Possible Values**
PrivacyID	Unique ID created for scoring
movein	Year moved to this house: reported as decade group
housbuilt	Year house was built: reported as decade group
remod	House addition/remodeled/painted inside: Yes, No or NA
remodyr	Addition/remodel/painted inside: Before/Since beginning of year or blank
work1	Kind of remodeling work done
basement	Basement or crawl space: basement, crawl space, neither
basemfin	Is basement: Finished or Unfinished
newrug	Rugs/carpets in house new within last year: Yes, No or NA
newrugair	New rug/carpet in sample collection room: Yes, No or NA
newfurn	Large furniture new within last year: Yes, No or NA
newfurnair	New large furniture in sample collection room: Yes, No or NA
garage	Garage attached to house: Yes, No or NA
winopen	# windows open for at least 1 hr in past 24 hrs
appl_gas	Appliances or heat that use natural gas: Yes, No or NA
elecheat	Has electric heat: Yes, No or NA
natgas	Has natural gas heat: Yes, No or NA
oilheat	Has oil heat: Yes, No or NA
gas_waterht	Has gas water heater: Yes, No or NA
woodstove	Has wood stove: Yes, No or NA
usedwood	Used wood stove in past 24 hours: Yes, No or NA
keroheat	Has kerosene heater: Yes, No or NA
usedkero	Used kerosene heater in past 24 hours: Yes, No or NA
woodfire	Has wood-burning fireplace: Yes, No or NA
usedfire	Used wood-burning fireplace in past 24 hours: Yes, No or NA
gasfire	Has gas-burning fireplace: Yes, No or NA
usedgfire	Used gas-burning fireplace in past 24 hours: Yes, No or NA
goven	Has gas oven: Yes, No or NA
opergoven	Gas oven operating in past 24 hours: Yes, No or NA
gstove	Has gas stove: Yes, No or NA
opergstove	Gas stove operating in past 24 hours: Yes, No or NA
elecoven	Has electric oven: Yes, No or NA
operelecoven	Electric oven operating in past 24 hours: Yes, No or NA
elecrange	Has electric range stove: Yes, No or NA
operelrange	Electric range stove operating in past 24 hours: Yes, No or NA
fanvent	Has fan over stove: Yes, No or NA
opervent	Fan over stove operating in past 24 hours: Yes, No or NA

indgrill	Has indoor grill: Yes, No or NA
operindgrill	Indoor grill operating in past 24 hours: Yes, No or NA
dishw	Has dishwasher: Yes, No or NA
operdishw	Dishwasher operating in past 24 hours: Yes, No or NA
atticfan	Has attic or window fans: Yes, No or NA
operatticfan	Attic or window fans operating in past 24 hours: Yes, No or NA
laundry	Has clothes washer in living area: Yes, No or NA
operlaund	Clothes washer in living area operating in past 24 hours: Yes, No or NA
fry_stove	Has fried food on stove: Yes, No or NA
vent_frystove	Vent fan was on while frying food: Yes, No or NA
broil_oven	Has broiled food in oven: Yes, No or NA
vent_broiloven	Vent fan was on while broiling food: Yes, No or NA
grill_indoor	Has grilled food indoors: Yes, No or NA
vent_grilling	Vent fan was on while grilling food: Yes, No or NA
bake_oven	Has baked food in oven: Yes, No or NA
vent_bakeoven	Vent fan was on while baking food: Yes, No or NA
toasteroven	Has operated a toaster or toaster oven: Yes, No or NA
vent_toaster	Vent fan was on while toasting food: Yes, No or NA
selfclean	Has cleaned the oven with self-clean heat: Yes, No or NA
vent_selfclean	Vent fan was on during the self-clean: Yes, No or NA
comp	Has computer printer: Yes, No or NA
opercomp	Computer printer operating in past 24 hours: Yes, No or NA
fax	Has fax machine: Yes, No or NA
operfax	Fax machine operating in past 24 hours: Yes, No or NA
photoc	Has photocopier: Yes, No or NA
operphoto	Photocopier operating in past 24 hours: Yes, No or NA
airfresh	Used solid air freshener in past 2 days: Yes, No or NA
airspray	Used spray air freshener in past 2 days: Yes, No or NA
hairspray	Used hair spray in past 2 days: Yes, No or NA
antipers	Used spray antiperspirant in past 2 days: Yes, No or NA
deterg	Used laundry detergent in past 2 days: Yes, No or NA
dishdeterg	Used dishwasher detergent in past 2 days: Yes, No or NA
surfclean	Used spray-on surface cleaner in past 2 days: Yes, No or NA
ovenclean	Used oven cleaner in past 2 days: Yes, No or NA
glues	Used glues or adhesives in past 2 days: Yes, No or NA
furnpol	Used furniture polish in past 2 days: Yes, No or NA
toilclean	Used toilet cleaner in past 2 days: Yes, No or NA
tileclean	Used tub or tile cleaner in past 2 days: Yes, No or NA
painthin	Used paint thinner/stripper in past 2 days: Yes, No or NA
bugkill	Used bug killers/pesticides in past 2 days: Yes, No or NA
carpclean	Used carpet cleaner in past 2 days: Yes, No or NA
spotrem	Used spot remover in past 2 days: Yes, No or NA
mothball	Used mothballs in past 2 days: Yes, No or NA
nailpol	Used fingernail polish in past 2 days: Yes, No or NA
homebus	Business operating in house: Yes, No or NA
homehobb	Workshop/hobby area in house: Yes, No or NA
everspray	House ever been treated for bugs: Yes, No or NA
sprayear	House treated for bugs in past year: Reported as decade
recentmth_treat	Most recent month treated for bugs during past year: Jan,...,Dec

numb_mthsrx	Number of months of treatment reported
sprayreason	Kind of bugs house treated for in past year
spraytype	What was house treated for bugs with in past year
treat_cat	Treatment category: Spray/Exterminator/Bomb, Bait/Stake/Borax, NoInfo
lastspray	Most recent year house treated for bugs: Reported as decade
lastsprayreason	Kind of bugs house treated for in most recent year
lastspraytype	What was house treated for bugs with in most recent year
lastsprayamt	How many times house treated for bugs in most recent year
sprayother	House treated for bugs any other years: None or NA
sprayothyr1a	Bug treatment 1, year 1: Reported as decade
sprayothyr1b	Bug treatment 1, year 2: Reported as decade
sprayothbug1	Bug treatment 1, kind of bugs treated for
sprayothtype1	Bug treatment 1, treated with
sprayothamt1	Bug treatment 1, how often
sprayothyr2a	Bug treatment 2, year 1: Reported as decade
sprayothyr2b	Bug treatment 2, year 2: Reported as decade
sprayothbug2	Bug treatment 2, kind of bugs treated for
sprayothtype2	Bug treatment 2, treated with
sprayothamt2	Bug treatment 2, how often
sprayothyr3a	Bug treatment 3, year 1: Reported as decade
sprayothyr3b	Bug treatment 3, year 2: Reported as decade
sprayothbug3	Bug treatment 3, kind of bugs treated for
sprayothtype3	Bug treatment 3, treated with
sprayothamt3	Bug treatment 3, how often
sprayothyr4a	Bug treatment 4, year 1: Reported as decade
sprayothyr4b	Bug treatment 4, year 2: Reported as decade
sprayothbug4	Bug treatment 4, kind of bugs treated for
sprayothtype4	Bug treatment 4, treated with
sprayothamt4	Bug treatment 4, how often
sprayothyr5a	Bug treatment 5, year 1: Reported as decade
sprayothyr5b	Bug treatment 5, year 2: Reported as decade
sprayothbug5	Bug treatment 5, kind of bugs treated for
sprayothtype5	Bug treatment 5, treated with
sprayothamt5	Bug treatment 5, how often
treatment_cat	Treatment category: Spray/Exterminator/Bomb, Bait/Stake/Borax, NoInfo
lawncare	Who cares for lawn: Household or Building management
lawntx	Lawn ever treated with insecticide or herbicide: Yes, No, Don't know
lawnyr	Lawn treated in past year: Yes, No, Don't know
lawnmonth	Most recent month lawn treated for bugs in last year: Jan,…,Dec
lawnmonth_num	Number of months lawn treated in last year
lawnreas	What was lawn treated for in past year
lawntype	What was lawn treated with in past year
lawntreat_cat	Lawn treatment category: Spray/Exterminator/Bomb, Bait/Stake/Borax
lawnyrlast	Most recent year lawn was treated: Reported as decade
lawnlastreas	What was lawn treated for in most recent year
lawnlastype	What was lawn treated with in most recent year
lawnoth	Lawn treated any other years: None or NA
lawnothyr1a	Lawn treatment 1, year 1: Reported as decade
lawnothyr1b	Lawn treatment 1, year 2: Reported as decade

lawnothreas1	Lawn treatment 1, treated for
lawnothtype1	Lawn treatment 1, treated with
lawnothyr2a	Lawn treatment 2, year 1: Reported as decade
lawnothyr2b	Lawn treatment 2, year 2: Reported as decade
lawnothreas2	Lawn treatment 2, treated for
lawnothtype2	Lawn treatment 2, treated with
lawnothyr3a	Lawn treatment 3, year 1: Reported as decade
lawnothyr3b	Lawn treatment 3, year 2: Reported as decade
lawnothreas3	Lawn treatment 3, treated for
lawnothtype3	Lawn treatment 3, treated with
lawnothyr4a	Lawn treatment 4, year 1: Reported as decade
lawnothyr4b	Lawn treatment 4, year 2: Reported as decade
lawnothreas4	Lawn treatment 4, treated for
lawnothtype4	Lawn treatment 4, treated with
lawntreat_cat2	Lawn treatment category for other years: Spray/…/Bomb, Bait/…/Borax
lawnpro	Ever used professional lawn care service: Yes, No, Don't know
lawnprolast	Most recent year used professional lawn service: Since start or NA
lawnprofirst	First year used professional lawn service: Reported as decade
lawnprooth	Used professional lawn service any other years: Yes, No, Don't know
lawnproyr1a	Professional lawn service 1, year 1: Reported as decade
lawnproyr1b	Professional lawn service 1, year 2: Reported as decade
lawnproyr2a	Professional lawn service 2, year 1: Reported as decade
lawnproyr2b	Professional lawn service 2, year 2: Reported as decade
lawnproyr3a	Professional lawn service 3, year 1: Reported as decade
lawnproyr3b	Professional lawn service 3, year 2: Reported as decade
lawnproyr4a	Professional lawn service 4, year 1: Reported as decade
lawnproyr4b	Professional lawn service 4, year 2: Reported as decade
pets	Any pets: Yes or No
fleatx	Any cats and/or dogs treated for fleas: Yes or No
fleatype	What type of flea treatment
flealast_mon	Most recent flea treatment – month: Jan,…,Dec
totalsquareft	Total square feet of living area in ranges: 450-500, 650-700, 700-1000, …
smoke	Anyone who lives in house smoke tobacco: Yes or No
smoke24	Anyone who lives in house smoke tobacco in past 24: Yes or No
room1samp	Room #1 – sampled: Checked or Not checked
room1	Room #1 – type: Living room, Kitchen, Bedroom, Bath, Other
norug1	Room #1 - no rug: Checked or Not checked
vinylfl1	Room #1 - vinyl flooring: Yes or No
rug1age	Room #1 - age of rug/carpet (yrs): Reported as decade
rug1wall	Room #1 - wall to wall carpet: Yes or No
rug1half	Room #1 - area rug > 1/2 of room: Yes or No
room2samp	Room #2 - sampled: Checked or Not checked
room2	Room #2 - type: Living room, Kitchen, Bedroom, Bath, Other
norug2	Room #2 - no rug: Checked or Not checked
vinylfl2	Room #2 - vinyl flooring: Yes or No
rug2age	Room #2 - age of rug/carpet (yrs) : Reported as decade
rug2wall	Room #2 - wall to wall carpet: Yes or No
rug2half	Room #2 - area rug > 1/2 of room: Yes or No
room3samp	Room #3 - sampled: Checked or Not checked

room3	Room #3 - type: Living room, Kitchen, Bedroom, Bath, Other
norug3	Room #3 - no rug: Checked or Not checked
vinylfl3	Room #3 - vinyl flooring: Yes or No
rug3age	Room #3 - age of rug/carpet (yrs) : Reported as decade
rug3wall	Room #3 - wall to wall carpet: Yes or No
rug3half	Room #3 - area rug > 1/2 of room: Yes or No
room4samp	Room #4 - sampled: Checked or Not checked
room4	Room #4 - type: Living room, Kitchen, Bedroom, Bath, Other
norug4	Room #4 - no rug: Checked or Not checked
vinylfl4	Room #4 - vinyl flooring: Yes or No
rug4age	Room #4 - age of rug/carpet (yrs) : Reported as decade
rug4wall	Room #4 - wall to wall carpet: Yes or No
rug4half	Room #4 - area rug > 1/2 of room: Yes or No
room5samp	Room #5 - sampled: Checked or Not checked
room5	Room #5 - type: Living room, Kitchen, Bedroom, Bath, Other
norug5	Room #5 - no rug: Checked or Not checked
vinylfl5	Room #5 - vinyl flooring: Yes or No
rug5age	Room #5 - age of rug/carpet (yrs) : Reported as decade
rug5wall	Room #5 - wall to wall carpet: Yes or No
rug5half	Room #5 - area rug > 1/2 of room: Yes or No
room6samp	Room #6 - sampled: Checked or Not checked
room6	Room #6 - type: Living room, Kitchen, Bedroom, Bath, Other
norug6	Room #6 - no rug: Checked or Not checked
vinylfl6	Room #6 - vinyl flooring: Yes or No
rug6age	Room #6 - age of rug/carpet (yrs) : Reported as decade
rug6wall	Room #6 - wall to wall carpet: Yes or No
rug6half	Room #6 - area rug > 1/2 of room: Yes or No
room7samp	Room #7 - sampled: Checked or Not checked
room7	Room #7 - type: Living room, Kitchen, Bedroom, Bath, Other
norug7	Room #7 - no rug: Checked or Not checked
vinylfl7	Room #7 - vinyl flooring: Yes or No
rug7age	Room #7 - age of rug/carpet (yrs) : Reported as decade
rug7wall	Room #7 - wall to wall carpet: Yes or No
rug7half	Room #7 - area rug > 1/2 of room: Yes or No
room8samp	Room #8 - sampled: Checked or Not checked
room8	Room #8 - type: Living room, Kitchen, Bedroom, Bath, Other
norug8	Room #8 - no rug: Checked or Not checked
vinylfl8	Room #8 - vinyl flooring: Yes or No
rug8age	Room #8 - age of rug/carpet (yrs) : Reported as decade
rug8wall	Room #8 - wall to wall carpet: Yes or No
rug8half	Room #8 - area rug > 1/2 of room: Yes or No
room9samp	Room #9 - sampled: Checked or Not checked
room9	Room #9 - type: Living room, Kitchen, Bedroom, Bath, Other
norug9	Room #9 - no rug: Checked or Not checked
vinylfl9	Room #9 - vinyl flooring: Yes or No
rug9age	Room #9 - age of rug/carpet (yrs) : Reported as decade
rug9wall	Room #9 - wall to wall carpet: Yes or No
rug9half	Room #9 - area rug > 1/2 of room: Yes or No
room10samp	Room #10 - sampled: Checked or Not checked

room10	Room #10 - type: Living room, Kitchen, Bedroom, Bath, Other
norug10	Room #10 - no rug: Checked or Not checked
vinylfl10	Room #10 - vinyl flooring: Yes or No
rug10age	Room #10 - age of rug/carpet (yrs) : Reported as decade
rug10wall	Room #10 - wall to wall carpet: Yes or No
rug10half	Room #10 - area rug > 1/2 of room: Yes or No
birth_yr	Year born in: Reported as decade
job	Working at a job: Yes or No
jobtype	Type of job: by industry
other_job	Anyone else in the house working at a job: Yes or No
other_jobtype	What kind of job is the other person working at: by industry
school	Highest grade in school completed: <= 8th grade, Some high school,...
own_home	Owns own home: Yes or No
race_white	White: White or NA
race_black	Black: Black or NA
race_his	Hispanic: Hispanic or NA
race_nam	Native American: Native American or NA
race_asian	Asian: Asian or NA
race_other	Other: Something else or NA
race_otherspe	Other race-specified
sex	Gender of respondent: Male or Female
SurveyLanguage	Survey language: English or Spanish

Air and Dust Files

Field	**Description**
Compound	Compound name; naming conventions use Chemlist file
Concentration	specific MRLs for dust and air.
Flag	Data flag. 1 = Detect; 0 = Non-detect; 0.5 and 0.6 = estimated value
Units	reporting units
Privacy.ID	unique participant identifier; re-coded from original values
Media	sampling media
Analyte.MRL	Compound-specific method reporting limit

B. HES Published Toxicology

Below is a reprint of selected summary statistics for the outdoor air results from the Household Exposure Study published as supporting information for an academic paper about the investigation [17]. The full table is available at http://pubs.acs.org/doi/full/10.1021/es100159c. The attackers used outdoor fluoranthene levels to distinguish homes in Richmond from homes in Bolinas.

Table S2. Summary statistics for endocrine disruptors detected in outdoor air in Richmond and Bolinas (ng/m3)

		Richmond Outdoor						Bolinas Outdoor						
Compound	Abbrev.	No.[a]	% > MRL[b]	Min.	Median	95th %ile	Max.	No.	% > MRL	Min.	Median	Max.	F.E. Test[c]	Wil. Test[d]
Phthalates														
benzyl butyl phthalate[e]	BBP	33	3	--	--	--	8.5	10	10	--	--	7.2		--
bis(2-ethylhexyl) adipate	DEHA	33	100	1.0	2.3	5.7	8.7	10	100	1.2	1.5	2.1		R
bis(2-ethylhexyl) phthalate[e]	DEHP	33	18	--	--	160	230	10	0	--	--	--		--
di-n-butyl phthalate[e]	DBP	33	33	--	--	18	32	10	40	--	--	15		--
di-n-hexyl phthalate	DHP	33	6	--	--	6.8	15	10	0	--	--	--		--
dicyclohexyl phthalate	DCP	33	6	--	--	1.1	2.0	10	0	--	--	--		--
diethyl phthalate[e]	DEP	33	39	--	--	150	610	10	70	--	99	220		--
diisobutyl phthalate[e]	DIBP	33	91	--	4.0	14	18	10	100	1.4	2.9	5.6		r
Alkylphenols														
4-nonylphenol[f]	NP	20	15	--	--	20.	40.	9	11	--	--	39		--
Polycyclic Aromatic Hydrocarbons														
acenaphthene	AcNThe	33	100	2	4.8	9.7	11	10	100	0.58	0.81	4.6		R
acenaphthylene	AcNThy	33	45	--	--	2.7	3.2	10	0	--	--	--	R	--
anthracene	Anth	33	15	--	--	0.8	1.3	10	10	--	--	1.1		--
fluoranthene	FluAn	33	100	0.41	1.0	2.3	2.7	10	20	--	--	3.8	R	--
fluorene	Flu	33	97	--	5.5	9.4	11	10	90	--	1.1	5.6		R
phenanthrene	Phenan	33	100	3.1	8.6	16	16	10	100	1.5	2.2	15		R
pyrene	Pyr	33	97	--	0.62	1.8	1.9	10	10	--	--	1.9	R	--
dibenzothiophene	DBTPhe	33	9	--	--	1.3	1.5	10	0	--	--	--		--
1-methyl phenanthrene	1MPhenan	33	79	--	0.42	0.88	1.0	10	10	--	--	0.67	R	--
2-methyl phenanthrene	2MPhenan	33	100	0.35	0.76	1.7	2.0	10	20	--	--	1.2	R	--
3-methyl phenanthrene	3MPhenan	33	97	--	0.69	1.6	2.0	10	20	--	--	1.2	R	--
9-methyl phenanthrene	9MPhenan	33	79	--	0.34	0.78	0.91	10	10	--	--	0.45	R	--

Authors

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Katie Boronow is a staff scientist at Silent Spring Institute, a scientific research organization that studies environmental chemicals and women's health, with a particular focus on breast cancer. Her research leverages digital tools for reporting personal exposure results to participants in biomonitoring studies as a platform for increasing knowledge about endocrine disrupting chemicals. She holds a master's degree from Harvard University in organismic and evolutionary biology and a bachelor's degree summa cum laude from Yale University in biology.

Phil Brown is University Distinguished Professor of Sociology and Health Science at Northeastern University, where he directs the Social Science Environmental Health Research Institute www.northeastern.edu/environmentalhealth He is the author of No Safe Place: Toxic Waste, Leukemia, and Community Action, and Toxic Exposures: Contested Illnesses and the Environmental Health Movement, and co-editor of Social Movements in Health, and Contested Illnesses: Citizens, Science and Health Social Movements. He studies biomonitoring and household exposure and reporting back data to participants in collaboration with Silent Spring Institute (silentspring.org), social policy concerning flame retardants and perfluorinated compounds (pfasproject.com), and health social movements. He directs an NIEHS T-32 training program, "Transdisciplinary Training at the Intersection of Environmental Health and Social Science." He heads the Community Outreach and Translation Core of Northeastern's Children's Environmental Health Center (Center for Research on Early Childhood Exposure and Development in Puerto Rico/CRECE) www.northeastern.edu/crece and both the Research Translation Core and Community Engagement Core of Northeastern's Superfund Research Program (Puerto Rico Testsite to Explore Contamination Threats (PROTECT) www.northeastern.edu/protect. He is on the National Advisory Environmental Health Science Council, which advises the director of NIH's National Institute of Environmental Health Sciences.

Julia Green Brody, Ph.D., is executive director and senior scientist at Silent Spring Institute, a scientific research organization that studies environmental chemicals and women's health, with a particular focus on breast cancer. She co-led the Household Exposure Study, which was described in Environmental Science & Technology as the most comprehensive study of endocrine disrupting compounds in homes. The study was the first to show that consumer products and indoor environments are major sources of exposure to phthalates, phenols, and flame retardants, among other chemicals. The value of this dataset led to her interest in the potential privacy risks of sharing environmental exposure data and to her partnership with

Dr. Sweeney. Dr. Brody's research has been funded by the National Institutes of Health and National Science Foundation and was recognized by the U.S. Environmental Protection Agency with an Environmental Merit Award in 2000. Dr. Brody is an adjunct assistant professor at the Brown University School of Medicine. She earned her Ph.D. at the University of Texas at Austin.

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Data

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Risk estimates of mortality attributed to low concentrations of ambient fine particulate matter in the Canadian community health survey cohort

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Abstract

Background: Understanding the shape of the relationship between long-term exposure to ambient fine particulate matter ($PM_{2.5}$) concentrations and health risks is critical for health impact and risk assessment. Studies evaluating the health risks of exposure to low concentrations of $PM_{2.5}$ are limited. Further, many existing studies lack individual-level information on potentially important behavioural confounding factors.

Methods: A prospective cohort study was conducted among a subset of participants in a cohort that linked respondents of the Canadian Community Health Survey to mortality ($n = 299{,}500$) with satellite-derived ambient PM2.5 estimates. Participants enrolled between 2000 and 2008 were followed to date of death or December 31, 2011. Cox proportional hazards models were used to estimate hazard ratios (HRs) for mortality attributed to $PM_{2.5}$ exposure, adjusted for individual-level and contextual covariates, including smoking behaviour and body mass index (BMI).

Results: Approximately 26,300 non-accidental deaths, of which 32.5 % were due to circulatory disease and 9.1 % were due to respiratory disease, occurred during the follow-up period. Ambient $PM_{2.5}$ exposures were relatively low (mean = 6.3 $\mu g/m^3$), yet each 10 $\mu g/m^3$ increase in exposure was associated with increased risks of non-accidental (HR = 1.26; 95 % CI: 1.19-1.34), circulatory disease (HR = 1.19; 95 % CI: 1.07–1.31), and respiratory disease mortality (HR = 1.52; 95 % CI: 1.26–1.84) in fully adjusted models. Higher hazard ratios were observed for respiratory mortality among respondents who never smoked (HR = 1.97; 95 % CI: 1.24–3.13 vs. HR = 1.45; 95 % CI: 1.17–1.79 for ever smokers), and among obese (BMI ≥ 30) respondents (HR = 1.76; 95 % CI: 1.15-2.69 vs. HR = 1.41; 95 % CI: 1.04–1.91 for normal weight respondents), though differences between groups were not statistically significant. A threshold analysis for non-accidental mortality estimated a threshold concentration of 0 $\mu g/m^3$ (+95 % CI = 4.5 $\mu g/m^3$).

Conclusions: Increased risks of non-accidental, circulatory, and respiratory mortality were observed even at very low concentrations of ambient $PM_{2.5}$. HRs were generally greater than most literature values, and adjusting for behavioural covariates served to reduce HR estimates slightly.

Keywords: $PM_{2.5}$, Fine particulate matter, Air pollution, Cardiovascular mortality, Respiratory mortality

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Background

Ambient fine particulate air pollution ($PM_{2.5}$) is known to contribute to cardiovascular and respiratory morbidity, and is recognized as an important contributor to global disease burden [1]. Recent estimates from Global Burden of Disease suggest that ambient air pollution was responsible for nearly 2.9 million deaths per year in 2013 [2]. While ambient $PM_{2.5}$ concentrations in Canada are generally below national and international guidelines, analyses from the 1991 Canadian Census Health and Environment Cohort (CanCHEC) suggest that long-term exposure to $PM_{2.5}$ in Canada (mean = 8.9 $\mu g/m^3$) may contribute to non-accidental and cardiovascular mortality [3]. However, that study did not include individual-level information on potentially important confounding factors such as smoking and obesity and applied an indirect approach to adjust for these and other factors [3, 4]. Analysis of the United States Agricultural Health Study (AHS) cohort also supports an association between cardiovascular mortality and long-term exposure to low concentrations of ambient $PM_{2.5}$ (mean = 9.2 $\mu g/m^3$) [5]. Moreover, a recent meta-analysis of studies conducted in North America and internationally supports an association between long-term exposure to $PM_{2.5}$ and mortality, with the strongest association observed for cardiovascular mortality [6].

The WHO $PM_{2.5}$ guideline of 10 $\mu g/m^3$ was based on the lower end of the exposure distribution in previous studies [1], though there are few studies that have evaluated concentration-response associations at very low exposures. The Global Burden of Disease 2010 study [1] developed a mortality risk model for $PM_{2.5}$ over the global range of concentrations. This model incorporated a counterfactual uncertainty distribution, below which no excess risk was assumed, and was specified by a uniform distribution between 5.8 $\mu g/m^3$ and 8.8 $\mu g/m^3$. This uncertainty distribution was selected based on the lack of empirical evidence of any statistical association between ambient $PM_{2.5}$ and mortality below their counterfactual distribution. These concentrations represent the 48.9^{th} and 79.9^{th} percentiles of the exposure distribution in this study, respectively. Therefore, it is of interest to examine the shape of the concentration-mortality association at these very low concentrations, as well as the statistical strength of evidence for such an association.

In this study, we examine the relationship between long-term exposure to ambient $PM_{2.5}$ and non-accidental, respiratory, and cardiovascular mortality in the Canadian Community Health Survey (CCHS) cohort. Participants in this cross-sectional survey were enrolled across Canada between 2000 and 2008 and provided detailed individual-level information on potentially important confounding factors (e.g. smoking, obesity) that were not available for the previous analysis of $PM_{2.5}$ and mortality in the CanCHEC study [3]. As such, the primary aim of this study was to examine the relationship between very low concentrations of $PM_{2.5}$ (mean = 6.3 $\mu g/m^3$) and different causes of mortality in Canada and the impacts of adjusting for potential confounding factors. Finally, an improved, finer-scale, satellite-derived exposure model for $PM_{2.5}$ (i.e., a 1 km^2 grid) was used to reduce exposure misclassification.

Methods

Data sources

The CCHS is a national, cross-sectional survey providing information about the health, behaviours, and health care use of the non-institutional Canadian population aged 12 or older. The survey excludes full-time members of the Canadian Armed Forces and residents of Indian reserves and certain remote areas. Exclusions represent less than 3 % of the target population of Canada [7]. The annual component of the CCHS was conducted every two years from 2000/01 to 2007, after which the survey was conducted on an annual basis. The CCHS response rates are as follows: 84.7 % in Cycle 1.1 (2000/01), 80.7 % in Cycle 2.1 (2003), 78.9 % in Cycle 3.1 (2005), 77.6 % in 2007, and 75.0 % in 2008 [7]. CCHS respondents were eligible for the CCHS-mortality cohort if they gave permission to share and link their information with other administrative datasets; 86.0 % of CCHS respondents agreed to the linkage.

The Canadian Mortality Database (CMDB) is a national database that contains all deaths registered in Canada since 1950. Deaths that occurred between January 1, 2000 and December 31, 2011 were eligible for linkage. The CMDB includes data on underlying cause of death and date of death.

The Historical Tax Summary File (HTSF) is a database of annual tax returns that represent all individuals who received a tax declaration in a given year. Tax years between 1996 and 2011 were eligible for linkage. The HTSF includes postal codes, names, and dates of death (if applicable).

Linkage methodology

The creation of the CCHS-Mortality Cohort was conducted in two steps. First, using a probabilistic linkage methodology based on the Fellegi-Sunter theory of record linkage [8], eligible CCHS respondents were linked to the HTSF (using date of birth, sex, name, and postal code), in order to capture these variables and date of death, as reported on tax files between 1996 and 2011. Approximately 85 % of eligible CCHS respondents were linked to the HTSF. Alternative postal codes and names were captured through this initial linkage and were used in the subsequent linkage to the CMDB, to improve linkage results. Second, all eligible CCHS respondents

(regardless of whether they were linked to the HTSF) were also linked to the CMDB (which included underlying cause of death), using standard probabilistic linkage techniques (as described above) and followed for mortality from cohort entry (i.e., date of CCHS interview) to December 31, 2011.

Data preparation

A total of 457,300 eligible CCHS-mortality respondents were included, with 117,800 respondents in Cycle 1, 112,900 respondents in Cycle 2, 113,900 respondents in Cycle 3, and 112,700 respondents in 2007/08. CCHS respondents who were first linked to the HTSF had a greater probability to be linked to the CMDB since additional data in the HTSF (e.g., alternate postal codes, name, and date of death), were used in the probabilistic linkage. In order to reduce the probability of false-negative links, we excluded those CCHS respondents who were not linked to the HTSF ($n = 69{,}300$ respondents excluded) (Additional file 1).

Since the purpose of this analysis was to evaluate long-term effects of air pollution exposure, the study population was restricted to adults aged 25 to 90 years of age at enrollment ($n = 72{,}000$ respondents excluded). Adults older than 90 years of age were excluded from this study to ensure a sufficient sample size within all age strata. Similar to the CanCHEC study [3], immigrants living in Canada for less than 20 years (i.e., those who had arrived in Canada less than 20 years before the start date), were excluded from this study ($n = 13{,}200$ additional respondents excluded) for the following reasons. Immigrants are known to have better health and live longer than the Canadian-born population [9]. Immigrants also more frequently live in areas of greater ambient air pollution (unpublished data), and their exposure to air pollution prior to living in Canada is largely unknown. Cause-specific mortality analyses among recent immigrants were also not meaningful due to small sample sizes in the CCHS cohort (i.e., < 250 deaths). Therefore, the use of a larger cohort would be necessary to examine the health effects of air pollution on recent immigrant populations. Finally, we excluded an additional 3,400 respondents who were not linked to air pollution estimates since they live beyond the boundaries of the air pollution models (i.e., in the northern Territories) (Additional file 1). The final analytical sample was 299,500 respondents (note slight inconsistencies due to rounding). All research using human data was carried out at Statistics Canada in accordance with the *Statistics Act* to meet standards of privacy and confidentiality associated with the internal use of survey data. The record linkage project was approved by the Executive Management Board at Statistics Canada (ref. num. 003–2015).

The place of residence of respondents at the date of entry into the Cohort was mapped in Geographic Information Systems (ArcGIS v.10; ESRI 2010) through the use of Statistics Canada's Postal Code Conversion File plus (PCCF+) V.6B, which assigns geographic coordinates to postal codes based on a population-weighted random allocation algorithm [10]. Respondent locations were then spatially linked to estimates from a surface layer of $PM_{2.5}$ concentration derived by relating total column aerosol optical depth retrievals from the Moderate Resolution Imaging Spectroradiometer (MODIS) instrument to near-surface $PM_{2.5}$ using the GEOS-Chem chemical transport model. Geographically weighted regression, which includes ground monitoring data and land use information, was subsequently applied to these estimates to produce average $PM_{2.5}$ concentrations at a $0.01^\circ \times 0.01^\circ$ (approximately 1 km^2) resolution from 2004 to 2012 [11]. These models included coverage for nearly all of mainland North America. These estimates were extended to 1998 to 2003 using the inter-annual variation of Boys et al. (2014) [12], who inferred global $PM_{2.5}$ trends at $0.1^\circ \times 0.1^\circ$ resolution using satellites from 1998 to 2012. Average $PM_{2.5}$ levels were strongly correlated with ground-level observations in North America ($R^2 = 0.82$, slope = 0.97; $n = 1440$) [11]. Outliers that included $PM_{2.5}$ values >20 ug/m^3 were excluded from analysis (<1 % of respondents were excluded in this manner in any year). These outliers were likely due to inaccurate estimates of aerosol optical depth from satellite retrievals. For each year in the cohort, respondents were assigned a $PM_{2.5}$ value corresponding to the mean of the three previous years to the follow-up year; therefore, exposure always preceded response. For example, for the follow-up year 2001, we assigned the mean $PM_{2.5}$ estimates from 1998 to 2000.

Covariates and statistical methods

Standard Cox proportional hazards models [13] were used for survival analysis of non-accidental and cause-specific mortality within the cohort, from the date of interview for the CCHS to either the date of death recorded in the CMDB or the final date of the linkage project (i.e., 31 December, 2011). All models were stratified by sex and age (5-year intervals). Socioeconomic covariates included: immigrant status, visible minority status, Aboriginal status, and marital status, educational attainment, income adequacy quintile, and employment status (Table 1). Visible minority status was defined as in the *Employment Equity Act*, as "persons, other than Aboriginal peoples, who are non-Caucasian in race or non-white in colour" [14]. Income adequacy quintiles were calculated based on the ratio of household income to the low-income cut-off for their household and community size. Low-income cut-offs represent families that spend more

Table 1 Descriptive statistics of the study cohort and $PM_{2.5}$ exposure, with Cox proportional HRs for each covariate

Covariate	Persons+	HR‡	95 % C.I.		$PM_{2.5}$	
			Lower	Upper	Mean	SD
All	299,500	–	–	–	6.32	2.54
Sex						
Male	137,800	–	–	–	6.28	2.54
Female	161,700	–	–	–	6.36	2.54
Age group†						
25–34 years	52,500	–	–	–	6.39	2.54
35–44 years	59,400	–	–	–	6.29	2.50
45–54 years	58,100	–	–	–	6.21	2.51
55–64 years	54,900	–	–	–	6.20	2.51
65–74 years	41,700	–	–	–	6.41	2.58
75–90 years	32,900	–	–	–	6.58	2.64
Immigrant status						
Not an immigrant	270,300	1.000	–	–	6.19	2.50
Immigrant (in Canada ≥ 20 years)	28,800	*0.863	0.834	0.894	7.57	2.52
Visible minority status						
White	281,000	1.000	–	–	6.31	2.53
Visible minority	17,700	0.938	0.877	1.004	6.49	2.67
Aboriginal status						
Not Aboriginal	289,600	1.000	–	–	6.36	2.54
Aboriginal	9,200	*1.390	1.267	1.525	5.12	2.21
Marital status						
Married or common-law	183,500	1.000	–	–	6.09	2.46
Separated, divorced, widowed	69,500	*1.344	1.306	1.382	6.62	2.60
Single, never married	46,400	*1.512	1.446	1.581	6.82	2.63
Educational attainment						
Not completed high school	71,700	1.000	–	–	6.01	2.58
High school diploma	113,500	*0.829	0.806	0.852	6.25	2.50
Post-secondary diploma/certificate	64,900	*0.723	0.694	0.753	6.43	2.51
University degree	47,100	*0.581	0.552	0.611	6.83	2.51
Low income adequacy quintile						
1st quintile - lowest	56,200	1.000	–	–	6.53	2.64
2nd quintile	54,500	*0.787	0.762	0.813	6.37	2.58
3rd quintile	53,000	*0.662	0.637	0.689	6.37	2.52
4th quintile	53,300	*0.583	0.557	0.610	6.34	2.49
5th quintile - highest	56,700	*0.483	0.458	0.509	6.17	2.43
Employment status						
Employed	174,500	1.000	–	–	6.31	2.50
Not employed: looked for work‡	7,300	*1.522	1.319	1.757	6.20	2.61
Not employed: did not look for work‡	78,100	*1.818	1.732	1.908	6.25	2.55
Permanently unable to work	9,800	*4.533	4.274	4.808	6.43	2.64
Body Mass Index[a]						
Underweight (<18.5)	3,700	*2.140	1.989	2.303	6.76	2.60
Normal weight (18.5 - 25.0)	93,700	1.000	–	–	6.54	2.55

Table 1 Descriptive statistics of the study cohort and $PM_{2.5}$ exposure, with Cox proportional HRs for each covariate *(Continued)*

Overweight (25.0 - 30.0)	114,900	*0.804	0.781	0.828	6.29	2.52
Obese I (30.0 - 35.0)	54,700	*0.884	0.852	0.917	6.14	2.52
Obese II (>35.0)	24,200	*1.270	1.209	1.334	6.06	2.53
Fruit and vegetable consumption						
<5 servings per day	153,200	1.000	–	–	6.38	2.56
≥5 servings per day	101,100	*0.828	0.806	0.851	6.52	2.52
Smoking						
Never smoked	84,100	1.000	–	–	6.41	2.53
Former smoker	139,200	*1.284	1.244	1.324	6.26	2.51
Current daily or occasional smoker	75,900	*2.604	2.509	2.702	6.33	2.59
Alcohol						
Regular drinker (≥1 drink per month)	141,700	1.000	–	–	6.51	2.55
Occasional or former drinker	80,800	*1.394	1.356	1.433	6.25	2.59
Never drinker	11,000	*1.274	1.214	1.337	6.17	2.64
Ecological covariates[b]						
% recent immigrants (CD-DA)	–	*1.102	1.064	1.141	–	–
% recent immigrants (CD)	–	*0.713	0.680	0.747	–	–
% completed high school (CD-DA)	–	*0.928	0.919	0.938	–	–
% completed high school (CD)	–	*0.897	0.886	0.908	–	–
% in low income families (CD-DA)	–	*1.119	1.107	1.131	–	–
% in low income families (CD)	–	*1.100	1.070	1.131	–	–

+Numbers were rounded to the nearest 100 for confidentiality
‡Models were stratified by age (5 year categories) and sex
*Significant HR ($p < 0.05$)
†At time of entry into the cohort
‡(Did not) look for work in past 4 weeks
[a]After adjusting for self-reporting bias in CCHS, as in [16]
[b]HRs provided for 10 % increase in population

than 20 % of their income on food, shelter and clothing, and are adjusted for size of family and area of residence [14].

Neighbourhood socioeconomic status, including both social and material deprivation, contributes to increased risk of mortality in Canadian cities, although the presence of immigrants can reduce mortality risk [15]. Ecological (contextual) covariates were derived from the long-form Canadian Census at the Census Division (CD) and Dissemination Area (DA) geographic scale, from the 2001 Census for respondents interviewed between 2000 and 2003, and the 2006 Census for respondents interviewed during or after 2004. Census Divisions are a subdivision of the provinces and territories that usually represent communities, regional districts, or several neighbouring municipalities, and range in size from several thousand to a few million persons [14]. Dissemination Areas are the smallest geographical unit used by the Census and are delineated based on population counts based on the previous census, to target a population of 400–700 persons [14]. There were 288 CDs and 54,623 DAs in Canada as of 2006 [14]. These contextual covariates were then linked to individual respondents through a common geographic identifier (i.e., a numeric code identifying the DA or CD). For each CD and DA, the proportion of recent immigrants (<5 years residency in Canada), educational attainment (the proportion of persons aged 15 years or older who had not graduated from high school) and low income (the proportion of persons below the low-income cut-off) were derived for both Census years [16]. The proportion of recent immigrants in a region may provide a health benefit in the form of social inclusion if the resident is a member of a unified community, though it also may represent social deprivation, since recent immigrants also include persons of very low SES upon arrival in Canada (e.g., refugees or temporary workers). The other two ecological covariates (educational attainment and low income) provide a more direct estimate of neighbourhood socioeconomic status. Although broader geographic scales such as Census Tracts (CTs) are more often used to derive neighbourhood contextual variables [16], CTs were not available for rural areas. Neighbourhood covariates were therefore calculated by taking the difference between CD

and DA estimates. It was expected *a priori* that the ecological covariates would attenuate risk estimates as in previous work on CanCHEC [3].

In addition to the socioeconomic and ecological covariates, this study included four health status/behavioural covariates. Body Mass Index (BMI) was derived from the self-reported height and weight of respondents, and adjusted using correction factors that were developed for the CCHS to account for self-reporting bias in BMI data [17]. The International Standard Classification was used to categorize Body Mass Index [18], with obesity subdivided into two categories (i.e., BMI 30 – 34.9 and BMI ≥ 35) to further differentiate health risks among obese persons within the study. Smoking behaviour was categorized as never, former, or current smokers. Detailed data on smoking behaviour (e.g., number of cigarettes smoked per day) were available only for daily smokers (ca. 21.3 % of respondents) and were therefore not included. Fruit and vegetable daily consumption and alcohol consumption were also included, as in previous studies [19] (Table 1).

Survival models were examined in a sequential manner by adding all of the socioeconomic covariates in a single model, then adding in the ecological covariates to the socioeconomic models, and finally by adding the behavioural covariates to create fully adjusted models for non-accidental mortality (ICD-10 codes A-R) and mortality attributed to circulatory disease (ICD-10: I00–I99, with and without diabetes, E10–E14), including the subgroups of ischemic heart disease (ICD-10: I20–I25), and cerebrovascular disease (ICD-10: I60–I69). We also considered models for mortality due to respiratory disease (ICD-10: J00–J99), also including chronic obstructive pulmonary disease (ICD-10: J19–J46), and lung cancer (ICD-10: C33–C34). We also examined a model of socioeconomic and behavioural covariates, excluding ecological covariates. We added groups of variables in this manner to specifically examine the influence of including the behavioural variables to a model which included both socioeconomic and ecological variables, as were available in previous cohort studies in Canada [3]. Effect modification by sex, smoking behaviour (ever smoked vs. never smoked), BMI (obese: BMI ≥ 30 and obese II: BMI ≥ 35 vs. normal weight: BMI = 18.5–25), fruit and vegetable consumption (<5 servings vs. ≥ 5 servings), alcohol consumption (regular drinker vs. occasional/never/former drinker), and age (<75 years vs. ≥ 75 years) were also evaluated in separate Cox proportional hazards models, and Cochran's Q-statistic heterogeneity tests were used to evaluate significant differences in HRs among groups [20]. These covariates were chosen for effect modification analysis due to known physiological differences between these groups of respondents, and interest in previous studies [6].

To examine the shape of the relationship between non-accidental mortality hazard ratio (HR) and air pollution exposure, we fitted spline-based HR curves using the smoothing method in the R package "smoothHR" on the fully adjusted model [21]. The package uses a combination of AIC and BIC to determine the optimal degrees of freedom to use in the model [21]. We also estimated the $PM_{2.5}$ threshold concentration (T) by fitting Cox proportional hazards models to a series of newly defined $PM_{2.5}$ based variables of the form: $PM_{2.5}$ (T) = $PM_{2.5}$ − T; if PM_i > T and 0 otherwise, for T = 1 to 10. Our estimate of T is the concentration corresponding to the largest (−2) log-likelihood value (−2LL) obtained from the Cox model. Ninety-five percent confidence intervals on T were based on changes in -2LL of 3.84 units.

All descriptive statistics reported from the survey were rounded to the nearest hundred for institutional confidentiality reasons.

Results

A total of 299,500 respondents were included in the study after excluding respondents who were not linked to a tax file, respondents who were not within the 25 to 90 year age range and were not recent immigrants (i.e., < 20 years in Canada), and respondents who were not linked to air pollution estimates. Respondents were followed for mortality for up to 12 years after cohort entry (mean follow-up period (± SD) was 7.6 ± 2.7 years). The mean exposure (± SD) of respondents to $PM_{2.5}$ estimated from the 3-year moving average was 6.3 ± 2.5 μg/m^3. The $PM_{2.5}$ person-year exposure percentiles within the final study cohort were: minimum: 1.0 μg/m^3, 5th: 3.0 μg/m^3, 25th: 4.2 μg/m^3, median: 5.9 μg/m^3, 75th: 8.3 μg/m^3, 95th: 11.3 μg/m^3, and maximum: 13.0 μg/m^3. In large cities (metropolitan pop. > 1 million), $PM_{2.5}$ estimates were generally greater than in surrounding areas, and there were areas of the downtown core exceeding 8 ug/m^3 in all of these cities (Fig. 1). Mean $PM_{2.5}$ exposure increased incrementally by decreasing income quintile and was highest for respondents in the poorest income quintile (Table 1). $PM_{2.5}$ exposure was also greatest for the most highly educated respondents (Table 1). Obese respondents were exposed to less air pollution than those of increasingly lower weight classes, with the greatest exposure among respondents classified as underweight (Table 1). Hazard ratios for non-accidental mortality were calculated for all variables and ecological covariates (Table 1). Among ecological covariates for DAs and CDs, the proportion of recent immigrants, high school graduates and low income families were positively correlated with average $PM_{2.5}$ air pollution exposure (Table 2). The proportion of recent immigrants was protective for mortality at the broader landscape level (i.e., the CT), though increased HRs at the

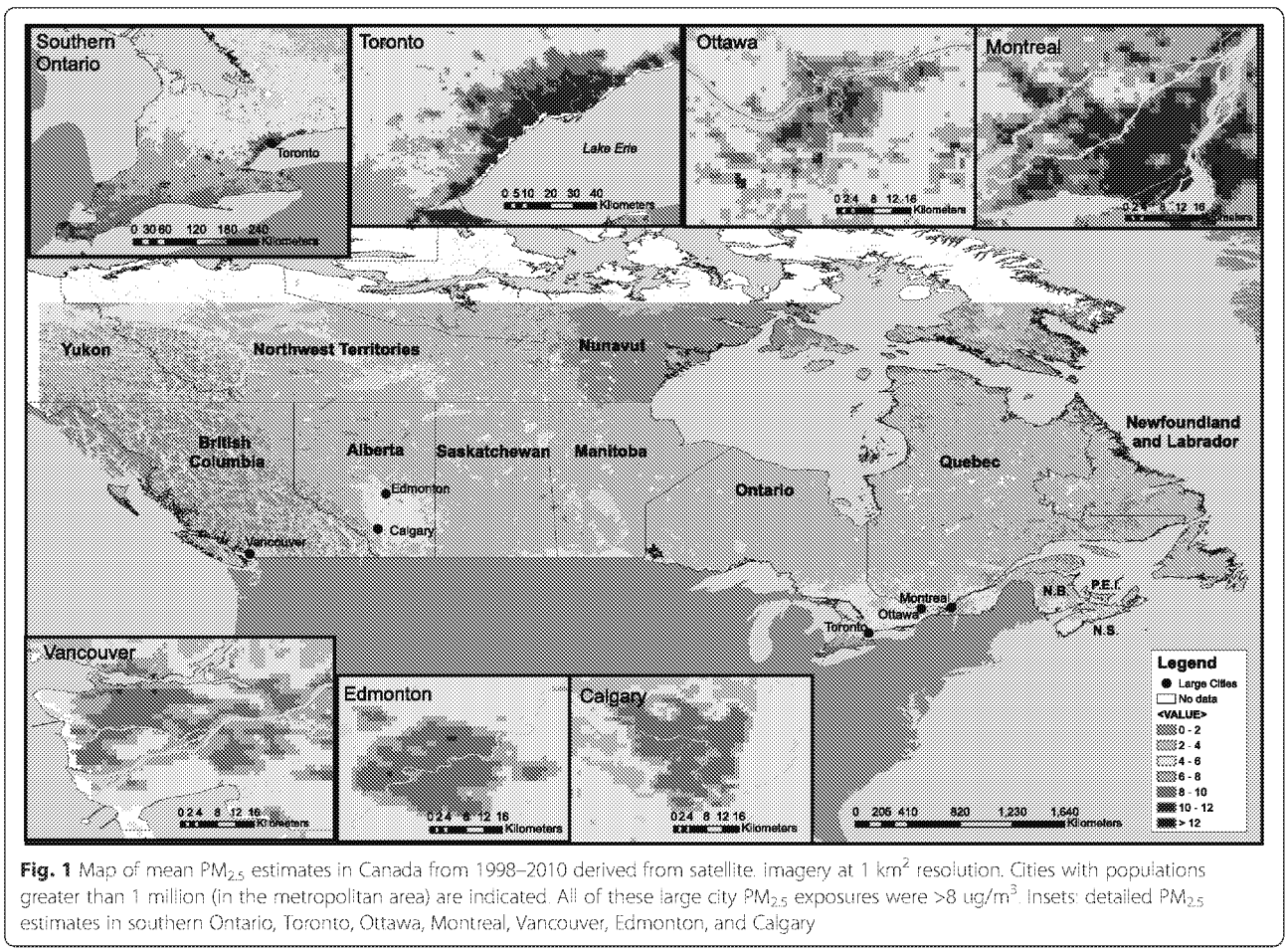

Fig. 1 Map of mean $PM_{2.5}$ estimates in Canada from 1998–2010 derived from satellite imagery at 1 km^2 resolution. Cities with populations greater than 1 million (in the metropolitan area) are indicated. All of these large city $PM_{2.5}$ exposures were >8 ug/m^3. Insets: detailed $PM_{2.5}$ estimates in southern Ontario, Toronto, Ottawa, Montreal, Vancouver, Edmonton, and Calgary

neighbourhood scale (i.e., DAs) (Table 1). Associations between all combinations of the covariates are provided in Additional file 2.

Separate Cox proportional hazards models were run for all covariates in the fully adjusted models. Immigrant status, greater educational attainment, higher income, being overweight or obese (type I), and increasing consumption of fruits and vegetables were all associated with a lower risk of non-accidental mortality (Table 1). Aboriginal status, being unmarried, being underweight or obese (type II), not employed, smoking, and not regularly drinking alcohol were associated with a greater risk of non-accidental mortality (Table 1).

Covariates were added in a stepwise manner to a Cox proportional hazards model for non-accidental mortality to assess their contribution to the model (Table 3). In

Table 2 Descriptive statistics of ecological covariates derived from the 2001 and 2006 Census[a]

Variable	Min	Percentile					Max	Correlation with mean $PM_{2.5}$
		5th	25th	50th	75th	95th		
Aggregated by Dissemination Area								
% recent immigrants	0.0	0.0	0.0	0.0	1.7	9.0	69.0	0.303
% completed high school	0.0	47.4	63.6	73.5	82.4	92.3	100.0	0.245
% in low income families	0.0	1.5	5.9	10.9	18.4	35.1	100.0	0.235
Aggregated by Census Division								
% recent immigrants	0.0	0.1	0.3	0.7	1.9	9.5	16.7	0.424
% completed high school	31.2	52.3	65.8	72.7	78.6	85.1	88.6	0.462
% in low income families	3.4	7.8	10.5	12.9	15.3	21.1	37.1	0.192

[a]Source: 2001 or 2006 Census data were chosen based on the closest year to the Cohort entry

Table 3 Cox proportional HRs for non-accidental mortality[a] in the cohort, with stepwise addition of covariates

		95 % CI		
	HR[b]	Lower	Upper	(−2) log l
Unadjusted	1.028	0.981	1.077	447,246
SES covariates added separately				
Immigrant status	*1.069	1.019	1.120	447,165
Visible minority status	1.031	0.984	1.080	447,237
Aboriginal status	1.035	0.988	1.085	447,217
Marital status	0.999	0.954	1.047	446,677
Educational attainment	*1.114	1.063	1.168	446,442
Income adequacy quintiles	1.031	0.985	1.081	446,127
Employment	1.032	0.985	1.081	445,050
All socioeconomic covariates	*1.103	1.052	1.157	443,829
All SES + ecological covariates added separately				
% recent immigrants	*1.253	1.190	1.320	440,157
% completed high school	*1.349	1.278	1.424	437,545
% low income	1.045	0.994	1.099	433,397
All SES + all ecological covariates	*1.345	1.270	1.424	433,080
All SES + all ecological + behavioural covariates added separately				
Smoking	*1.341	1.267	1.420	431,304
Alcohol consumption	*1.292	1.221	1.368	432,308
Fruit and vegetable consumption	*1.342	1.267	1.421	433,004
Body Mass Index	*1.345	1.270	1.424	432,338
All SES + all ecological + all behavioural covariates	*1.261	1.190	1.336	429,524

[a]Number of deaths = 26,300
[b]Models are stratified by age (5 year categories) and sex
*Significant HR ($p < 0.05$)
SES Socioeconomic

general, the addition of socioeconomic covariates improved the model fit, and resulted in a significantly increased HR from the unadjusted model (Table 3; Cochran's Q = 4.29; $p = 0.04$). The additional of behavioural covariates to the socioeconomic model reduced HRs somewhat, though not significantly (Table 3; Cochran's Q = 0.23, $p = 0.63$). The addition of ecological covariates to the socioeconomic model, particularly the percentage of recent immigrants and high school graduates, also improved model fit and significantly increased HRs (Table 3; Cochran's Q = 27.30, $p < 0.01$). The addition of behavioural covariates to create a fully adjusted model also improved model fit, though the HRs declined non-significantly from the second adjusted model (Table 3; Cochran's Q = 2.41, $p = 0.12$).

Table 4 presents the HRs and 95 % CI for Cox proportional hazard models for non-accidental mortality and mortality due to circulatory or respiratory causes. In the fully adjusted model, HR estimates for non-accidental mortality were 1.26 (95 % C.I.: 1.19–1.34) per 10 μg/m^3 increase in ambient $PM_{2.5}$. The strongest association was observed for respiratory disease mortality, with an HR of 1.52 (95 % C.I.: 1.26–1.84) per 10 μg/m^3 increase in ambient $PM_{2.5}$. In fully adjusted models, HRs were significantly greater than one for all causes of death except cerebrovascular disease and lung cancer, though the HRs were significant in the models that did not include behavioural covariates (Table 4). For all causes of death, HRs were greater in the fully adjusted model than in the unadjusted model, though were reduced after adding behavioural covariates (Table 4).

The results of effect modification by sex, age, BMI (i.e., obese vs. normal weight), fruit and vegetable consumption (i.e., < 5 or ≥ 5 daily servings), smoking (i.e., ever smoked vs. never smoked) and alcohol consumption are presented in Table 5. In a fully adjusted model, the HR for non-accidental mortality among men was 1.34 (95 % C.I.: 1.24–1.46) per 10 μg/m^3 increase in ambient $PM_{2.5}$ and was significantly greater than that of women (Cochran's Q; Table 5). The HRs for circulatory and respiratory disease mortality among men were also greater than among women, though the differences in HRs were not statistically significant (Cochran's Q; Table 5). None of the other comparisons among groups

Table 4 Cox proportional HRs for mortality per 10 μg/m^3 increase in ambient $PM_{2.5}$ in the study cohort ($n = 299{,}500$)

		Unadjusted[+]			Adjusted: SES[†]			Adjusted: SES[†] + behavioural cov.[§]			Adjusted: SES[†] + ecological cov.[‡]			Adjusted: SES[†] + ecological cov.[‡] + behavioural cov.[§]		
			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI	
Cause of mortality	Deaths	HR	To	From	HR	To	From	HR	To	From	HR	To	From	HR	To	From
Non-accidental[a]	26,300	1.028	0.981	1.077	*1.103	1.052	1.157	*1.085	1.034	1.139	*1.345	1.270	1.424	*1.261	1.190	1.336
Circulatory disease[b]	8,600	0.940	0.866	1.020	1.014	0.932	1.102	0.997	0.917	1.085	*1.297	1.174	1.434	*1.187	1.073	1.313
Circulatory-diabetes[c]	9,500	0.939	0.868	1.015	1.016	0.938	1.100	1.011	0.933	1.096	*1.313	1.194	1.444	*1.210	1.099	1.331
Ischemic heart d. [d]	4,700	0.979	0.877	1.093	1.090	0.975	1.220	1.078	0.963	1.207	*1.408	1.232	1.610	*1.290	1.127	1.477
Cerebrovascular d. [e]	1,500	1.064	0.879	1.288	1.082	0.890	1.316	1.063	0.872	1.295	*1.360	1.078	1.715	1.241	0.981	1.570
Respiratory disease[f]	2,400	1.133	0.970	1.324	*1.269	1.083	1.487	*1.214	1.034	1.425	*1.628	1.347	1.969	*1.522	1.257	1.843
COPD[g]	1,400	1.032	0.839	1.268	1.191	0.966	1.469	1.109	0.897	1.370	*1.480	1.150	1.903	*1.398	1.085	1.801
Lung cancer[h]	2,700	1.007	0.871	1.166	*1.170	1.008	1.357	1.088	0.937	1.263	*1.216	1.017	1.453	1.167	0.975	1.396

[+]Unadjusted and all adjusted models were stratified by age (5 year categories) and sex

[†]SES covariates: immigrant status, visible minority status, Aboriginal status, marital status, income adequacy quintile, educational attainment, and employment

[§]Behavioural covariates: smoking, alcohol consumption, fruit and vegetable consumption, and BMI

[‡]Ecological covariates: (CD-DA and CD) for % recent immigrants, % completed high school, and % low income household

*Significant HR, $p < 0.05$

[a]Includes ICD-10 codes A-R. [b]Includes ICD-10 codes I00-I99. [c]Includes ICD-10 codes I00-I99 and E10-E14. [d]Includes ICD-10 codes I20-I25. [e]Includes ICD-10 codes I60-I69. [f]Includes ICD-10 codes J00-J99. [g]Includes ICD-10 codes J19-J46. [h]Includes ICD-10 codes C33-C34

Table 5 Effect modification of Cox HRs[†] by sex, age[‡], smoking, obesity, and fruit/vegetable and alcohol consumption

			95 % CI				95 % CI		Cochran's Q	
Cause of death	Deaths	HR	Lower	Upper	Deaths	HR	Lower	Upper	Q	p
	Females ($n = 161,700$)				Males ($n = 137,800$)					
Non-accidental	12,700	*1.181	1.088	1.282	13,000	*1.344	1.239	1.457	4.829	0.028
Circulatory	4,100	1.109	0.959	1.282	4,300	*1.268	1.101	1.459	1.687	0.194
Respiratory	1,100	1.323	0.998	1.754	1,300	*1.698	1.307	2.206	1.617	0.204
	<75 years old[‡] ($n = 266,600$)				≥75 years old[‡] ($n = 32,900$)					
Non-accidental	13,100	*1.248	1.151	1.353	12,600	*1.237	1.140	1.342	0.023	0.880
Circulatory	3,500	*1.239	1.058	1.450	4,900	1.100	0.965	1.254	1.295	0.255
Respiratory	1,000	*1.553	1.158	2.083	1,300	*1.461	1.136	1.878	0.096	0.757
	Ever Smoked ($n = 215,100$)				Never Smoked ($n = 84,100$)					
Non-accidental	19,400	*1.231	1.152	1.315	6,300	*1.397	1.242	1.571	3.381	0.066
Circulatory	6,000	*1.164	1.034	1.311	2,300	*1.287	1.060	1.563	0.749	0.387
Respiratory	1,900	*1.449	1.174	1.788	400	*1.966	1.236	3.129	1.376	0.241
	Obese I and II ($n = 78,900$)				Normal weight ($n = 93,700$)					
Non-accidental	6,200	*1.215	1.077	1.370	8,700	*1.264	1.147	1.394	0.250	0.617
Circulatory	2,100	1.110	0.903	1.364	2,700	1.125	0.945	1.339	0.009	0.922
Respiratory	500	*1.757	1.146	2.694	900	*1.408	1.041	1.905	0.688	0.407
	Obese II ($n = 24,200$)[b]				Normal weight ($n = 93,700$)					
Non-accidental	1,900	1.142	0.919	1.419	8,700	*1.264	1.147	1.394	0.698	0.403
Circulatory	700	0.888	0.609	1.294	2,700	1.125	0.945	1.339	1.247	0.264
	<5 fruit/veg servings ($n = 153,200$)				≥5 fruit/veg servings ($n = 101,100$)					
Non-accidental	12,900	*1.217	1.124	1.318	8,500	*1.199	1.087	1.322	0.054	0.817
Circulatory	4,100	1.098	0.954	1.263	2,900	*1.322	1.117	1.563	2.764	0.096
Respiratory	1,200	*1.421	1.091	1.852	700	*1.505	1.078	2.101	0.070	0.792
	Regular drinker ($n = 141,700$)				Not regular drinker[a] ($n = 91,800$)					
Non-accidental	9,600	*1.280	1.168	1.403	13,300	*1.280	1.182	1.387	<0.001	1.000
Circulatory	2,900	*1.257	1.065	1.483	4,600	*1.201	1.048	1.376	0.174	0.677
Respiratory	800	*1.473	1.070	2.027	1,300	*1.449	1.120	1.875	0.006	0.938

[†]All models are stratified by age (5 year categories) and sex, and adjusted for the following covariates: immigrant status, visible minority status, Aboriginal status, marital status, educational attainment, income adequacy quintile, employment, body mass index, fruit and vegetable consumption, smoking, and alcohol. For each comparison, the stratum or covariate being compared was not included as a stratum/covariate in the model (i.e., smoking was not included as a covariate in the smoking comparison)

[‡]Age at entry into Cohort

+Cochran's Q test for significant difference of HR between groups

*Significant HR ($p < 0.05$)

[a]Includes occasional, former, or never drinker

[b]Respiratory mortality not shown; mortality for obese II: n < 200

were statistically significant (Table 5). However, the HR of respiratory disease mortality was particularly high among never smokers (HR: 1.97; 95 % CI: 1.23–3.13 per 10 μg/m^3 increase in $PM_{2.5}$) and among obese respondents (HR = 1.76, 95 % CI: 1.15–2.69 per 10 μg/m^3 increase in $PM_{2.5}$) (Table 5).

We fitted a nonparametric smoothing (spline) to examine the shape of the association between exposure and non-accidental mortality within the fully adjusted model. The relationship between the logarithm of the hazard function and $PM_{2.5}$ is presented in Fig. 2 in addition to its 95 % confidence intervals. We specified a reference concentration of 1 μg/m^3 which forces the predicted log-hazard function to equal 0 at the reference level. The smoothed curve generally increased with increasing concentration, however the confidence intervals are relatively wide making it difficult to speculate on a specific shape of the concentration-mortality association based on this graphical evidence. Our estimate of the threshold concentration was 0 μg/m^3 with an upper 95 % CI value of 4.5 μg/m^3.

Discussion

Within our cohort, exposure to $PM_{2.5}$ assigned at baseline was associated with an increased risk of non-accidental mortality and mortality due to circulatory and respiratory disease. Risks for all causes of death examined were greatest after adjusting for socioeconomic and ecological covariates, though were reduced after adjusting for smoking, alcohol consumption, BMI, and fruit/vegetable consumption. The largest hazard ratios per 10 μg/m^3 increase in $PM_{2.5}$ were observed for respiratory mortality compared to the other cause-specific estimates. Elevated risk was observed for respiratory mortality associated with air pollution among obese respondents and never-smokers, though the differences between these and reference groups were not statistically significant. We also examined the shape of the exposure-response curve, and although the lowest measured concentration of $PM_{2.5}$ was 1 μg/m^3, we found no lower threshold for response. Although this finding is potentially informative for burden assessment, it is worth noting that we did not distinguish between anthropogenic and natural sources of $PM_{2.5}$ in this study.

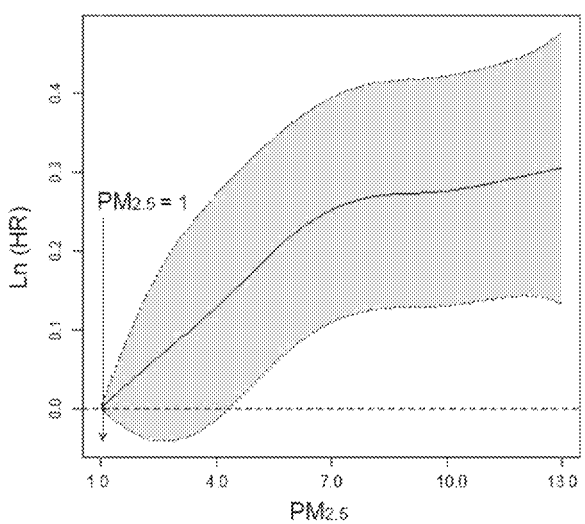

Fig. 2 Nonparametric estimates of the dependence of non-accidental mortality on $PM_{2.5}$ exposure among in-scope respondents in the CCHS-cohort linked to a $PM_{2.5}$ dataset (log hazard ratio with 95 % confidence intervals). The model was stratified by age and sex, and adjusted for all covariates (Table 1). Model predictions were made up to the 99th percentile of the $PM_{2.5}$ exposure distribution

This study adds to previous work in Canada, which has a generally lower mean $PM_{2.5}$ exposure than other countries, by providing direct adjustments for behavioural covariates (i.e., smoking and obesity) that are known contributors to mortality. This study used similar methodology to a previous study in Canada, the Canadian Census Health and Environment Cohort (CanCHEC) [3], but was unable to directly evaluate the role of behavioural covariates. In general, our HR estimates for non-accidental mortality (HR = 1.26; 95 % CI: 1.19–1.34) were greater than those in CanCHEC (HR = 1.15; 95 % CI: 1.13–1.16; Cochran's Q = 9.3, $p < 0.01$), though our estimates for circulatory death were similar (CCHS HR = 1.19; 95 % CI: 1.07–1.31; CanCHEC HR = 1.16; 95 % C.I.: 1.13–1.18; Cochran's Q = 0.1, $p = 0.8$) (all units per 10 μg/m^3 increase in $PM_{2.5}$) [3].

The fact that we found stronger associations between mortality and $PM_{2.5}$ here than were observed in the CanCHEC study [3] might be due to improvements in estimates of $PM_{2.5}$. A new $PM_{2.5}$ model developed at a much finer scale (1 km^2 grid rather than 10 km^2 grid) allowed respondents to be assigned more accurate, finer-scale estimates exposure to of $PM_{2.5}$. This improved exposure model may have a particularly strong effect on respondents who live in mid-sized cities (e.g., Calgary, Edmonton) that would otherwise have been assigned a lower, regional (i.e., rural) average (Fig. 1). However, this improvement is expected to be limited somewhat by the limitations of location error in geocoding residences based on postal code, as well as respondent mobility throughout the study area, resulting in differences in personal exposure. Another strength of this study was that it assigned exposures to respondents in the three years preceding death, thereby ensuring that exposure always preceded health effects rather than being assigned concurrently. This method also takes long-term variation of exposure into account.

In our study, HR estimates increased after the addition of ecological covariates, which differs from the

earlier CanCHEC study, in which the addition of ecological covariates served to decrease the HR estimates [3]. As described earlier, the ecological covariates used here were derived for smaller areas than in the CanCHEC study due to the absence of Census Tracts in rural areas. The methodological differences in deriving ecological covariates, particularly at a finer scale (i.e., assigning DA-level covariates rather than CT-level covariates), may also be one of the primary reasons why differences in HR estimates were observed between this study and CanCHEC, since fine scale covariates would be more spatially variable and covariates would more accurately reflect local socioeconomic conditions. Indeed, when the ecological covariates were removed from the Cox models of non-accidental mortality, the otherwise fully adjusted model provided an HR = 1.085 (Table 3), which is more consistent with the fully adjusted models in CanCHEC [3]. Ecological covariates included in this study were all positively correlated with $PM_{2.5}$ (Table 2). Given the much greater $PM_{2.5}$ exposure in urban environments, this association for recent immigrants and persons of high educational attainment is possibly due to a higher population of both in cities. The correlation with $PM_{2.5}$ was weaker for the proportion of low income families, which was consistent with the similar proportions of regional-adjusted low-income families in rural and urban environments [22].

Our HRs for non-accidental mortality were greater than those reported for all-cause mortality in other, international studies that had considered the same behavioural covariates, though were generally similar when ecological covariates were excluded from our estimates [6, 23–25]. For example, the American Cancer Society study, which included 1.2 million adults in the United States, estimated an HR for all-cause mortality of 1.06 per 10 $\mu g/m^3$ increase in $PM_{2.5}$ (95 % C.I.: 1.02–1.11) after controlling for behavioural covariates, though that study did not include ecological covariates [23]. Similarly, a global, pooled meta-analysis estimated an all-cause mortality HR of 1.06 (95 % C.I.: 1.04–1.08) per 10 $\mu g/m^3$ increase in $PM_{2.5}$ [6]. However, our results with ecological covariates were not significantly different from those of a large meta-analysis of European studies, where the pooled HR estimate for natural-cause mortality adjusted for socioeconomic and behavioural covariates (though not large-scale socioeconomic covariates) was 1.09 per 5 $\mu g/m^3$ increase in $PM_{2.5}$ (95 % C.I.: 1.03–1.14) [26]. This estimate was not significantly lower than in our study (Cochran's Q = 0.8, $p = 0.4$), where HR = 1.12 (95 % C.I.: 1.09–1.16) when scaled to a 5 $\mu g/m^3$ increase in $PM_{2.5}$.

Hazard ratio estimates for mortality due to circulatory disease (i.e., HR = 1.19) were generally consistent with those reported in the international literature, including the Harvard Six Cities study extended follow-up, which reported a HR of 1.28 per 10 $\mu g/m^3$ increase in $PM_{2.5}$ [6, 27], and a study in the U.K., which reported an HR of 1.05 per 1.9 $\mu g/m^3$ increase in $PM_{2.5}$ after adjustment for sex, age, BMI, and smoking (our study: HR = 1.03, 95 % CI: 1.01–1.05 when scaled to a 1.9 $\mu g/m^3$ increase) [28]. However, our estimate was much greater than that reported from a study in Rome (HR = 1.06, 95 % CI: 1.04–1.08), which adjusted for some individual and area-based socioeconomic covariates [24], and the Dutch Environmental Longitudinal Study (DUELS), which reported an HR of 1.09 (95 % CI: 1.06–1.12) per 10 $\mu g/m^3$ increase in $PM_{2.5}$ [25].

Our hazard ratio estimates for respiratory disease (HR = 1.52) were generally greater than those in the literature, though literature estimates for HRs vary among studies. For example, one study in Rome that used area-based socioeconomic covariates identified a non-significant HR of 1.03 for respiratory disease [24]. On the other hand, the California Teachers Study identified an HR for respiratory mortality of 1.21 [29], and the Dutch cohort (DUELS) estimated an HR of 1.18 [25], which were similar to our HR estimate for respiratory mortality prior to adjustment for ecological covariates (HR = 1.21). Another study in the UK reported an HR of 1.17 (95 % CI: 1.12–1.22) per 1.9 $\mu g/m^3$ increase in $PM_{2.5}$ [28]. Our HR estimate after adjustment for ecological covariates was lower than this study (HR = 1.08, 95 % CI: 1.04–1.12) when scaled to a 1.9 $\mu g/m^3$ increase in $PM_{2.5}$.

Our study also evaluated the role of effect modification by sex, age and behavioural covariates, and found a significantly greater HR estimate for non-accidental mortality among men than women. In a pooled European analysis of multiple cohorts, HRs were elevated among men but not women [26]. Our results are overall similar, although our generally greater HR estimates for non-accidental mortality might explain why HR was significant for both men and women. Men also had a greater HR than did women for circulatory disease mortality (though the differences were not significant), similar to the AHS cohort [5]. This finding was inconsistent with the results of a small ($n = 3,239$) cohort of white, non-smoking adults, where the relative risk of coronary heart disease mortality was elevated among women but not among men in a fully adjusted model [30]. Observed differences might be, at least in part, explained by relatively small cohort sizes.

Our HR estimates for non-accidental and circulatory mortality among obese and normal weight groups were not significantly different. Effect modification of cardiovascular mortality by obesity had previously been evaluated elsewhere in two all-female cohorts. One study identified a significantly greater HR with increasing

BMI, with an HR for obese women of 1.35 (95 % C.I.: 1.12–1.64 per 10 μg/m^3 increase in $PM_{2.5}$) [31]. The other study did not test differences statistically among groups but did report an HR of 1.99 (95 % C.I.: 1.23–3.22 per 10 μg/m^3 increase in $PM_{2.5}$) for obese women [32]. The ACS also reported a greater HR among obese men [5]. In our study, obese respondents also had a high risk of respiratory mortality (HR = 1.76; 95 % C.I.: 1.15–2.69), though possibly due to a small number of deaths (n = 500), the HR estimate was not significantly different from the normal weight population.

In our study, persons who had never smoked had a qualitatively greater risk of non-accidental and circulatory mortality from fine particulate exposure than those who had smoked, though the difference between groups was non-significant (Table 5). This finding was consistent with the literature, where a marginally greater risk of cardiovascular mortality was observed among never smokers than among current or former smokers [6, 23, 33, 34]. In a Dutch cohort, respiratory mortality was qualitatively greater among current smokers than never smokers [34], a finding that was not consistent with our study.

There were several limitations with our study that may contribute to uncertainty in our estimates. The cohort was chosen because of the inclusion of various behavioural covariates, but it is generally much smaller than that of CanCHEC, which used the Census of population (i.e., 20 % of the population of Canada) [3]. Mean estimates of $PM_{2.5}$ in Canada are generally lower than in other study countries [6], and the effect size is relatively small, requiring a large sample size to have adequate power for HR estimation. As a result, in our study the 95 % CIs were very wide in comparison to other studies [3], and we were also unable to adequately assess the shape of the concentration-response curves for other causes of death. It is also worth mentioning that our study relied on self-reported estimates for BMI and smoking. Although we were able to mathematically adjust BMI for self-reporting error based on measured BMI from another survey, it is possible that estimates of smoking may underrepresent actual smoking rates. Additionally, the follow-up period in our study was relatively short, particularly for respondents who entered the cohort in the final survey year (i.e., 2008, with a maximum of 4 years of follow-up). However, respondents entering the cohort in the first year of survey and who had remained in the cohort for the entire period were followed for a maximum of 12 years, which is comparable to the mean follow-up period (i.e., 12.6 years) in a review of other cohorts examining the same relationship [6]. The limitation of having a short follow-up period was mitigated somewhat by considering exposures that preceded the event.

In creating the cohort, 69,300 CCHS respondents were excluded since they were not linked to the HTSF (tax) file and were therefore not candidates for the probabilistic linkage. The excluded population were those who did not file a tax return, and the characteristics of this population differed somewhat from the cohort. In general, the excluded population was younger and had a lower educational attainment than the final cohort. Therefore, the cohort might be slightly biased towards higher educational attainment and those active in the labour market, though these same characteristics were used for adjustment in survival models.

Estimates of $PM_{2.5}$ exposure were assigned at baseline at the person's place of residence. Accuracy in geocoding residences was limited by the program PCCF+, which assigns residences to postal code representative points. The size of postal codes is relatively small (i.e. typically a few city blocks) in urban centres; therefore the PCCF+ program is highly accurate within these areas. However, estimates of $PM_{2.5}$ exposure in rural areas are less likely to have been assigned accurately since postal code areas can be quite large. We performed a sensitivity analysis that considered only cohort members that lived within urban areas (i.e., Census Metropolitan Areas), and despite exposures being much greater in urban areas, results were not significantly different than those reported above (HR = 1.19, 95 % CI: 1.11–1.27, Cochran's Q = 1.71, p = 0.19). Given the short follow-up period, we also did not assess mobility in this study, making the assumption that respondents did not move. By not assigning air pollution exposures based on changes to residential history, it is expected that there would be some degree of exposure misclassification associated with this limitation. A previous study using CanCHEC considered the assignment of exposures at baseline *vs.* considering mobility during the follow-up period on mortality risk attributed to $PM_{2.5}$. In general, there was very little difference in HR estimates (i.e., HR = 1.03, 95 % CI: 1.02–1.03 from baseline exposure, *vs.* HR = 1.04, 95 % CI: 1.03–1.04 for exposure considering mobility) [35]. Although about 41 % of Canadians moved within the five-year period of 2001 to 2006 [36], the majority of moves were within cities or regions of similar $PM_{2.5}$ exposures (not published). To assess this limitation, we ran a sensitivity analysis where we included only persons who had at least 3 years of residence in the same postal code. HRs for non-accidental mortality were similar to those for the entire cohort (HR = 1.28, 95 % CI: 1.19–1.37).

Finally, the cohort was developed based on a probabilistic linkage methodology to assign deaths to CCHS members. We attempted to reduce the potential for linkage error by limiting our cohort to persons linked to a tax file, since mortality rates among cohort members not linked to a tax file were substantially lower due to fewer

elements of respondent data that could be used for linkage.

Conclusions

In general, this study documented an association between non-accidental, circulatory, and respiratory mortality and fine particular matter in a cohort adjusted for socioeconomic, ecological, and behavioural covariates and exposed to a relatively low exposure distribution (mean = 6.3 $\mu g/m^3$). Although our CI were wide in the concentration-response curve, an increased risk of mortality was observed even at very low concentrations of $PM_{2.5}$ (Fig. 2), at values lower than the WHO guideline of 10 $\mu g/m^3$ [2]. Further studies on a larger cohort are needed to evaluate the shape of the concentration-response curve at these lower concentrations of $PM_{2.5}$. We also updated the results of previous Canadian studies by using an improved, finer-scale exposure model to assign $PM_{2.5}$ estimates to cohort members, which may have, in part, caused observed increases in HR estimates relative to CanCHEC [3]. Finally, this study indicates that the addition of fine-scale behavioural covariates serves to reduce the HR estimates compared to the otherwise fully adjusted survival models.

Additional files

Additional file 1:Figure S1. Selection of Study Cohort.(PDF 88 kb)

Additional file 2: Table S1. Comparison of all variables (Pearson's correlation or ANOVA/T-Test). (XLSX 22 kb)

Abbreviations

AHS: United States Agricultural Health Study; BMI: Body Mass Index; CanCHEC: Canadian Census Health and Environment Cohort; CCHS: Canadian Community Health Survey; CD: Census Division; CI: confidence interval; CMDB: Canadian Mortality Database; CT: census tract; DA: dissemination area; HR: hazard ratio; HTSF: Historical Tax Summary File; -2LL: (−2) Log-likelihood ratio; MODIS: moderate resolution imaging spectroradiometer; PCCF+: Postal Code Conversion File Plus; $PM_{2.5}$: Fine particulate matter; WHO: World Health Organization.

Competing interests

The authors do not declare any competing interests.

Authors' contributions

LP designed the study, linked the cohort to the air pollution models, conducted the statistical and GIS analyses, and drafted the manuscript. MT participated in the study design, the cohort linkage, and provided feedback on the cohort. DLC participated in the study design, and provided assistance with statistical techniques and covariate preparation. SW conceived of the study and participated in the study design and in drafting the manuscript. AVD and RVM developed the air pollution models and provided feedback on their use in an epidemiologic context. MB and HC provided early feedback to improve the analyses and the presentation of results. RTB coordinated the study and participated in the study design and the statistical analysis. All authors actively edited the manuscript and approved the final manuscript.

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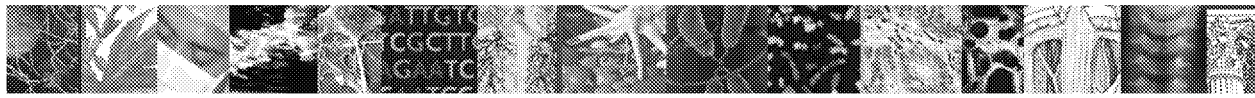

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Perspective

"Transparency" as Mask? The EPA's Proposed Rule on Scientific Data

Joel Schwartz, Ph.D.

The Environmental Protection Agency (EPA) recently proposed excluding from consideration in setting environmental standards any studies whose raw, individual-level data are not publicly available. This proposal was preceded by the wholesale exclusion from the EPA's scientific advisory boards of academic scientists who receive research grants from the agency — and their replacement by industry-funded scientists. It is hard to interpret these actions as anything other than an attack on the use of hard scientific evidence to set environmental standards.

Open science has growing support, and justly so. However, studies conducted at academic institutions and involving humans, which are regulated by the Health Insurance Portability and Accountability Act (HIPAA) and institutional review boards (IRBs), must maintain a basic regard for privacy. Great progress in understanding pollution's effects has been made by adding exposure information to large cohort studies that were established to explore cardiovascular disease or cancer. Such studies have been used, for example, to analyze concentrations of metals in blood, urine, or toenails and to attribute air pollution exposure to people according to their residential address. Precisely because these studies include measurements of many potential confounding factors, it is difficult to make the data public without also making participants identifiable. Although some progress has been made in deidentifying some types of data, studies of environmental exposures present more serious issues, because often exposure levels are attributed on the basis of geocodes, and neighborhood covariates are based on public geocoded data. This practice makes it much easier to identify participants. For example, after Hurricane Katrina, a local newspaper published a map of the locations of deaths. It showed no roads, and the only geographic data included were neighborhoods. Yet researchers were able to correctly identify the residential address for most of the people who died.[1]

A cohort study of pollution rarely includes individual geocodes as covariates, but it typically controls for 15 to 20 potential confounders, usually including census-based measures of socioeconomic status (SES) and other geocoded information. If those covariates were all dichotomous, there would be more than 32,000 unique combinations. If some variables are based on publicly available geocoded data, such as census-tract measures of race, SES, population density, housing value, local air

pollution levels, and county-level data from the Behavioral Risk Factor Surveillance survey of the Centers for Disease Control and Prevention, it may be possible to identify each participant's census tract. With continuous confounders, the situation is worse. Identifiability is thus a major concern: if you know someone's age, race, sex, and other individual covariates, adding the census tract may make the participant unique, particularly if the outcome being studied is death, given that death certificates are obtainable.

This problem is well recognized: the National Academy of Sciences has reported on an "experiment to discover whether confidentiality could be preserved while opening . . . data for public review," which demonstrated that even after all participant features not required to allow other scientists to replicate a study's basic findings were deleted from study questionnaires, investigators could identify the participants.[2]

Recently, a study examined the identifiability of records from an environmental health study in Northern California. Using data considered under HIPAA to be sufficiently deidentified to be made public, they were able to correctly identify more than 25% of the participants.[3] Previously, the lead author showed that people from a supposedly anonymized hospital-admissions database could be identified on the basis of news stories. Since many obituaries are printed every day and death certificates are publicly available, the identifiability problem is vast.

In the Harvard Six Cities Study, conducted in the 1980s and 1990s, participants were recruited from one neighborhood in each city, including Watertown, Massachusetts (population, 35,000). The average number of deaths per year in Watertown is 208 — less than 1 death per day. Obviously, knowledge of the date of death would uniquely identify most participants. But even if the data made public included only the year of death, age, race, sex, and cause of death, most people could be identified from those facts.

The Canadian Community Health Survey followed 300,000 people and examined the association of exposure to fine particulate matter (particles with a mass median aerodynamic diameter of less than 2.5 μm [$PM_{2.5}$]) with mortality.[4] Because of privacy laws, the data were not given to the investigators, and analysis was performed on the computers at Statistics Canada. Yet this study is critical for the EPA to consider as it reviews the adequacy of its 12 μg-per-cubic-meter $PM_{2.5}$ standard, because essentially all the participants lived in locations with $PM_{2.5}$ levels below that standard.

The EPA's proposed rule on evidence for policymaking will exclude European and Canadian studies involving human participants from being considered by the EPA in regulating environmental pollutants. The new General Data Protection Regulation (GDPR) in the European Union (EU) defines private data as including information on a person's medical, physical, physiological, genetic, mental, economic, cultural, or social identity. Under the GDPR, such data must be controlled by a data controller who must demonstrate that any use of the data has been consented to by the individuals involved — which obviously precludes making data publicly available.

EPA leaders have argued that data can be sufficiently deidentified to be made public while still permitting reanalysis. But the number of variables included in original analyses that would have to be omitted or condensed into crude categories is so large that any reanalysis would be unable to reproduce the original results. More plausible is the EPA's argument that protected data centers could house the data and allow people to analyze them. But if the Canadian government would not allow the initial investigators to have the data mentioned above, then it's unlikely that it would agree to convey those data to an EPA computer, even with restricted access. Similar barriers probably apply to most of the cohort studies the EPA relies on: IRB and EU privacy rules are unlikely to allow transfer of data to EPA or other U.S. government computer centers.

Moreover, the "gold standard" of science is not reanalysis, but replication. In the case of $PM_{2.5}$-mortality studies, a recent meta-analysis found 53 cohorts, indicating that the results have been replicated many times by many groups in many countries.[5] Of what value, then, is a reanalysis of a minimal subset of covariates from any given study — particularly if it can't control for important covariates?

It is difficult to believe that EPA leaders do not know that few human cohort studies could comply with their requirements — and therefore difficult not to conclude that the real purpose of the proposal is to eliminate a vast body of highly relevant data from consideration, resulting in a weakening of standards that are no longer supported by "sufficient scientific evidence." This approach was

outlined in a 1996 e-mail message, revealed in tobacco litigation, from a law firm to R.J. Reynolds. Addressing possible regulation of environmental tobacco smoke (ETS), it stated, "Because there is virtually no chance of [e]ffecting change on this issue if the focus is ETS, our approach is one of addressing process as opposed to scientific substance, and global applicability to industry rather than focusing on any single industrial sector." It highlighted ozone and $PM_{2.5}$ regulations as also ripe for this approach. Subsequently, polluting industries hired actors to stage a demonstration demanding that the Six Cities Study data be made public. Combined with the recent removal of impartial scientists from the EPA's scientific review boards, the current proposal appears to be a multipronged attack on the use of scientific data to set regulatory standards.

Rules suggesting that individual personal information might be made public can also endanger wider research on cancer, heart disease, and other conditions. People may be much less likely to agree to participate in long-term epidemiologic studies if they hear that they may be identified or their data made public. The EPA has not made a decision yet on this proposal and, I believe, should be encouraged to make one that preserves scientific input into its rulemaking.

Disclosure forms provided by the author are available at NEJM.org.

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Message

From: Cawiezell, Thomas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EB3BE5507FBC4947BF3AC3D03AF1F3AB-CAWIEZELL,]
Sent: 8/27/2018 7:27:40 PM
To: Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: Recent letters on transparency rule
Attachments: 18-001-0114.pdf; 18-001-0029.pdf; 18-000-9983.pdf; 18-000-9922.pdf; 18-001-0025.pdf; 18-000-9920.pdf

Thomas Cawiezell
ORAU NSSC Research Contractor for
U.S. Environmental Protection Agency
Office of the Science Advisor
☎ 202-564-0221
✉ cawiezell.thomas@epa.gov

August 7, 2018

Personal Matters / Ex. 6

Email: Personal Email / Ex. 6

Mr. Andrew Wheeler
Acting Administrator
United States Environmental Protection Agency
Mail Stop 1101A
1200 Pennsylvania Ave. NW
Washington, DC 20460

Dear Acting Administrator Wheeler,

As a retired EPA toxicologist formerly associated with the Office of Pesticide Programs (OPP), I know first hand the frustrations of having to deal with epidemiological reports from the open literature.

I believe that Mr. Pruitt's directive regarding transparency in regulatory decisions especially related to epidemiological studies has merit. With this communication, I hope to provide a path forward that will produce a document that clearly indicates that the EPA conducted a thorough critical review of epidemiological studies occurring in the open literature or otherwise. The resulting document will clearly articulate the basis for its decision to allow the use of such publications to impact the risk assessment or determine that the study does not provide sufficient proof for its conclusions.

First of all, there is a great discrepancy in the review of the toxicology studies that industry is required to submit in order to register their chemical products. These studies follow strict protocol guidelines and are conducted under stringent good laboratory practices (GLP), quality assurance (QA) and animal ethics reviews as well as rigid reporting standards. These studies in the OPP have multiple layers of primary and secondary review most often by contractors at a very significant expenditure of taxpayer funds and program resources. The studies are essentially transcribed into Data Evaluation Records (DERs) that have to state what was done and what the results were since the reviewers cannot misrepresent what the study reported. The reviewers, however, can indicate study deficiencies and identify responses not already indicated by the report. The reviewers responsible for the reviews are clearly identified and responsible for their decisions.

In marked contrast, epidemiological studies appearing in the open literature (or otherwise) follow a mixed bag of study designs, GLP, QA, ethics and reporting practices. However, these studies are most often accepted at their face value without evidence of a critical review or identification of the responsible individuals.

This practice is unfair to the public. Studies used for risk assessment should have the same level of critical review no matter what their source is.

A current example is how the OPP handled chlorpyrifos that I have personal experience with. The most recent SAP review indicated problems with the original Columbia epidemiological study that should have been resolved long before several previous expensive SAP meetings were held. There are no similar DER reviews indicating the responsible reviewers provided to support the OPP's actions or attempts to use the study endpoints for risk assessment that I know of.

With the concept of a disparity in the degree of review of animal studies conducted to support the registration of a pesticide (or other chemical) and the acceptance of epidemiological studies on their face value, I am proposing that:

An Epidemiological Study Peer Review Council be established with the goal of creating a transparent document reflecting a thorough review of the study be established by EPA.

The details of this Council are in the attached document entitled "**Proposal for the Review of Epidemiology Studies from the Open Literature (or otherwise) Being Considered for a Basis for Regulatory Action: Establishment of Agency Wide Epidemiology Study Peer Review Council (ESPRC) and the resulting product Record of Epidemiology Study Review (ROESR).**"

The resulting product should provide a transparent assessment and whether or not an epidemiology study can be used for risk assessment. The responsible individuals are identified and would defend their decisions from objections from either industry or public interest groups.

I certainly hope that you will find this proposal helpful and forward it to the appropriate individuals concerned with evaluation of toxicity and risk assessment. If there are questions concerning how this Council could be implemented, please contact me. I will be happy to make a presentation on how this Council can contribute to the goal of making transparent decisions for risk assessment. Electronic copies of the proposal can be provided on request from EPA staff.

Thank you for giving this suggestion your consideration.

John D. Doherty, Ph.D.
(DABT 1982-2017)
Independent Toxicologist
Email: Personal Email / Ex. 6

PS. This proposal was presented at the afternoon session of the open meeting on Transparency held on July 17, 2018.

August 7, 2018

Subject: **Proposal for the Review of Epidemiology Studies from the Open Literature (or otherwise) Being Considered for a Basis for Regulatory Action: Establishment of Agency Wide Epidemiology Study Peer Review Council (ESPRC) and the resulting product Record of Epidemiology Study Review (ROESR).**

To: **Mr. Andrew Wheeler**
Acting Administrator
Environmental Protection Agency
Mail Code 1101A
1200 Pennsylvania Ave NW
Washington, DC 20460

From: **John D. Doherty, Ph.D.**
(DABT: 1982-2017)
Email: Personal Email / Ex. 6

As a retired toxicologist in the EPA's Office of Pesticide Programs, I believe that there is merit to Mr. Pruitt's directive that only studies where the public can review the supporting data can be used for regulatory decisions. Epidemiological studies should not be accepted based on their face value without critical evaluation of all aspects of the study. I also recognize that such supporting data may not be available because of various reasons including the confidentiality of the subjects in the study cohort.

There should be a middle ground where the Agency determines that the study can be used for regulatory decisions when all supporting data are not available. The decision to use the study in the absence of an independent review of the original data should *not be* the responsibility of one individual. The following is a proposal to justify the use of an epidemiological study when not all of the supporting data are available. Or to otherwise state clearly why the study cannot be used without the submission of additional data.

A Call for the Standardization of the Review of an Epidemiology Studies – Establishment of an Agency wide Epidemiology Study Peer Review Council (ESPRC) and the product Record of Epidemiological Study Review (ROESR).

Each epidemiology study occurring in the open literature or otherwise needs to have a supporting formal **Record of Epidemiological Study Review (ROESR)** that clearly delineates the justification for a decision to include or not include the study in the regulatory decisions for the chemical or environmental situation. The production of the ROESR will consist of the separate and independent reports of several Sub-Committees that will be integrated by the **Epidemiological Study Peer Review Council (ESPRC)** and signed by the Council Chairperson and each Council member.

It is important to have *independent* Sub-discipline committees review the study so that the biases of other sub-disciplines are minimized. The Sub-committee members should be drawn from the relevant staff throughout the Agency as well as other government agencies as needed. Each member of the Sub-committees will sign their respective Sub-committee reports.

The roles of the six suggested Sub-Committees and Council Chairperson are as follows:

1. ***Ethics Evaluation Sub-Committee.*** This sub-committee will evaluate all aspects of the ethical treatment of the individuals in the cohorts. This includes that it will identify how additional data can be provided to the Agency in a manner that will assure the identities of the individuals are protected.

2. ***Endpoint Evaluation Sub-Committee:*** This evaluation would limit its conclusions with regard to how well the character of the endpoint itself was assessed for and whether or not the effect reported is plausibly related to treatment or within normal variation. The latter includes how many subjects in a cohort are needed to make a meaningful statistical difference for the particular lesion in question.

This Sub-committee will provide commentary on the consistency of characterization of the endpoint, resolution of confounds as well as any known other chemicals or conditions that affect the normal distribution of the endpoint.

The experts in this Sub-committee will vary depending upon the endpoint claimed by the epidemiological study and consist of experts in cancer, behavioral response, or other appropriate discipline for interpretation of the significance of the endpoint.

3. Exposure Assessment Sub-Committee: The role of the exposure assessment Sub-committee is limited to determining that the methodology and reliability used to determine the exposure of the cohort is adequate and appropriate. The Sub-committee would provide commentary on whether or not exposure was supported by analytical chemical data, by oral history or otherwise. Also, if the actual persons exposed provided oral history by direct conversation, survey or by telephone. The committee will determine if indirect exposure information was provided by a relative (or friend or coworker) is reliable.

4. ***Statistical Evaluation Sub-Committee***: In the initial review of the study, the sole role of the statistical evaluation sub-committee is limited to determining if the statistical methods were/were not appropriate and adequately conducted to support the conclusion of the report. This committee would not redo the statistics at this time since the original data would be needed. Input from Sub-committees 1 (ethics), 2 (3ndpoint evaluation) and 3 (exposure assessment) that clarifies all

issues that are the responsibility of their respective disciplines would be needed before statistical reanalysis could be conducted. Thus, receipt of the original data in a manner that satisfies Sub-committees 1, 2 and 3 and well as any requests by the Statistical Evaluation Sub-committee before any statistical reanalysis would be conducted.

5. Analytical Chemistry Assessment Sub-Committee: The role of the analytical chemistry committee is limited to determining if the analytical techniques/ methodology were appropriate and adequate for the study. In some cases where no analytical chemistry data were generated, the committee will comment on the need to have included such data and/or if quantitative analysis of exposure data was even possible.

6. Animal Toxicity and Structure Activity Relationship (SAR) Assessment Sub-Committee: In most cases with chemicals, the Agency should already have a battery of standard animal toxicity studies that were required for the registration of that chemical. There may also be studies in the open literature attempting to define the toxicity of the chemical. Thus, the person(s) responsible for evaluating the animal toxicity studies would be a member of this Sub-committee. In addition, this Sub-committee will have individuals that can address the SAR issues in relation to the possibility that the chemical could affect the endpoint in question.

It should be noted here that a Record of Review (ROR) signed by at least two qualified toxicologist is needed for any publication supporting a mechanism of action for the chemical.

If the endpoint occurs in animals or has SAR correlates, such information can support the epidemiological findings. If not, it does not automatically dismiss the epidemiological findings since the effect on the endpoint may be unique to humans.

7. Council Chairperson, Council meetings and resulting product: ROESR:

The ***Council Chairperson*** should not be in the same program that has responsibility for regulating the chemical or environmental condition. That is, if the chemical is a pesticide, the Chairperson cannot be from the Office of Pesticide Programs (OPP). Representatives of OPP may still be on the Council if an epidemiological study with a pesticide is being reviewed.

At the initial **Council meeting,** the Council will discuss the conclusions of each the six Sub-committees. In some cases, the Council may determine that the association between exposure and the endpoint is otherwise strong enough to support regulatory action to protect the public health and no additional information is needed from the study authors.

During the initial meeting the Council can overrule a request for additional data made by any of the Sub-Committees. However, clear justification for overruling a Sub-Committee's decisions must be provided.

In other cases, the Council may determine that there is a definite need to require additional data supporting the study methodologies and conclusions are required. The Council would then notify the authors articulating of the need for the specific additional information.

The Council will also determine if the authors of the epidemiological report should be requested to attend a closed meeting with the Council and Sub-committee members. The purpose of the meeting will be an opportunity for the study authors to address any concerns that the Sub-committees have. This will include problems with providing any additional information that the Sub-committees requested. If the study authors refuse to attend a requested meeting, the Council will determine if the study should be rejected outright.

The Council Chairperson (or secretary of the Council) will prepare the **ROESR** product that contains the decision with supporting justification. The ROESR product would include the report of the Council with the Chairperson and Council members' signatures. Separate attachments for the *signed* Sub-Committee reports and the original epidemiological report (i.e. a publication) will also be attached. An executive summary of any meeting(s) with the study authors will also be appended.

Purpose:

The purpose of this procedure is to assure that responsible persons for each of the critical Sub-disciplines *independently* reviewed the study in terms of their expertise. The resulting ROESR that either determines that the study can be used in the absence of additional original data or the need for critical additional data is determined will be clearly indicated.

The Council Chairperson and members of the Council and the sub-discipline committees own their decisions and are responsible for defending them.

If industry or any concerned public interest groups object to the conclusions, they can address the conclusions presented in the ROESR and/or the sub-disciplines.

Therefore the decisions in the resulting ROESR should be transparent. The current system renders too much power to individuals that are sometimes not clearly identified who can profit by making career projects for themselves based on the face value of the publication.

I am well aware that an epidemiological publication (or otherwise) in the open literature is going to be controversial. However, preparing a ROESR for such studies with the several sub-disciplines all independently contributing to the Agency's determination of the conclusions in the report should greatly help to minimize controversies.

The ROESR is not a final conclusion (no documents in EPA should be considered final). It is very likely that a Science Advisory Panel will ultimately review the ROESR. Also, as new information is generated, the ROESR can be updated and the recommendations for use (or otherwise) can be adjusted as appropriate.

Edw. Doherty, Ph.D

Personal Matters / Ex. 6

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AUG 10 2018

Andrew Wheeler
Deputy Administrator
United States Environmental Protection Agency
Mail Stop 1101A
1200 Pennsylvania Ave. N.W.
Washington, DC. 20460

RETURN RECEIPT REQUESTED

Route EPA Mail

To: Wheeler, Andrew

Mailstop ARN

Department: 1101A

Certified

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Personal Matters / Ex. 6

August 3, 2018

Current Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Dear Sir or Madam:

I am writing about EPA's Proposed Rule:
"Strengthening Transparency in Regulatory Science."
As the EPA develops regulations governing clean air, clean water and exposure to toxic substances and pesticides, it needs to include all valid, peer-reviewed studies, even if their underlying data sets cannot be released to the public. I believe that the proposed rule's premise is faulty, because it excludes studies whose data is not publicly available. The proposed rule should be withdrawn.

I object to the fact that the scientific community was not consulted as the proposed rule was being prepared. Certainly, at least the EPA's own Science Advisory Board should be consulted.

Thank you.

Sincerely,

Margery M. Donn

Margery M. Donn

OFFICE OF THE EXECUTIVE SECRETARIAT
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Current Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

AUG 10 2018

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M. Rom

Personal Matters / Ex. 6

Gernatt
13870 Taylor Hollow Rd.
Collins, NY 14034
716-532-3371
716-532-9000 (fax)
www.gernatt.com

August 8, 2018

Andrew R. Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: EPA Proposed Rule: Strengthening Transparency in Regulatory Science. 83 Fed. Reg. 18,768 (Apr. 30, 2018). Docket Number EPA-HQ-OA-2018-0259.

Dear Administrator Wheeler,

I am writing to you on behalf of Gernatt Asphalt Products, Inc. and it's 200+ employees from southwestern New York State, as members of the National Stone, Sand & Gravel Association (NSSGA). We support the above-referenced rule which will strengthen transparency in regulatory science. As active sand and gravel miners, we are intimately familiar with the myriad of existing Federal environmental regulations that govern our operations. We are also keenly aware of the importance of a healthy environment, which supports our business by providing products and jobs now, and for the future of our children and Country.

Our goal has always been to operate within the regulatory framework of whatever entity we are working within, not merely to avoid the legal ramifications of non-compliance, but also in the spirit that sound environmental regulation keeps the playing field level for everyone in the industry while promoting sustainability. The products we supply are imperative to the infrastructure that supports the well-being of every citizen and business in this Country. Many people do not make the connection between a sound and stable aggregate mining industry and our vibrant, safe, and progressive way of life. These folks assume our industry is inherently a detriment to the environment, resulting in long-term negative impacts. As a result, popular sentiment is often that more regulation of industry like ours is not only needed, but somehow heroic. This is simply not true.

That is why it is extremely important for regulations to be thoroughly vetted for their need, effectiveness, and beneficial result before they're imposed on industry like ours. The proposed transparency rule will help ensure that only scientifically sound regulatory initiatives are considered for implementation, saving producers from poorly thought out, knee-jerk type of regulations that result from over-reaction.

As an active member of the NSSGA, we fully support their comments on this issue. Please consider those comments, and our position as stated above, when considering this rule. Thank you.

Sincerely,

Richard Pecnik

Richard Pecnik
Regulatory Affairs
Gernatt Asphalt Products, Inc.

Gernatt
13870 TAYLOR HOLLOW RD.
COLLINS, NEW YORK 14034

ADDRESS SERVICE REQUESTED

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Andrew R. Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

AUG 14 2019

ED_002389_00028919-00002

Wed Aug 15 15:03:49 EDT 2018
CMS.OEX@epamail.epa.gov
FW: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259
To: "cms.oex@domino.epamail.epa.gov" <cms.oex@domino.epamail.epa.gov>

From: Hope, Brian
Sent: Wednesday, August 15, 2018 7:03:47 PM (UTC+00:00) Monrovia, Reykjavik
To: CMS.OEX
Subject: FW: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259

DRF

From: Stephanie Hayes Schlea [mailto:schlea@amwa.net]
Sent: Wednesday, August 15, 2018 2:27 PM
To: Wheeler, Andrew <wheeler.andrew@epa.gov>
Cc: Ross, David P <ross.davidp@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Subject: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259

On behalf of the Association of Metropolitan Water Agencies, please find attached the comment letter regarding EPA's proposed rule, *Strengthening Transparency in Regulatory Science* (EPA-HQ-OA-2018-0259).

Stephanie Hayes Schlea
Manager, Regulatory and Scientific Affairs
Association of Metropolitan Water Agencies
Office: 202.331.2820
1620 I Street NW Suite 500
Washington, DC 20006
http://www.amwa.net/

ASSOCIATION OF
METROPOLITAN
WATER AGENCIES

LEADERS IN WATER

1620 I Street, NW, Suite 500
Washington, DC 20006

P 202.331.2820 F 202.785.1845
amwa.net

August 15, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Re: Docket No. EPA-HQ-OA-2018-0259, *Strengthening Transparency in Regulatory Science*

Dear Acting Administrator Wheeler,

The Association of Metropolitan Agencies (AMWA) is an organization representing the largest publicly owned drinking water utilities in the United States. Any changes in how the agency formulates rulemakings, particularly in regards to national primary drinking water regulations, significantly impact our members. EPA has published a request for comment on the proposed rule: *Strengthening Transparency in Regulatory Science* published in the *Federal Register* on April 30. AMWA applauds EPA's goal to strengthen transparency and supports this objective whenever possible, but would like to emphasize that increasing transparency in concert with the development of regulations, health advisories and guidance that protect public health and the environment is particularly important.

While EPA's objective to increase transparency is commendable, and AMWA appreciates the opportunity to provide feedback and strengthen the final rule, the current proposal is far too vague and missing key components that must be included in the final rule to ensure its understandability and appropriate implementation. For example, currently the proposal lacks definitions for many key terms, omits critical protocols and methodologies necessary to put this rule into action, and does not fully explore the implications of implementing a rule of this nature.

However, due to the importance of this proposed rule, AMWA is pleased to submit these comments for EPA's consideration. Our specific comments are provided as an attachment. If you have any questions, please contact Stephanie Hayes Schlea (schlea@amwa.net), AMWA's Manager of Regulatory and Scientific Affairs.

Sincerely,

Diane VanDe Hei
Chief Executive Officer

Attachment

cc: David Ross, Assistant Administrator for Water
Peter Grevatt, Director, Office of Ground Water and Drinking Water

General

1. AMWA agrees that any data, methodology, or models produced by EPA itself should be transparent and available to the public in a reproducible manner.
2. EPA should refrain from banning all studies from being used in the regulatory process solely due to data availability. For data that is not produced by EPA, such as in scientific journals, and particularly when dealing with sensitive data, the process of peer reviewing should often be sufficient. If multiple studies have gone through the peer review process and have come to the same conclusions, the agency should not disregard these findings simply because the raw data is not available. Raw data may not be available for a variety of reasons including privacy, age of the data, or due to a researcher's reluctance to share this information. However, an open process for justifying the use of data that is not public should be developed.
3. AMWA also encourages EPA to not base any regulatory determination on a single study, regardless of whether or not the data is publicly available. Relying on a single study, no matter how robust it may be, can bring bias to a model or regulatory decision. If EPA must base a decision off of a single study, it should be imperative that the data be publicly available as well as the reasoning and methodology behind why the study was chosen, how it is being used and why no other studies were deemed sufficient to be included.
4. EPA released a document titled *Plan to Increase Access to Results of EPA - Funded Scientific Research* in 2016 in response to a 2013 memo released by the White House Office of Science and Technology Policy (OSTP)[1]. The memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research" directs Federal departments and agencies that spend more than $100 million per year on research and development (R&D) to develop and submit a plan to OSTP to increase public access to peer-reviewed, scientific research publications and research data resulting from agency-funded R&D.[2] What is the status of this plan and what does this rule cover that this document does not regarding data funded and produced by EPA?

Definitions and Clarifications

1. According to Goodman, Fanelli, and Ioannidis (2016)[3], there is no scientific consensus for what "methodologically reproducible" is. If EPA wants to build a rule around transparency in regards to methodology, "methodologically reproducible" must be defined.

---

[1] Office of Science and Technology Policy, Executive Office of the President. (2013, February 22). Memorandum for the Heads of Executive Departments and Agencies: Increasing Access to the Results of Federally Funded Research. Retrieved from https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

[2] Environmental Protection Agency. (2016). Plan to Increase Access to Results of EPA - Funded Scientific Research Version 1.1.

[3] Goodman, S.N., Fanelli, D., & Ioannidis, J.P.A. (2016). What does research reproducibility mean? *Science Translational Medicine*. *8*(341). pp. 1-6.

2. If the agency wants a rule focused on the raw data then EPA must better define what "data" would be included within this rule. Is it just data produced by EPA? If not, is it the methods and protocols or the actual raw data?
3. There are multiple terms that will need to be defined in the final rule. In particular, "transparency"; "data", singular versus set; and "reasonable effort/endeavor", in relation to how much work the agency must put in before justifying the use of data that can not be made available to the public.
4. EPA should also clarify what it considers to be "publicly available". A significant number of journals require a subscription or payment in order to read their articles. Does EPA consider these studies publicly available?

Methodologies and Protocols

5. EPA's proposal states, "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed though the application of solutions commonly in use across some parts of the federal government." While this is reassuring, it is important that the agency outline a clear protocol that is transparent and clear and should solicit public comment on this protocol before implementing it agency-wide.
6. In an EPA news release the agency states, "[The] proposed rule is in line with the scientific community's moves toward increased data sharing…[and] is consistent with data access requirements for major scientific journals like *Science, Nature*, and *Proceedings of the National Academy of Sciences*[4]." However, those same journals have written a joint statement responding to the proposal and support "maintaining the rigor of research published in our journals and increasing transparency regarding the evidence on which conclusions are based", but caution stating, "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes[5]." AMWA encourages EPA to consult with entities, including the journals that EPA references, that have implemented similar efforts in order to better inform the methods and protocols that should be in place for a rule of this nature.
7. Related to this, the proposed rule and Lutter and Zorn[6] (2016), which is cited in the proposal, both discuss current publishers and journals, which require authors to submit their data to public repositories. EPA should work to encourage the continuation of this, as well as

[4] Environmental Protection Agency Press Office, Office of the Administrator. (2010, April 24). *EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations*. [Press Release]. Retrieved from https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations

[5] Berg, J., Campbell, P., Kiermer, V., Raikhel, N., & Sweet, D. (2018, April 30). *Science*. Retrieved from http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

[6] Lutter, R., & Zorn, D. (2016). On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making. Mercatus Working Paper. Accessed from https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf July 12, 2018.

considering giving preference, when possible, to studies where the data is publicly available in this manner.

8. Allowing for exemptions in a rule of this nature is useful and allows for flexibility within the implementation. However, regardless of when or how the Administrator is able to exempt significant regulatory decisions on a case-by-case basis, there should be explicit and clear expectations for what may or may not qualify for an exemption. Does the exemption cover the agency's project as a whole or just a single study and/or data set? Decisions to allow an exemption should be transparent and made available to the public.

Application

1. EPA's proposal states that it is looking for comment on how to make more data and models used throughout the agency's regulatory process available to the public "over time". AMWA agrees with the idea that, regardless of the strategy used, EPA should seek to phase-in whatever requirements are justified. The agency should note that the scientific community has just recently begun data access requirements. For example, EPA's proposal cites the journal PLOS ONE as informing the development of the rule's policies. However, this journal has only been requiring this open data since 2013[7]. Therefore, while the scientific community has been moving towards the idea of "open science", the policies are still new and phasing in requirements would give the scientific community sufficient time to respond and prepare for the implications of this rule. EPA would need to ensure that there are explicit and clear milestones to be achieved throughout the process.
2. This rule should not apply to the previous record. Trying to apply this proposal to models, rules, and research that has already begun or has concluded would only serve to set current work back and complicate work already done. It makes sense to "grandfather" what has already been completed and to implement this rule in stages in order to not compromise or delay EPA's work.
3. In order for full transparency, the finished rule should apply to all stages of regulatory development. This would include full transparency in the methods, particularly in the development of models. The public does not need the individual data in order to determine if there are inherent issues within the study itself. The analysis of the data is already done multiple times throughout the publication process, via peer review. While it is useful to have the data EPA uses, it is perhaps more important to understand the methodology and reasoning behind why EPA chooses the data it does. In order to increase transparency it would be important to have the agency give a thorough explanation as to why certain studies and data sets were chosen and not others, rather than relying on public access to the individual data.

[7] PLOS ONE. Data Availability. Accessed from http://journals.plos.org/plosone/s/data-availability#loc-acceptable-data-sharing-methods

Wed Aug 15 15:02:37 EDT 2018
CMS.OEX@epamail.epa.gov
FW: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"
To: "cms.oex@domino.epamail.epa.gov" <cms.oex@domino.epamail.epa.gov>

From: Hope, Brian
Sent: Wednesday, August 15, 2018 7:02:34 PM (UTC+00:00) Monrovia, Reykjavik
To: CMS.OEX
Subject: FW: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"

DRF

From: Yogin Kothari [mailto:YKothari@ucsusa.org]
Sent: Wednesday, August 15, 2018 2:47 PM
To: Wheeler, Andrew <wheeler.andrew@epa.gov>
Cc: Darwin, Henry <darwin.henry@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Subject: Rescinding EPA's proposed rule, "Strengthening Transparency in Regulatory Science"

Dear Acting Administrator Wheeler:

Attached, please find a letter from nearly 80 public health, science, labor, transparency, accountability, and environmental organizations requesting that you withdraw the proposed rule entitled "Strengthening Transparency in Regulatory Science." This proposal is flawed beyond repair and in fact make it more difficult for EPA to use the best available science to protect public health and the environment. If you have any questions or are interested in meeting with our organizations about this matter, please let me know.

Sincerely,

Yogin Kothari

Yogin Kothari

Senior Washington Representative, Center for Science and Democracy

Union of Concerned Scientists

desk: 202-331-5665 | c Personal Matters / Ex. 6

Personal Matters / Ex. 6

August 15, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, D.C. 20460

Re: Rescinding EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science"

Dear Acting Administrator Wheeler:

The undersigned public health, science, labor, transparency, accountability, and environmental organizations urge you to withdraw the proposed rule entitled "Strengthening Transparency in Regulatory Science," issued by former EPA Administrator Scott Pruitt on April 30, 2018.[1] The ill-conceived, badly written, and unlawful proposal is flawed beyond repair and should be rescinded. Further, this proposed rule runs counter to your stated commitment to "robust and civil dialogue with the public."[2] Any further time and money spent on this proposal would be a waste of valuable public resources. EPA and OMB should focus their limited resources on protecting public health and the environment rather than continuing to consider such a flawed proposal.

In your first address to EPA staff, you emphasized that you "will seek the facts" and aim to carry out "the vital mission of protecting human health and the environment."[3] To extend the benefits of science to all people, including those communities that already bear a disproportionate burden of environmental pollution, EPA must preserve the role of science as a key input for crafting public policy.

Unfortunately, the implementation of this rule would do just the opposite, undermining the ability of the Agency to use the best available science to protect public health and the environment. The proposal will not improve the use of science at EPA, but instead would restrict the types of science the Agency may use in regulatory decisionmaking. This includes, but is not limited to, studies that rely on personal health data, confidential business information, intellectual property, or older studies where the authors or data sources may not be accessible. Restricting the use of robust and well-established scientific information prevents EPA from meeting its mission.

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[1] Federal Register. 2018. Strengthening Transparency in Regulatory Science, April 30. Vol 83, No. 83. Online at https://www.gpo.gov/fdsys/pkg/FR-2018-04-30/pdf/2018-09078.pdf, Accessed July 31, 2018.
[2] Wheeler, A.R. 2018. Message from the Acting Administrator: Public Participation and Transparency in EPA Operations, July 30. Online at https://www.eenews.net/assets/2018/07/30/document_pm_02.pdf, Accessed July 31, 2018.
[3] Environmental Protection Agency (EPA). 2018. Acting Administrator Wheeler Addresses EPA Staff (News Release), July 11. Online at https://www.epa.gov/newsreleases/acting-administrator-wheeler-addresses-epa-staff, Accessed July 31, 2018.

Equally problematic, the proposed rule is not authorized by any authority delegated to EPA by Congress and is contrary to a number of statutes under EPA's authority. This includes, but is not limited to, the Clean Air Act; Clean Water Act; Toxic Substances Control Act; Lautenberg Chemical Safety Act; Safe Drinking Water Act; Federal Insecticide, Fungicide, and Rodenticide Act; and more. Substantively, the rule violates numerous public health and environmental provisions contained in these laws, as well as requirements to use the best available science or to consider all available information, while procedurally, it violates the Administrative Procedure Act and a number of other laws that set forth specific procedures EPA must follow during its rulemaking process. It also lacks an environmental justice analysis even though the rule will have the greatest impact on low-income and minority communities that benefit from protections based on the very studies the rule restricts from consideration when setting exposure limitations for pollution and toxic chemicals. Simply put, the proposal cannot withstand legal scrutiny.

The proposed rule also lacks justification and has little information on what implementation would mean for external researchers or how it would affect EPA's work to protect public health and the environment. It was developed without meaningful input from the scientific community. EPA's Science Advisory Board (SAB), tasked with reviewing the Agency's regulatory agenda and recommending actions that merit independent review, only learned about the rulemaking after it was already proposed. As a result, an SAB workgroup recommended that the advisory body review the merits of the rule because "it deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board."[4] After a nearly unanimous vote concurring with the memo, the SAB wrote in a June 28 letter to former Administrator Scott Pruitt that "[t]he SAB urges the Agency to … request, receive, and review scientific advice from the SAB before revising the proposed rule."[5]

Numerous scientific voices have spoken out in opposition to the proposed rule, including those with standards EPA claimed were consistent with the proposed rule. For example, the editors of leading peer-reviewed scientific journals, *Science*, *Nature, Public Library of Science (PLoS), Proceedings of the National Academy of Sciences,* and *Cell* wrote:

> "[I]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[6]

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[4] Cullen, A. EPA Science Advisory Board, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science. 2018. Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14), May 12. Online at https://yosemite.epa.gov/sab/sabproduct.nsf//E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf, Accessed May 14, 2018.

[5] Honeycutt, M. 2018. Letter Re: Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science, June 28. Online at https://yosemite.epa.gov/sab/sabproduct.nsf/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf, Accessed July 18, 2018.

[6] Berg, J., P. Campbell, V. Kiermer, N. Raikhel, and D. Sweet. 2018. Joint statement on EPA proposed rule and public availability of data. *Science*, April 30. DOI: 10.1126/science.aau0116. Online at http://science.sciencemag.org/content/early/2018/04/30/science.aau0116/, Accessed July 30, 2018.

Among those not consulted in the crafting of this rule were the National Academies of Sciences, Engineering, and Medicine (NASEM), though EPA nonetheless frequently cited the NASEM in the proposed rule. EPA's reliance on the NASEM is misrepresented, as the Academies have held several committee meetings and carried out a series of reports detailing how scientific literature can be evaluated transparently without the full disclosure of underlying datasets.[7] In a comment on the rule, the NASEM urged EPA to seek objective and expert guidance in evaluating scientific standards at EPA and offered itself as an independent review body.[8]

Likewise, the Bipartisan Policy Center (BPC) clarified in a comment to the agency that "the proposed rule is not consistent" with its report on the use of science in policymaking that EPA cited in "substance or intent."[9] BPC supports enhanced transparency, but "the report never suggested excluding studies from consideration in developing regulation if data from those studies were not publicly available."[10]

The damage inflicted by this rule would have far-reaching consequences beyond undermining EPA's scientific research processes. It would weaken public health and environmental protections that keep people safe from toxic chemicals and hazardous pollution, and would ultimately mean less protection for communities who already bear the brunt of environmental contamination and associated health impacts.

Decision makers and the public need access to the best-available scientific evidence, and our health and safety depend on using that valuable information to make regulatory decisions. It is critical that as acting Administrator you follow through on your pledge to "seek the facts," by withdrawing this flawed proposal that would politicize science and prevent the agency from fulfilling its mission.

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[7] National Academies of Science, Engineering, and Medicine. 2017. *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals.* Washington, DC: The National Academies Press. DOI: 10.17226/24758; National Academies of Science, Engineering, and Medicine. 2014. *Review of EPA's Integrated Risk Information System (IRIS) Process.* Washington, DC: The National Academies Press. DOI: 10.17226/18764.; Institute of Medicine. 2011. *Finding What Works in Health Care: Standards for Systematic Reviews.* Washington, DC: The National Academies Press. DOI: 10.17226/13059; National Research Council. 2009. *Science and Decisions: Advancing Risk Assessment.* Washington, DC: The National Academies Press. DOI: 10.17226 /12209.; National Research Council. 2007. *Models in Environmental Regulatory Decision Making.* Washington, DC: The National Academies Press. DOI: 10.17226/11972.; National Academies of Science, Engineering, and Medicine. 2017. *Innovations in Federal Statistics: Combining Data While Protecting Privacy.* Washington, DC: The National Academies Press. DOI: 10.17226/24652.; National Academies of Science, Engineering, and Medicine. 2017. *Federal Statistics, Multiple Data Sources, and Privacy Protections: Next Steps.* Washington, DC: The National Academies Press. DOI: 10.17226/24893.

[8] McNutt, M., C.D.Mote, Jr., and V.J. Dzau. 2018. Comment Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259), July 16. Online at http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf, Accessed July 23, 2018.

[9] Grumet, J. 2018. Bipartisan Policy Center comments on "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259, May 22. Online at https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0670, Accessed July 30, 2018.

[10] *Id.*

Signed,

AFGE Local 704
Alaska Community Action on Toxics
American Medical Student Association
American Rivers
Anacostia Watershed Society
Association of Reproductive Health Professionals (ARHP)
Association of Research Libraries
Blackwater Nottoway RiverGuard
Breast Cancer Prevention Partners
Buffalo River Watershed Alliance
Cahaba River Society
CATA - The Farmworker Support Committee
Center for Biological Diversity
Center for Food Safety
Center for Inquiry
Center for Progressive Reform
Clean Water Action
ClimateTruth.org
Coming Clean
Concerned Citizen
CRLA Foundation
Des Moines County Farmers and Neighbors for Optimal Health
Earthjustice
Endangered Species Coalition
Environmental Defense Fund
Environmental Law & Policy Center
Environmental Protection Network
Farmworker Association of Florida
Farmworker Justice
Friends of the Earth
Gasp
Government Accountability Project
Government Information Watch
Green Science Policy Institute
Greenpeace USA
Gulf Restoration Network
Harpeth Conservancy
Helping Others Maintain Environmental Standards (HOMES)
Jacobs Institute of Women's Health
Kentucky Resources Council, Inc.
Kentucky Waterways Alliance
League of Conservation Voters
Massachusetts Rivers Alliance
Mississippi River Collaborative

Moms Clean Air Force
National Equality Action Team (NEAT)
National Family Farm Coalition
National Health Law Program
National LGBTQ Task Force
National Organization for Women
National Parks Conservation Association
National Partnership for Women & Families
Natural Resources Defense Council
New Hampshire Rivers Council
Northwest Watershed Institute
Ohio River Foundation
Pequabuck River Watershed Association
Pesticide Action Network
Pesticide Action Network North America
Physicians for Social Responsibility
Pollinate Minnesota
Poweshiek CARES
Public Justice
Rivanna Conservation Alliance
River Network
Save EPA
Schuylkill Pipeline Awareness
Science and Environmental Health Network
Sciencecorps
Sierra Club
Union of Concerned Scientists
United Steelworkers
US PIRG
Waterkeeper Alliance
West Virginia Rivers Coalition
Women's Voices for the Earth
Yukon River Inter-Tribal Watershed Council

Cc: Acting Deputy Administrator Henry Darwin
Principal Deputy Assistant Administrator for Science for the Office of Research and Development and EPA Science Advisor Jennifer Orme-Zavaleta
Deputy Assistant Administrator for the Office of Research and Development Richard Yamada

Luke Breit

Personal Matters / Ex. 6

8/9/2018

Mr. Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington DC 20460

Dear Mr. Wheeler:

I am writing to express my objection to and concern about the Environmental Protection Agency's (EPA) "Strengthening Transparency in Regulatory Science" proposal (Docket ID No. EPA-HQ-OA-2018-0259). I believe that science plays a pivotal role in ensuring our health and safety, preserving our environment, and informing evidence-based policy. This new proposal would undermine the EPA's mission of preserving public health and the environment.
For the EPA to utilize the best available science to shape public health and environmental safeguards, the agency needs to have the ability to use the best research and information.

While this proposed rule promises "transparency," it reduces confidentiality and privacy protections by requiring the raw data from these studies to be made public. Consequently, the best available scientific studies in numerous public health fields, where patient privacy prohibits sharing the raw data, would be sidelined. This arbitrary rejection of data from research on air quality, public health, drinking water, hazardous waste, and so many other fields would inhibit the EPA's ability to implement science-based protections.

When policies play a role in our health, safety, and environment, the EPA needs to use the best available evidence and research when finalizing safeguards. This ill-advised proposal would significantly limit the EPA's ability to make the informed policy decisions that the agency is required to under landmark public health and environmental laws, including the Clean Air Act, Safe Drinking Water Act, and the Toxic Substances Control Act.

I urge you to reconsider this proposed rule and withdraw it immediately.

Sincerely,

Luke Breit

SACRAMENTO CA 957

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AUG 20 2018

Mr. Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington DC 20460

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20460-

Mr. Luke W. Bretl

Personal Matters / Ex. 6

Luke Breit

Personal Matters / Ex. 6

8/13/2018

Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington DC 20460

RE: Docket ID No. EPA-HQ-OA-2018-0259, Proposed Rule, "Strengthening Transparency in Regulatory Science"

Dear EPA Administrators:

I strongly oppose the proposed rule on "Strengthening Transparency in Regulatory Science" and urge the EPA to withdraw it. The proposed rule would make it harder to share important science, needlessly slow down scientific advancements, and put the health of our citizens and environment at risk.

While increasing the public availability of scientific data and models underlying regulatory science would be a step in the right direction, this rule would not achieve this goal.

If enacted, the proposed rule would prohibit the use of confidential data – like health studies – in EPA's rule-making processes unless that private information is made public. This policy would essentially bar the EPA from consulting most large-scale medical studies when creating rules about air pollution, toxic chemical, and water contaminants. Rather, the EPA should use the best available data and models available to it, regardless of whether these data and models are publicly available.

Additionally, if adopted, the proposed rule would make it harder, not easier, to share important scientific data by excluding studies that do not meet rigid standards set in place by this policy. Limiting the amount of science used in crucial decision making would be detrimental to the EPA's ability to ensure we have clean air and water.

Instead of leading to better or more transparent science, the EPA proposal is far more likely to lead to less science, more biased decision making and weaker public health and environmental rules. Due to these numerous issues, I urge the EPA to withdraw the proposed rule.

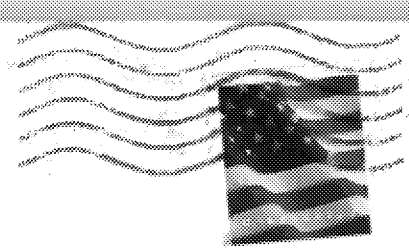
Sincerely,

Luke Breit

Mr. Luke W. Reif

SACRAMENTO CA 957

13 AUG 2018 PM 1 L



AUG 20 2018

Administrators
EPA
1200 Pennsylvania Ave. NW
Washington DC 20460

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Message

From: Peffers, Mel [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B6116FBB41448B38B3CAEFC882165FE-PEFFERS, MELISSA]
Sent: 8/16/2018 8:09:22 PM
To: Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Hetes, Bob [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4547e0bdff9145c3af6ff8e3556222b7-Hetes, Bob]; Lowit, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d3428a2c0b84d5099124a0460babd53-Anna B. Lowit]; Camacho, Iris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5598d2cc8e3c4302aff255a840a991dc-Camacho, Iris]; Sheppard, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63186a03f8e14015ba94b59c699363fc-Sheppard, Tracy]; Raffaele, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc48281bbab34bf5bf3ab1a63780d5ca-Kathleen Raffaele]; Birchfield, Norman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; Foster, Stiven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d242767f304355ad415ec856988213-sfoste02]; Dockins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c8db533f0c847c98d706f1a52b0482b-CDockins]; Flaherty, Colleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88c8ad9e16d64daeb5e50c1d69574c12-Colleen Flaherty]; Scozzafava, MichaelE [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd15262a06994ecca083bbc76cbc7080-MEScozza]; Schappelle, Seema [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c19296c1164a8dab7c8a7cb7b99d3c-Schappelle, Seema]; Burden, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aca392a7aea849bfbce1fdbc1a1ed88e-Burden, Susan]; Suero, Maryann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1f0d67522a5a42d5acd1ac3e14c70cf2-MSuero]; Shao, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36641c9d93784a1899d4e3640f8c6ac3-Shao, nicole]; Diaz, Denisse [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c334462ce64c44579d9559064e38b5ce-Diaz, Denisse]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]
Subject: InsideEPA: Citing Legal Flaws, States Urge EPA To Withdraw Or Clarify Science Rule
Attachments: TCEQ comments.pdf; NESCAUM 9Aug18 comment.pdf; NACAA 26July18 comment.pdf; ACWA 9Aug18 comment.pdf; AStateWetlandsManagers 3Aug18 comment.pdf

InsideEPA: Citing Legal Flaws, States Urge EPA To Withdraw Or Clarify Science Rule

Citing significant legal flaws, state environmental agencies are urging EPA to withdraw or delay and clarify its proposed rule barring the use in major regulatory decisions of any science where the underlying raw data and models are not publicly available, arguing that the proposal is vague and the agency has not engaged with states on its content.

August 9, 2018

U.S. Environmental Protection Agency
EPA Docket Center
EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Avenue NW, Washington, DC 20460

Via regulations.gov: Docket ID No. EPA-HQ-OA-2018-0259

RE: Strengthening Transparency in Regulatory Science

The Association of Clean Water Administrators ("ACWA") is the independent, nonpartisan, national organization of state, interstate, and territorial water program managers, who on a daily basis implement the water quality programs of the Clean Water Act ("CWA"). As the primary entities responsible for carrying out CWA programs, states are very interested in any and all national regulatory or policy positions that may impact their ability to implement the CWA in their states.

The stated intent of this rule is to strengthen regulatory transparency of scientific information that the Environmental Protection Agency (EPA) uses for regulatory decision making, and to ensure that the underlying data and models are publicly available in a manner sufficient for independent validation and analysis. ACWA and the states are very supportive of scientific transparency in regulatory development. Unfortunately, the rule is vague in several areas and does not provide specific regulatory language for review and comment.

In the spirit of cooperative federalism, and before the rule is finalized, we ask that EPA host coregulatory discussions that provide more details regarding the intent, scope, and implementation processes associated with this proposal. ACWA believes these discussions will improve the quality of the comments on the rule and will contribute to an enhanced and improved final rule, should this rulemaking go forward. Further, ACWA requests that EPA issue a supplemental notice of proposed rulemaking that includes actual regulatory language. As part of this supplemental notice, ACWA also requests that EPA provide sufficient detail for an analysis of whether this new approach will achieve the results intended, while also continuing to support states efforts to implement the requirements of the CWA.

Questions Not Fully Addressed

ACWA supports use of best available science and the goals of public transparency and independent verification. States also recognize the importance of ensuring data and the models used for regulatory actions,

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WWW.ACWA-US.ORG

provides defensible science for aquatic life and human health be made publicly available, consistent with relevant privacy laws.

In considering this rule, ACWA and states were uncertain of the potential CWA implications. For example, the National Recommended Water Quality Criteria (NRWQC) development, and the state water quality standards established based on these criteria, rely on an extensive number of scientific studies for both aquatic life protections and human health. In what way could this rule affect the use of those studies? Additionally, EPA is currently reviewing and evaluating toxicity data for several perflourinated compounds. These toxicity evaluations and resulting toxicity data are crucial, as most states do not have the resources do this on their own. States have raised questions as to whether implementation of this rule would delay these evaluations or affect the scope of what is evaluated.

Likewise, EPA has historically developed several industry specific effluent guidelines (ELGs) are periodically developed and/or updated. These technology-based standards are intended to represent the greatest pollutant reductions economically achievable for an industry and are incorporated into National Pollutant Discharge Elimination System (NPDES) permits issued by States and EPA regional offices. States raised questions regarding the number of ELGs that qualified as "significant."

During the extended comment period, ACWA was able to confirm with EPA's Office of Water (OW) three rules that met the $100 million "significant impact" threshold set out in the proposed rule in the last ten years:

1. National Primary Drinking Water Rule: Stage 2 Disinfectants and Disinfection Byproducts Final Rule published on January 2, 2006 (71 FR 388-493)

2. Cooling Water Intake Existing Facilities Rule, Final Regulations to Establish Requirements for Cooling Water Intake Structures at Existing Facilities and Amend Requirements at Phase I Facilities (aka CWA Section 316(b)) published on August 15, 2014 (79 FR 48299)

3. Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category published on November 3, 2015 (80 FR 67837)

ACWA was also able to confirm with OW that in looking at all other less significant actions, almost all the information used has traditionally been available to share. EPA was not aware of any national recommended water quality criteria where modeling, science or data could not be shared with states or the public due to privacy issues, or because of intellectual property, confidential business information, security risk, or other potentially justifiable reason. Similarly, all information and data within the NPDES permit applications and permits can be shared, with just a few exceptions. For example, the program office may receive confidential business information from industrial facilities that use proprietary processes and studies, and sometimes there may be an instance where a model used may not be shared due to its proprietary nature. It was also noted by OW that national security related facility information is not shareable.

The proposed rule also raises questions that states believe should be considered before the rule is finalized. These questions include:

1. How would the $100 million economic threshold analysis be implemented? Would new rules be assessed differently than updates to current rules?

2. Where data masking, coding, or de-identification is not technically feasible, will EPA still consider using high quality scientific research?

3. While it appears this rule would only apply prospectively to regulations, would there be any impact to science historically used to inform regulations that have existed for years/decades? How will EPA ensure the science remains timely?

4. If EPA were to phase in the requirements or prioritize certain specific actions, will states have any role in helping identify those priorities?

5. What impact, if any, would this rule have on institutions of higher education, hospitals, and other nonprofit organizations that received EPA funding through grants and cooperative agreements?

Conclusion

Thank you for the opportunity to comment. ACWA and states support regulatory transparency but believe there are still several important questions that should be considered before EPA moves forward. As this rule is developed, ACWA requests that EPA periodically meet with states to share information the agency has learned, and to consider any intended and unintended impacts to state programs. Our members, the directors of state surface water quality programs, possess unique knowledge and insight into those clean water program areas that rely most heavily on data, scientific studies, and models. As with all ACWA comment letters, we encourage the agency to also consider recommendations provided by individual states. If you have any questions regarding this comment letter, please contact ACWA Executive Director Julia Anastasio at janastasio@acwa-us.org or (202) 756-0600.

Jennifer Wigal
ACWA President
Deputy Water Quality Administrator
Oregon Department of Environmental Quality

The Association of State Wetland Managers, Inc.

"Dedicated to the Protection and Restoration of the Nation's Wetlands"

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Edward Clements
IN Dept. of Environmental Management

Lauren Driscoll
WA State Dept. of Ecology

Timothy Rach
FL Dept. of Environmental Protection

August 3, 2018

U.S. Environmental Protection Agency
EPA Docket Center
EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington DC 20460

Submitted via www.regulations.gov:
Docket ID No. EPA-HQ-OA-2018-0259
Re: Strengthening Transparency in Regulatory Science

To Whom It May Concern:

These comments were prepared by the Association of State Wetland Managers (ASWM) in response to the April 30, 2018 *Federal Register* notice "Strengthening Transparency in Regulatory Science." ASWM represents states and tribes in promoting the sound management of wetlands and other waters. Our technical support of states and tribes includes state and federal dredge and fill permit programs including § 404 of the Clean Water Act; development of water quality standards for wetlands; § 401 Certification of federal permits and licenses; and coordination with other state and federal programs impacting aquatic resources. Thus, although we recognize the broad scope of the proposed regulation, our comments are focused on the potential impact of the proposed rule on these areas of public policy.

We are cognizant that discussion of this proposed rule has focused on the impacts of environmental contamination on public health. However, the rule as written is very broad, and also clearly extends to other CWA programs. CWA §104 – which authorizes environmental surveillance and monitoring for a wide array of programs – is included in the legislative provisions used to justify the rule. The definition of "*dose response data and models*" included in the proposed rule directly refers not only to public health but also to environmental impact. Therefore, we anticipate that the proposed rule would directly alter the programs of interest to our member states.

The stated intent of the proposed rule is "to strengthen the transparency of EPA regulatory science" by "ensuring that the data underlying [pivotal regulatory decisions] are publicly available in a manner sufficient for independent validation." ASWM strongly agrees that environmental regulatory decisions should be based on the best available science, including both peer-reviewed science and other pertinent information. However, we are greatly concerned that the proposed rule would unnecessarily limit the use of available sound science to an extent that would undermine EPA's mission to protect public health and the environment. We question whether there is a need for greater public access to raw data, given the extensive measures already in place to ensure scientific transparency.

GENERAL COMMENTS

- **Ambiguity of the proposed rule.** ASWM finds it difficult to predict the effect of the proposed transparency rule given the broad and general nature of the described intent and applicability, and lack of information regarding how it would be implemented in practice. It is impossible based on the information provided in the *Federal Register* notice to fully evaluate the potential demand on time and agency resources, and to ascertain the benefits or impediments that might result from the proposed regulation. We are concerned that the notice fails to provide sufficient detail for an analysis of whether the new approach will achieve the stated purpose without creating unintended consequences that make it difficult for states to implement clean water programs.

- **Role of Science in Decision Making.** One of the most important factors in decision-making associated with environmental issues and public health is the application of sound science. While other factors such as economics, public values, availability of technology, coordination with other laws and programs etc., are important to consider, it is science that is the most transparent and that should provide the foundation for decision makers. The application of sound science results in a fact-based decision and supports consistency and predictability in regulatory actions. It also allows decision makers to more clearly articulate and defend their decisions.

- **Need for the proposed rule.**
  EPA solicits comments on how this proposal can be "promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation." In fact, ASWM believes that the Federal programs that are the province of our members already provide sufficient opportunities for public review and analysis. This is in addition to the rigorous peer review provided by the scientific publications. We therefore question the need for the rule. We find the justification for the proposed rule – the statement that "*EPA has not previously implemented [policy and guidance that has called for increasing public access to data] in a robust and consistent manner*" -- to be unconvincing. If the issue is with implementation rather than the underlying policies and guidance, then a new rule is not what is needed.

  We suggest that EPA provide documentation of the inability of the public to review important data, and the resulting environmental impact. We also request examples of how additional review by the public could improve the regulatory process without adding an unacceptable cost or delay, and/or excluding information essential to the validity of decision making.

  Existing published literature often plays a role in decision making and predicts environmental and economic impacts. Scientific journals typically have a peer review system in place to evaluate the soundness of the research submitted for publication. It is unclear when and why use of this type of information would require more transparency, as methods of data collection and analysis are clearly described to inform the results and conclusions.

- **Potential impact on third parties and grantees.**
  The proposed rule applies to scientific data gathered by third parties and grantees. EPA grant funding supports the efforts of states to conduct research and carry out their own respective regulations. It is unclear how this regulation would impact science gathered and applied independently by the states. Grant recipients are required to document their approaches for

data collection and analysis, and overall quality control. ASWM recommends that the sufficiency of existing approaches be fully considered before making substantive changes. ASWM further recommends that adequate safeguards be considered in any proposed rules to protect personal information of relevant parties.

- **Consistent treatment of data regardless of source.**
  ASWM notes that the proposed rule applies to the transparency of data used by federal agencies in rule and decision making. We recommend that federal agencies apply the same stringent standards for transparency and quality of data to all information used in decision-making regardless of its source, that is, whether provided by public agencies, the academic community, regulated entities, or other sources. Moreover, we believe that scientific transparency would be increased by requiring information regarding the entity providing financial support for the related research. Funding by federal agencies and many foundations are typically identified in research reports, but corporate and other private funders may not be. Given that funding entities may influence the formulation of scientific questions raised by the research, this information is necessary to fully understand the conclusions that may be drawn from the research.

RESPONSE TO REQUEST FOR COMMENTS IN SECTION III OF *FEDERAL REGISTER* NOTICE.

1. Effect of the proposed rule on individual programs.

- Clean Water Act definition of Waters of the United States (WOTUS).
  The proposed rule language indicates that it is generally applicable prospectively to final agency actions. However, the agencies also request comments on applicability to other stages of rulemaking. EPA is currently engaged in a very extended proposed modification to the definition of Waters of the United States (WOTUS). ASWM continues to urge expedited resolution of the various proposed revisions to the definition of WOTUS and it is unclear how the proposed rule might affect current rulemaking efforts.

  Although the definition of "*dose response data and models*" may not apply directly to the WOTUS rule, the *Federal Register* notice also indicates that EPA is considering expansion of the rule "*to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulation interventions on complex economic or environmental systems.*" Given the in-depth scientific analysis undertaken to support development of the 2015 rule regarding WOTUS – based heavily on a publicly available analysis of the pertinent peer-reviewed literature – ASWM recommends completion of the WOTUS rule using the existing scientific analysis. That is, we recommend that the WOTUS rule be exempted from any application of the proposed rule regarding transparency in science. Applying the proposed rule to the information gathered to support a WOTUS rule is unnecessary given currently availability of the underlying science to the public.

- Water Quality Standards.
  It is unknown how the proposed rule would impact development of Water Quality Standards for wetlands. Please note that many states include pollutant and toxic discharge standards

among those that are applied to wetlands. The proposal should clearly address and answer this question, and also clarify the impact on grants to states.

- National Environmental Policy Act.
  The Administration is currently engaged in a multi-year effort to streamline NEPA. ASWM recommends that the proposed rule not undermine that initiative either by excluding information that does not meet the requirements or by requiring more time for the required transparency standards to be met.

2. Request for comments regarding the scope of the proposed regulation.
ASWM has based this set of comments on our understanding that the text of the proposed rule would apply to a "significant regulatory action" as defined in E.O. 12866. That definition reads as follows:

> *"...any regulatory action that is likely to result in a rule that may:*
>
> *(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;*
>
> *(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;*
>
> *(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or*
>
> *(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.*

- **Should the proposed rule be expanded "*...to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulation interventions on complex economic or environmental systems.*"**

  ASWM supports the use of numerous types and sources of data and information in decision-making. Particularly where legal standards require consideration of a wide array of factors in reaching a regulatory decision - including not only ecological and economic factors, but practicality and alternatives to the proposal, secondary impacts, and other criteria - many types and sources of data are routinely necessary for a sound decision. However, data requirements are already defined in the rules and guidance associated with specific regulatory programs; such information is already subject to public review both in rule-making and in other program decisions such as permit approval. Use of the broadest possible range of information increases the validity and accuracy of decisions and should not be limited by overly burdensome requirements as described by the proposed rule.

- **Should the requirements in the proposed rule also apply to, "... other stages of the rulemaking process...as well as to other types of agency actions and promulgations, such**

as guidance."

ASWM believes that applying such strenuous requirements for data early in the development of a rule would restrict initial consultation with other agencies, with stakeholders, and with the public. We see no valid reason to impose such restrictions.

ASWM also opposes application of the requirements of the proposed rule to promulgation of guidance. In environmental programs, guidance often supports implementation of a rule in a practical manner at the field level. As such, it may explain how to accurately and effectively apply regulations in different geographic areas, or under other conditions that may vary from site to site such as specific soil conditions. Practical, accurate, and efficient application of regulations in the field typically depends upon guidance based not only on published science, but also on professional experience and results of field testing. It would be highly impractical to make such information available to the public in the format described by the proposed rule. On the other hand, failure to develop guidance because of lack of extensive published data would cripple implementation of necessary regulatory programs.

- **Should the scope of coverage by the proposed rule be narrowed.**

In general, we support significant narrowing of the scope of the proposed rule, if it is finalized. EPA should define a more specific category of decisions that demand the level of public access to data defined by this rule, and more fully explain how the benefit of greater public access to raw data justifies the cost of implementation.

EPA has suggested only that the scope be limited to a "major" decision under the Congressional Review Act – which is defined as "economically significant under E.O. 12866"; or, alternatively, to a regulation found to be "economically significant" under E.O. 12866 – which is essentially the same thing. ASWM fails to understand the distinction among these criteria, and that proposed in the rule. We request clarification.

- **Should the provisions of the proposed rule apply to, *"individual party adjudications, enforcement actions, or permit proceedings that EPA determines are scientifically or technically novel or likely to have precedent setting influence on future actions."* Should *"...other agency actions... such as site-specific permitting actions or non-binding regulatory determinations"* be included.**

While ASWM has concerns regarding the impact of the proposed rule in decisions on rulemaking, we have even *greater* concerns regarding the suggested application of the proposed rule to individual permit actions. Such requirements would be grossly inconsistent with sound and timely authorizations under the §404 dredge and fill permit program in particular.

Tens of thousands of actions – including numerous dredge and fill construction activities undertaken both by private landowners and public agencies – are authorized annually under §404 of the CWA, through the collaboration of EPA, the U.S. Army Corps of Engineers, and the states and tribes. The expeditious review and issuance of authorizations under this program is essential for the range of projects authorized under §404. Moreover, data collected and submitted by the applicant to support the decision, and by the regulatory agencies to inform the

decision, are both essential and collected on a case-by-case basis as needed. The level of detail of a permit specific analysis is generally commensurate with the scope of a particular project (e.g. repair of a private seawall, versus construction of an interstate highway). Regulations that subject all data to identical requirements regarding data collection, evaluation, and release would interfere with the permitting process in an unacceptable manner.

Under §404, the vast majority of permits are issued by the U.S. Army Corps of Engineers through general permits. Many associated state programs include statutory deadlines for review and approval. Thus, any delay associated with re-review of original supportive data beyond what is already provided for in the public notice process would have the effect of slowing and delaying these authorizations, at a significantly increased regulatory cost. Moreover, the exclusion of non-peer reviewed data - which is typically collected at the time of a permit application for the purpose of clarifying both the extent and limitations of adverse impacts – would undermine the accuracy of individual permit decisions. Finally, ASWM notes that there are existing options for appeal and legal recourse for applicants or permittees to question the validity of scientific data used in decision making; therefore, there is no need to apply the proposed provisions to individual cases.

3. Should the proposed rule apply retroactively to data collected prior to the effective date of the rule.

It is difficult to envision how the proposed rule could be applied retroactively to the science developed through long term experience in the implementation of various regulations and standards. Exclusion of research that was accepted as scientifically valid in the past could only result in the need to duplicate such research, adding needless cost and delay to the process of decision making. ASWM objects to this concept.

Current regulations under the CWA have evolved over decades, supported by extensive peer reviewed science and other data collected by federal agencies, state and local agencies, academic institutions, stakeholders, and the general public. Supporting data includes the results of long-term monitoring of the impact and effectiveness of previous regulations, thereby supporting adaptive management and adjustments needed to address those impacts. Reports of such studies are readily available.

4. Request for comments on additional implementation challenges.

The proposed rule itself could be defined as a "significant regulatory action" under E.O. 12866 based both on the cost to implement the action (that is, to subject all agencies and organizations that provide data to EPA to the provisions of the proposal), and on the fact that the rule could, "*...create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.*" We suggest that EPA develop a comprehensive cost-benefit analysis to support this action, reflecting both the full benefit of resources protected, and the cost of any resulting delay in execution of regulatory actions.

The Congressional Budget Office consulted with EPA in recent analyses of related legislation, H.R. 1030 in 2015, and H.R. 1430 in 2017. The 2015 analysis determined that the agency would need to expend $250 million/year initially in implementation of the measure, even if the number of studies that EPA relied on was reduced by one half. The CBO determined that meeting the H.R. 1430 requirements would cost EPA an average of $10,000 per study.

5. Comments regarding the proposed authority of the Administrator to exempt regulatory decisions from the rule.

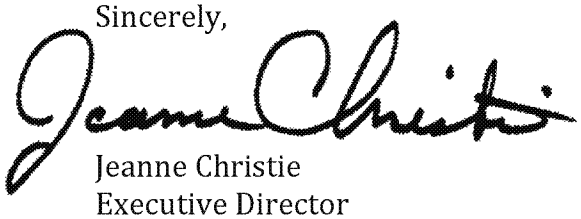
The proposed rule gives the EPA Administrator the authority to "exempt significant regulatory decisions on a case-by-case-basis" from the requirements of this new subpart. This appears to give EPA Administrators a great deal of discretionary authority now and in the future pursuant to the implementation of this rule. It is unclear why an exemption from compliance with the rule would be needed if the final rule is not excessively burdensome; how that discretionary authority will be exercised; and what, if any, standards would be applied by the Administrator in determining exemptions. In our experience, consistent application of regulations and standards is necessary to provide the clarity and predictability needed in carrying out science-based programs. This authority could be applied very differently over time as EPA leadership changes, with unintended consequences for applicant clarity or sound management of environmental resources.

SUMMARY

Given the broad scope and potential effect of the proposed rule, we recommend that an additional step be added for EPA to hold discussions with impacted states and tribes and other stakeholders to provide supplemental information to the current proposal. We also request that EPA provide a supplement to the rule to explain more fully how the proposed rule would increase transparency without delaying decision-making or excluding consideration of traditionally acceptable data and publications, given the numerous federal provisions already in place to achieve the goal of ensuring transparency.

As always, we appreciate the opportunity to review and comment on this proposal. While these comments have been prepared with input from the ASWM Board of Directors, they do not necessarily represent the individual views of all states and tribes; we therefore encourage your full consideration of the comments of individual states and tribes and other state associations. Please do not hesitate to contact me should you wish to discuss these comments.

Sincerely,



Jeanne Christie
Executive Director

Cc: Mr. Tom Sinks, Office of the Science Advisor, USEPA
ASWM Board of Directors
Marla Stelk, ASWM

NACAA
national association of clean air agencies

July 26, 2018

U.S. Environmental Protection Agency
EPA Docket Center
Attention: Docket ID No. EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

To Whom It May Concern:

The National Association of Clean Air Agencies (NACAA) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) proposed rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018). NACAA is the national, non-partisan, non-profit association of 156 local and state air pollution control agencies in 41 states, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

NACAA agrees with EPA that "the best available science must serve as the foundation of EPA's regulatory actions."[1] Indeed, reliance on best-available science is a fundamental requirement of the Clean Air Act and other environmental statutes that EPA administers. For example, the Clean Air Act requires EPA to establish National Ambient Air Quality Standards (NAAQS) at levels "requisite to protect the public health" with "an adequate margin of safety."[2] In meeting this obligation, EPA is required to develop air quality criteria that "*accurately reflect the latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[3] Science-based decision making is at the very core of our shared mission to protect public health and the environment from the harmful effects of air pollution.

[1] 83 Fed. Reg. at 18,769.

[2] 42 U.S.C. § 7409(b)(1).

[3] *Id.* § 7408(a)(2) (emphasis added).

NACAA also recognizes that there is a laudable, long-term trend toward increased transparency in science – in particular, toward providing greater public access to underlying data and analytical techniques after scientific studies are published. There is much to value in this trend toward more "open science," and NACAA supports the continued development of methods that would permit the public disclosure of information on which scientific studies are based without violating, in EPA's words, "confidential or private information in a manner that violates applicable legal and ethical protections."[4] However, at the present time, complete public access to underlying data is not always possible, especially in the case of epidemiological studies based on private health data that must remain confidential. To the extent that techniques are available to anonymize such data, we support their use and we encourage their further development.

Transparency concerns, however, must not override EPA's obligation to consider the full range of peer-reviewed, sound scientific research that is available and relevant to its regulatory decisions. In NACAA's view, the proposal would likely hinder, rather than promote, EPA's use of best-available science and it would tend to diminish public confidence in the integrity of EPA's scientific decision making.

The proposal includes three main components. First, it would require EPA to ensure that the data and models underlying the scientific studies on which its regulatory actions are based are "publicly available in a manner sufficient for independent validation."[5] Second, it would impose upon the agency requirements for the analysis of dose-response models used in scientific studies upon which it relies.[6] Third, it would require EPA to conduct "independent peer review" of scientific studies used to justify its regulatory decisions.[7] Notably absent from the proposal are any details about how, exactly, the agency intends to implement those requirements, or what it might cost.

Our concerns with the proposed rule fall into two main categories: (1) its potential to restrict the scientific studies that EPA will consider in the development of health-based air quality regulations, particularly studies that are based on confidential individual health data, and (2) its vagueness, including its lack of clarity as to how EPA intends to implement the rule in a consistent, clear manner that does not compromise its obligation to protect public health and the environment. We elaborate on these concerns below.

NACAA recommends that EPA withdraw the proposed rule. Prior to proposal, a regulation with such significant ramifications for EPA's science-based decision making should be thoroughly vetted by the scientific community[8] and other key stakeholders, including the state

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[4] 83 Fed. Reg. at 18,771.

[5] *Id.* at 18,773-74 (proposed § 30.5).

[6] *Id.* at 18,774 (proposed § 30.6).

[7] *Id.* (proposed § 30.7).

[8] In a memorandum dated May 12, a Science Advisory Board (SAB) Work Group Chair indicated that EPA made no effort to seek the input of its own scientific advisors and that Work Group members were only made aware of the proposal "via the *Federal Register* and news articles." The Work Group concludes that the action warrants further review by the SAB and lays out a number of specific concerns with the proposal, all of with which NACAA concurs

and local air agencies that rely on the scientific integrity of EPA's regulations to protect public health and the environment from the harmful effects of air pollution.

I. EPA Has Not Established that the Proposed Rule Is Necessary or Reasonable

EPA has not adequately explained the purpose and rationale for the proposed rule. The agency suggests that both the "integrity" and "validity" of its decision making will be strengthened by requiring full public disclosure of the data and models underlying the scientific studies on which it relies. The logical implication is that EPA believes those characteristics are currently lacking. The agency does not explain how it reached that conclusion, or what particular "problems" the rule is intended to solve. EPA never explains why, specifically, it believes that existing policies and tools for vetting scientific research are insufficient, why this rule (or any rule) is the best way to address those deficiencies, or why the proposal would better serve and protect the public than its existing policies and practices.

Public access to underlying data and models can be beneficial. However, full public access is not necessary to assure the validity of scientific studies. Rather, the most effective assurance of scientific validity and accuracy is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. There are many steps involved in converting scientific information into policy. Scientists collect data, analyze them, create a model to test theories, compare the model to the data, and then adjust the model. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all these components to establish validity. The process of peer review has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it is incumbent on the agency to explain exactly *why* it believes the process is inadequate and how its proposal specifically addresses those inadequacies.

The proposal does not acknowledge that EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts. The primary function of EPA's Science Advisory Board (SAB) is to review the quality and relevance of scientific and technical information being used by EPA or proposed as the basis for EPA regulations. With respect to the Clean Air Act in particular, EPA's Clean Air Scientific Advisory Committee (CASAC) provides independent advice to the EPA Administrator on the technical bases for the NAAQS. By ignoring the existence of these bodies in the proposed rule, EPA suggests that it does not trust its own scientific advisors. This tends to undermine public confidence in EPA decision making, rather than to bolster it.

The U.S. Court of Appeals for the District Columbia Circuit has affirmed EPA's use of non-public data in support of NAAQS, and in so doing it characterized as "persuasive" EPA's approach to data availability, which the court quoted as follows:

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warrant serious consideration. *See* Memorandum to Members of the Chartered SAB and SAB Liaisons from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration, "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN" (May 12, 2018).

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment. [S]uch data are often the property of scientific investigators and are often not readily available because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].[9]

Now, EPA indicates that it intends to reverse this policy and adopt one that would expressly preclude it from using studies based on such "non-public data."[10] It is inappropriate for EPA to undertake such a consequential policy change without explaining why it believes the concerns it expressed above are incorrect or no longer valid.

II. The Proposed Rule Could Have Serious, Adverse Effects on the Nation's Air Program

Another concern is that, if enacted, the rule would serve to bar EPA's consideration of relevant scientific literature in the establishment of air regulations designed to protect human health and the environment. Taking one key example, many commenters have opined that the landmark Harvard School of Public Health "Six Cities" epidemiological study, which established the strong association between fine particulate matter pollution and mortality, would not meet the requirements of the proposed rule because it relies on human health data subject to patient confidentiality agreements that were entered into decades ago. EPA should publicly confirm that it would consider existing literature such as the Six Cities Study in future rulemakings, should the proposed rule be enacted.

Unfortunately, EPA suggests in footnote 3 of the proposal that it would exclude such studies from consideration. There, EPA cites two D.C. Circuit cases that upheld its reliance on data that is protected from widespread view by third parties in setting NAAQS for lead and fine particulate matter, respectively, and states, "EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions." NACAA is concerned by the clear implication that EPA will discard rigorously vetted scientific literature such as the Six Cities Study, withdrawing from its legal obligation and stated intention to rely on the best available science.

The proposal would also allow the EPA Administrator to grant exemptions to the rule's requirements on a case-by-case basis if he or she determines it is "not feasible" to make underlying data publicly available or to conduct independent peer review of scientific studies. However, this provision does not alleviate concerns about the potential exclusion of relevant data, because the rule does not include any criteria for how the Administrator would make such a determination. Making the EPA Administrator the ultimate arbiter of what scientific literature should be considered by the agency, based solely on his or her determination of what is or is not "feasible," would have the effect of interjecting the appearance of politics into what should be a

[9] *Am. Trucking Ass'ns., Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

[10] 83 Fed. Reg. at 18,769 n.3.

fair and unbiased scientific assessment. It is an opportunity for arbitrary decision making and is insufficient to protect against the exclusion of relevant, valid scientific studies.

III. Requiring EPA to Conduct "Independent Peer Review" of Scientific Studies Is Unnecessary and Would Be Difficult to Implement

The proposed rule would require EPA to conduct "independent peer review" of scientific studies underlying its significant regulatory decisions, such as the establishment of health-based air quality standards. EPA's in-house peer reviewers would also be tasked with articulating "the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results."[11]

It is difficult to provide meaningful comments on this aspect of the proposal because EPA has included no details about how the "independent peer review" requirement would be implemented. The fact that EPA has requested comment on "which parts of the Agency should be responsible for carrying out these requirements" suggests that it has not worked out a plan for this fundamental provision. Peer reviewers must be experts in their fields of scientific study. Would EPA have to hire new experts, and if so, how many and in what fields? How much would this cost? More fundamentally, why should scientific literature that has already undergone peer review and been vetted by EPA's science advisory panels be subjected to an additional layer of government peer review? These key questions should have been considered, and the answers made public, prior to the rule's proposal.

IV. The Proposed Rule Should Not Be Applied Retrospectively

EPA requests comment on whether the requirements of the proposed rule should be applied retrospectively, should the agency decide to adopt it. Specifically, it asks whether for regulatory programs like the NAAQS, in which future significant regulatory actions may be based on the administrative records from previous reviews, the rule should apply to that previous administrative record. This would be inappropriate. To apply such a rule retroactively would create significant regulatory uncertainty by calling into question existing regulatory standards as well as the permits, state implementation plans and other decisions that are based on those standards. Moreover, the rule should not be applied to data and models underlying studies that have already been completed or are currently underway.

V. The Rule Could Be Extremely Costly to Implement

EPA has not estimated the costs of implementing the proposed rule. The preamble states only that "EPA believes the benefits of this proposed rule justify the costs," while providing no information to support that belief. Considering that the rule would require the agency to assemble an in-house group of experts to conduct independent peer review of scientific studies, and to devote staff resources to ensure that data and other information underlying the studies are publicly available in a format sufficient to allow others to replicate their results, it is reasonable to expect those costs could be very high.

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[11] 83 Fed. Reg. at 18,774.

The Congressional Budget Office (CBO) was able to estimate the costs of implementing proposed legislation on which we understand the proposed rule to be based, namely, H.R. 1430, the Honest and Open New EPA Science Treatment (HONEST) Act of 2017. CBO estimated that "[i]f EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions," the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data to the level required by the bill.[12] Such high costs would reduce the number of scientific studies EPA can consider, which is contrary to the intent and literal language of the Clean Air Act to consider the best available science. We recognize that the proposed rule is somewhat narrower in scope in that its requirements apply to what EPA characterizes as "pivotal regulatory science," but that does not explain why EPA could not provide a cost estimate for the proposed rule when CBO was able to do so for the HONEST Act.

* * * * * *

For all the foregoing reasons, NACAA respectfully requests that EPA withdraw the proposed rule. If the agency intends to update its approach to transparency and reproducibility, it should do so in consultation with the National Academy of Sciences and its own scientific advisors. The implementation details should be worked out in advance, not left to speculation. In the spirit of cooperative federalism, EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation's environmental laws.

If you have any questions about these comments, please do not hesitate to contact me or Karen Mongoven at NACAA. We can be reached by phone at (202) 624-7864 or by email at mkeogh@4cleanair.org and kmongoven@4cleanair.org.

Sincerely,

Miles Keogh
Executive Director
National Association of Clean Air Agencies

[12] Congressional Budget Office, Cost Estimate, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (March 29, 2017).

NESCAUM
www.nescaum.org

Northeast States for Coordinated Air Use Management
89 South Street, Suite 602 Boston, MA 02111
Phone 617-259-2000 Fax 617-742-9162
Arthur N. Marin, Executive Director

August 9, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Attention: Docket ID No. EPA–HQ–OA–2018–0259

Re: *Proposed Rule on Strengthening Transparency in Regulatory Science*

Dear Acting Administrator Wheeler:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the U.S. Environmental Protection Agency's (EPA's) Proposed Rule, published in the Federal Register April 30, 2018 and entitled "Strengthening Transparency in Regulatory Science" (83 FR 18768-18774). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.[1] We submit these comments out of our concern that failure to consider the best available science will endanger public health.

The EPA invokes "strengthening transparency" as a primary driver for the proposal, yet fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of where "EPA has not previously implemented these policies and guidance in a robust and consistent manner" nor what are the specific "agency culture and practices regarding data access" that require changing. Furthermore, when EPA was legally challenged after setting the 1997 ozone and fine particulate matter ambient air quality standards, the court in *American Trucking Assns. v. EPA* [283 F.3d 355 (D.C.Cir. 2002)] differentiated the substantial difference and administrative hardship between reliance on peer-reviewed scientific studies cited in a rulemaking record rather than on the raw data underlying those studies:

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.... [S]uch data are often the property of scientific investigators and are often not readily available

[1] These comments reflect the majority view of NESCAUM members. Individual member states may hold some views different from the NESCAUM states' majority consensus.

> because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].

In light of the court's holding, and without additional clarity from EPA, we are having difficulty identifying the problem EPA seeks to address with this Proposed Rule. Therefore, as explained below, we request that the Agency withdraw it.

The proposal is too vague as written to provide the public with a meaningful opportunity to comment

The Proposed Rule, as written, lacks credible specificity and is overly vague in its terms and scope. Under the Administrative Procedures Act (APA), a federal regulatory agency must publish notice of either the substance of a proposed rule or a "description of the subjects and issues" covered by a proposed rule (5 U.S.C. § 553(b)(3)). In Fertilizer Institute v. EPA, 935 F.2d 1303 (D.C.Cir. 1991), the court observed that it "has consistently interpreted that requirement to mean that an agency's notice must 'provide sufficient detail and rationale for the rule to permit interested parties to comment meaningfully'" [*citing* Florida Power & Light Co. v. United States, 846 F.2d 765, 771 (D.C.Cir. 1988), cert. denied, 490 U.S. 1045 (1989)]. As such, EPA is required to articulate the specifics of its proposed rulemakings in a manner that provides a valid opportunity for public comment.

In this proposal, EPA solicits comment across a long list of topic areas, but fails to provide the Agency's own "sufficient detail and rationale" on the solicited comment areas, in contravention to APA § 553(b)(3). Commenters are left in the position of speculating on EPA's views and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment. In Fertilizer Institute v. EPA, the court held "Commenting parties cannot be expected to monitor all other comments submitted to an agency." In commenters' trying to anticipate potential rule revisions in response to comments from others, the court has also stated, "the EPA must *itself* provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment" [Fertilizer Institute v. EPA, at 1312, *quoting* Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 547 (D.C.Cir. 1983) (emphasis in original)].

EPA must describe how the proposed text in sections 30.5, 30.7, and 30.9 affect current practice

Without clearly articulated and appropriate bounds, the Proposed Rule can restrict the scientific literature that is the basis for reviews of the National Ambient Air Quality Standards (NAAQS). Along with the changes to the NAAQS review process outlined in EPA's May 9, 2018 "Back to Basics" memo[2] and the recent requirement that members of the Clean Air Science Advisory

[2] Memorandum from E. Scott Pruitt, EPA Administrator, to [EPA] Assistant Administrators, *Subject: Back-to-Basics Process for Reviewing National Ambient Air Quality Standards* (May 9, 2018). Available at https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed May 21, 2018).

Committee and related panel members not receive any current EPA funding,[3] the Proposed Rule would constrain both the range of expertise and body of scientific literature that is available to be considered in these reviews, undermining the NAAQS. This will impede setting NAAQS levels with an adequate margin of safety necessary for public health protection, as required by the Clean Air Act, by preventing EPA from relying on scientific studies previously utilized to set them. Members of EPA's Science Advisory Board (SAB) have recently expressed similar concerns, stating that "The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs."[4]

Sections 30.5 and 30.7 of the Proposed Rule respectively say: "the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation," and "EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions[.]" The approaches for "independent validation" and "independent review" are not described. Would EPA's staff scientists conduct these validations and reviews, or would EPA contract this out to third parties? How would EPA determine that third parties have the necessary qualifications and resources to perform these validations and reviews? Would peer reviewers be anonymous, or will their names and reviews be made public?

Without the above listed information elements, commenters are left to guess at the scope and potential impact of EPA's proposal as it applies to "independent validation" and "independent review." For example, a recent study that is likely to be considered "pivotal regulatory science" for the current PM NAAQS review is by Di, *et al.*, "Air pollution and mortality in the Medicare population."[5] This study of chronic effects, along with a complementary study on acute effects,[6] uses 460,310,521 person years of follow-up and has billions of data points. The computational resources necessary to replicate or validate the analysis are available only at large institutions like the Harvard-MIT Data Center.[7] How does EPA's proposal on independent validation and review apply to a study like this?

The Proposed Rule in section 30.5 also includes qualifying language that "The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner

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[3] U.S. EPA, "Strengthening and Improving Membership on EPA Federal Advisory Committees," (Oct. 31, 2017). Available at https://www.epa.gov/faca/strengthening-and-improving-membership-epa-federal-advisory-committees (accessed May 21, 2018).

[4] Memorandum from Alison Cullen, Chair SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB Liaisons, *Subject: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)* (May 12, 2018). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf (accessed May 21, 2018).

[5] Di, Q., *et al.* "Air pollution and mortality in the Medicare population." *New England Journal of Medicine* 376.26 (2017): 2513-2522. DOI: 10.1056/NEJMoa1702747.

[6] Di, Q., *et al.* "Association of short-term exposure to air pollution with mortality in older adults." *JAMA* 318.24 (2017): 2446-2456. DOI: 10.1001/jama.2017.17923.

[7] Harvard-MIT Data Center, The Institute for Quantitative Social Science, "Research Computing Environment," https://projects.iq.harvard.edu/hmdc/book/research-computing-environment (accessed May 21, 2018).

consistent with law and protection of privacy, confidentiality, national and homeland security is not possible." If EPA concludes this "is not possible," does EPA then discard the science, or does it proceed in incorporating its consideration in recognition of other legitimate concerns limiting release of some, or even all, the underlying data and methodologies? This is an instance where clear examples of how the proposal applies to "pivotal regulatory science" would be most useful. Possible examples are the Harvard Six Cities Study[8] and the American Cancer Society Study[9] of particulate air pollution and mortality, and their reanalysis sponsored by the Health Effects Institute (HEI).[10] The original two studies are subject to medical history confidentiality requirements of the study subjects. The HEI effort maintained those confidentiality requirements while conducting an independent reanalysis that largely confirmed the original two studies' results. Are these examples in line with EPA's Proposed Rule, or are there other unidentified issues that would lead EPA to discard studies like these if subjected to this Proposed Rule?

Adding to the vagueness of sections 30.5 and 30.7, section 30.9 would provide the Administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions "on a case-by case basis if he or she determines that compliance is impracticable." The Proposed Rule lists several general considerations, but fails to provide specific criteria for determining when "compliance is impracticable." This creates the potential for inconsistent application, and leaves the public with no salient points upon which to provide comments. In addition to lacking specific criteria for evaluating what is "impracticable," the Proposed Rule does not describe the process that will be used to determine whether or not a regulatory decision is eligible for such an exemption, nor whether the basis of the Administrator's decision for such an exemption will be publicly disclosed. Lacking clear guidelines for transparent decision-making, the Administrator's discretion would appear to be unbounded and haphazard in application, with an undisclosed rationale.

EPA has provided no meaningful cost estimate for the Proposed Rule

Should EPA impose additional undefined peer review requirements on "pivotal regulatory science," EPA has failed to provide a regulatory impact assessment of costs from imposing such requirements. The costs are likely quite significant, however, based on a Congressional Budget Office (CBO) cost estimate[11] of a similar legislative proposal in H.R. 1430 "Honest and Open New EPA Science Treatment (HONEST) Act of 2017" passed in the House on March 29, 2017. Depending on the scope of "peer review" under this Proposed Rule, costs can be inferred from the CBO analysis to range "between a few million dollars per year to more than one hundred million dollars per year over the 2018-2022 period to ensure that data and other information

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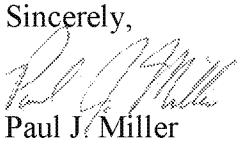
[8] Dockery, D.W. *et al.*, "An Association between Air Pollution and Mortality in Six U.S. Cities," *New England Journal of Medicine*, 329 (1993) 1753-1759.
[9] Pope, C.A. *et al.*, "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *Am. J. Respir. Crit. Care Med.*, 151 (1995) 669-674.
[10] Health Effects Institute, "Special Report: Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," July 2000, https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air (accessed May 14, 2018).
[11] Congressional Budget Office, "Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017" (March 29, 2017), at https://www.cbo.gov/publication/52545 (accessed May 14, 2018).

underlying studies are publicly available in a format sufficient to allow others to substantially reproduce the results of studies." EPA has provided no relevant information specific to this proposed rulemaking in order to evaluate the value of the additional costs this rule imposes beyond current practice, nor can we weigh potential foregone benefits should an overly broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse health outcomes.

Conclusion

EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific Proposed Rule requirements, and the rule's potential benefits and costs. These are well understood and basic elements that federal regulatory agencies must include to ensure informed public comment. Given these elements are completely missing from this proposal, EPA should withdraw it.

Sincerely,



Paul J. Miller
Deputy Director and Chief Scientist

cc: NESCAUM state directors
Dave Conroy, EPA R1
Richard Ruvo, EPA R2

COMMENTS BY THE TEXAS COMMISSION ON ENVIRONMENTAL QUALITY REGARDING STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE PROPOSED RULE

EPA DOCKET ID NO. EPA-HQ-OA-2018-0259

I. Summary of Proposed Action

On April 30, 2018, the United States Environmental Protection Agency (EPA) published a proposed rule in the *Federal Register* (83 FR 18768) titled *Strengthening Transparency in Regulatory Science*. The EPA provided a 30-day public comment period, ending on May 30, 2018. On May 25, 2018, the EPA extended the public comment period to August 16, 2018 (83 FR 24255). This proposed rule (hereafter referred to as the proposed data transparency rule) would establish an EPA policy that would only allow scientific data that is publicly available and independently verifiable to be used as the basis for significant regulations. The EPA specifically requested comment on numerous details related to the proposed data transparency rule's scope and implementation.

II. Comments

A. General Comments

The Texas Commission on Environmental Quality (TCEQ) appreciates the EPA's intention to provide greater transparency to the broader community of scientists, regulators, regulated entities, and interested members of the public who rely on and are impacted by the EPA's regulations. We encourage the EPA to interact with experts in each of these areas throughout the development process to ensure that all the opportunities and challenges presented with this proposed data transparency rule are fully realized and considered.

The TCEQ appreciates the EPA's commitment to having a strong scientific foundation for environmental regulations. We agree that many of the EPA's environmental regulations impact the daily lives of Americans and the importance of maintaining their trust through our shared scientific integrity cannot be overstated. The proposed rule emphasizes the need for major environmental regulations to be comprehensive, unbiased, and transparent. Because this is the first of its kind both within the EPA and among federal agencies, we hope that the EPA considers this proposed data transparency rule to be one step toward a longer conversation about these shared objectives.

The proposed data transparency rule language was silent on several important technical considerations, presumably to allow the public an opportunity to shape the rule. However, the lack of specific policy design has led to confusion among experts and particularly the media about the real consequences of this proposed rule. Numerous news articles have decried the expected significant loss of scientific studies that this rule may cause to be excluded from future analyses. In contrast to this view, the proposed data transparency rule could be used to continue to drive scientific investigation by allowing researchers from different backgrounds to re-analyze important datasets. Critical review, reanalysis, and replicable results are cornerstones of science. Further, the global scientific community has already been discussing the importance of the availability of de-identified data for reanalysis since at least 2010 (IOM 2012). It is also consistent with the EPA's Enterprise Architecture and Quality System for Environmental Data

and Technology that is committed to improving data quality and promotion of data sharing. Several journals (e.g., Public Library of Science (PLoS), the Annals of Internal Medicine) already have a publication condition that requires authors to make their data available upon request. In addition, many repositories already exist for sharing certain data, including clinical trial data. Just a few examples include the Yale University Open Data Access (YODA) project, the Harvard Library Dataverse Project, Dryad, and the Health and Medical Care Archive. Although there may be challenges to gathering, storing, and releasing de-identified data, a thoughtfully implemented data transparency rule could build upon the scientific community's growing trend and compel current and future generations of scientists to share their data, leading to stronger scientific understanding and more meaningful regulations.

The potential opportunities and challenges of the proposed data transparency rule are numerous and should be vetted through existing experts. Rather than collect and respond to numerous disjointed comments, it would benefit the EPA and the rule to engage the expertise of the many organizations that have vast experience with collecting, storing, and sharing confidential information. As such, the TCEQ strongly encourages the EPA to convene a work group or review panel of experts to help in guiding the agency on several of the important details that are needed to make this proposed data transparency rule succeed. The work group should comprise diverse perspectives, including members from other federal agencies (e.g. the United States Department of Health and Human Services; the Health Services Advisory Group; the National Academies of Sciences, Engineering, and Medicine; the National Institutes of Health) and institutional review boards who would best be able to discuss the most recent and relevant methods for collecting and sharing health data from human studies. The work group should also examine economic and environmental modeling data, the extent to which data should be replicable, necessary privacy restrictions, exception criteria, and the potential for inadvertent bias due to the proposed data transparency policy. The EPA should then provide a more explicit proposed data transparency rule for public inspection and comment. Taking these steps will lead to a more thoughtful and meaningful policy that promotes and is led by scientific research while providing necessary regulatory transparency.

B. Specific Comments

Governance

The TCEQ strongly encourages the EPA to give governing authority for granting exceptions to the proposed data transparency rule, as well as the oversight of raw data collection, storage, and access to an external entity or entities to ensure independence and objectivity.

The proposed data transparency rule solicits public comment on key implementation details, such as criteria for granting exceptions to the rule, how to ensure an appropriate balance of regulatory transparency and data protection, and a data sharing platform. Consistently and thoughtfully granting exceptions will be one of the most crucial steps in ensuring the success of the data transparency rule, and more importantly the ongoing success of using science to inform policy. The true tone of this proposed rule will be set through exception determinations that either exclude certain evidence or justify using non-accessible data. Exceptions will also ensure that regulatory action continues to take place in the event that the EPA has a statutory requirement to make a decision using data that are not available (e.g., an older study for which the original dataset no longer exists) or cannot be released (e.g., confidential business information). Because the EPA has a vested interest in the outcome of such a decision, the TCEQ recommends that exception decisions rest with an external, third-party entity, such as the EPA's Science Advisory Board or a new cross-disciplinary board. As with many ethical determinations, organizational independence provides greater trust that decisions were reasonable, objective,

and unbiased. The governing entity could keep abreast of upcoming regulations and determine whether the pivotal scientific methods, data, or models used in the regulation's assessment document(s) would be subject to this proposed data transparency rule. Over time, the entity could develop a list of pivotal scientific articles, methods, data, or models that could then be available to the public on an open access website. Documenting pivotal works would help ensure consistent application of the rule and guide researchers in further framing and building their own research agendas. To be successful, the governing entity should be given limited authority to enforce its exclusion determinations. The balance between data privacy and regulatory transparency would best be respected through both this governing body and the prioritization of regulatory actions that fall under this rule.

Depending upon the identity and role of this governing entity, the same body or a separate third-party entity should oversee the storage of the data and grant access to qualified researchers. Other organizations already have infrastructure and policies in place to handle sensitive information, and it makes sense to use these existing capabilities, rather than attempting to re-create them at the EPA. In addition to the convenience, though, the independence of the entity that would grant access to the data also ensures that the EPA is not put in the paradox of collecting data to ensure data transparency and then possibly having to reject requested access to that data. More specific comments related to data accessibility are provided in the last section of this document.

Scope and Timing

The EPA should focus this proposed rule on a narrow set of actions that includes "major" or "economically significant" regulations and should apply data transparency rule requirements to documents that inform a proposed rule so that the public has adequate time to evaluate the data. This will better ensure timely regulatory action, as well as balance the need for confidentiality with regulatory transparency.

Although transparency is important throughout all regulatory actions, increasing levels of transparency can concomitantly complicate the review process, particularly when the data include sensitive personal information or confidential business information. The additional scientific and legal review, considerations, analyses, and approvals necessary to validate pivotal studies will likely lengthen the rule development and external review process.

The challenge, then, is to balance the need for regulatory transparency with preservation of sensitive information *and* the need for timely regulatory action. This can be accomplished in part through restricting the scope of the proposed data transparency rule to those actions that have the greatest impact on public health and regulated entities. Specifically, those rules that are considered "major" under the Congressional Review Act or "economically significant" under Executive Order 12866. Regulatory actions outside of this scope (e.g., site-specific permitting actions) may still impact the public, though the impact is much less than that of major or economically significant rules.

In order to have meaningful public involvement in the development of major rules, the EPA should apply the requirements from this data transparency rule as early in the process as is scientifically practical. Waiting until a final rule (or even a proposed rule, in the case of some rule-makings) to notify the public of pivotal research would leave no time to determine whether data could be accessed or for the public to review or comment on the revised analysis, should the EPA exclude a key study or be granted an exception from this data transparency rule. Further, if subsequent post-rule validation attempts prove unsuccessful, the EPA would then be put in the difficult position of repealing a rule that would likely have already cost state governments and regulated entities capital and resources to implement. To ensure that the goal of greater

transparency does not stymie the EPA's already extensive scientific review of available literature, the EPA should continue its existing evaluation process of surveying all possible materials first and providing its technical support documents or assessment documents for public inspection. Once available studies have been reviewed, pivotal scientific evidence (e.g., articles, models, etc.) can be identified and either retrieved or granted an exception through a standardized review process conducted by the third-party governing authority. A subsequent draft of the technical support or assessment document should then be provided if the exclusion of pivotal evidence required additional review or reliance on other, formerly non-pivotal, scientific evidence.

The proposed data transparency rule should also apply to scientifically or technically novel guidance, and the resulting guidance document should be made available for public comment.

If the EPA chooses to issue guidance that includes new scientific or technically novel approaches and intends to impose compliance on state, tribal, and local governments and grantees tasked with implementing environmental quality rules, the guidance document should be subject to this proposed data transparency rule and should be made available for public review and comment. Allowing this opportunity for public involvement safeguards the larger goal of regulatory transparency, as operational guidelines can often be just as impactful as official regulatory actions.

The EPA should consider pivotal scientific research as rules are formally reviewed, rather than retrospectively.

The EPA requested comment on whether the proposed data transparency rule should be applied retroactively to rules that have already been promulgated. Retroactive application of this proposed rule to existing rules would be infeasible due to the volume of significant environmental rules already in place and the time and expertise it would take to reanalyze the technical and legal aspects of these rules while maintaining oversight of ongoing agency business. Fortunately, for the most part, retroactive application is likely unnecessary. Many of the EPA's significant rules have already been implemented and are on a statutorily-mandated review cycle. Once the EPA solidifies the requirements of this proposed data transparency rule, they should commit to applying the new transparency standards to pivotal scientific studies, both old and new, that justify agency actions on rules as they are formally reviewed on their existing cycle. In a separate analysis, the EPA should evaluate whether any rules that are not on a review cycle should be re-evaluated through the lens of this data transparency rule and the EPA should receive feedback on their determinations from the public and any applicable review boards or entities.

The EPA should consider using an upcoming major or significant rule-making as a test case to help solidify how the intent of the data transparency rule could be thoughtfully implemented before phasing in the final data transparency rule.

Because the proposed data transparency rule offers limited implementation details, it is difficult to provide meaningful comment on the potential intentional and unintentional consequences of its enactment. Rather than promulgate an untested final rule that could potentially impact all agency actions, the EPA should consider choosing a major upcoming rule-making as a test case. Ideally, the test case would help sketch out more specific guidelines for data transparency rule implementation that could then be vetted with an external, cross-disciplinary work group and provided for public review and comment. As stated above, once more solidified guidance is available the EPA should phase in the final data transparency rule by ensuring that data transparency guidelines are followed during the formal review process for new and existing major rules.

Dose-Response Models

The TCEQ applauds the proposed rule language relating to consideration of dose-response models and uncertainty, rather than relying on default assumptions.

The TCEQ strongly supports the EPA considering multiple dose-response models based on information such as biological plausibility, mode of action, mechanism of action, etc. that is relevant to the selection of the most scientifically-appropriate model(s). Biologically-based models (e.g., the formaldehyde CIIT model) should be explicitly included for consideration in addition to those listed in the proposal (i.e., linear, threshold, and U-shaped, J-shaped, bell-shaped). Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data. Adequate scientific justification to include an alternative model in an assessment should not be an ever-changing and insurmountable standard, but rather should be based on an objective evaluation of the scientific weight-of-evidence of relevant and robust data. This approach is consistent with regulatory agencies encouraging new research to generate data to replace conservative defaults. Strong, science-based regulations should always be guided and driven by the actual data at hand as opposed to mere defaults.

Definitions

Where possible, the EPA should be explicit about important definitions, including "publicly available," "pivotal regulatory science," "dose response data and models," and "validation."

The lack of explicit definitions in the proposed data transparency rule has caused confusion and uncertainty among experts outside the EPA. The broadest, and likely unintentional, interpretation of several key terms used in this proposed rule could completely stall or alter the existing state of the EPA's scientific and regulatory process. A hasty and incorrect assumption made by many has been that this concern makes the entire proposed rule faulty and unworkable. Some of this confusion will be cleared with more detailed implementation information; however, the EPA should also provide more explicit definitions of key terms wherever possible.

Perhaps one of the more frequently used terms that has caused the most confusion is "publicly available." Outside the context of this proposed rule, "publicly available" generally means that information is available without restriction to anyone who wants it. While this level of accessibility is acceptable for most information, it becomes problematic for sensitive personal information, personal health information, or confidential business information. In order to meet existing privacy and confidentiality laws that protect this type of information, increased accessibility tends to come with reduced refinement (i.e., less detailed information) in the data. For many health studies, data could become so unrefined as confidential data are removed from the dataset in order to become publicly available that results would be incomparable to those in the original study, and therefore not replicable or verifiable. The Institute of Medicine (IOM) defines and provides examples of three varying forms of data sharing that the EPA should consider in better framing their intended accessibility of health and study data (IOM 2015). The TCEQ recommends that the EPA strongly consider implementing a formal request and approval process for qualified researchers to obtain access to data that is protected by confidentiality laws, rather than aiming for all data to have unrestricted access. This process would still allow identifiable or fairly refined de-identified data to be re-evaluated by experts external to the EPA or the original study authors, while protecting the privacy of the study participants or businesses who created the model or dataset.

Other definitions that would be helpful in framing the proposed rule include "pivotal regulatory science," "dose response data and models," and "validation." Although "pivotal regulatory science" is likely intended to mean just the key study or studies underlying a regulatory analysis, it could be argued that supporting studies (i.e., those that help to build the weight of evidence or describe the mode of action) are also pivotal to the analysis. In addition, it is unclear what the term "dose response data and models" includes. This term could mean anything from summary data to specific calculations and code, which matters for the potential sensitivity of the information. Finally, the EPA should define what it means to "validate" study results. This could be interpreted to mean that the study must be repeated (i.e., a new group of human subjects are exposed in a controlled experiment or are assessed in an observational setting) or simply that the statistics and models are recalculated from the existing data. Further, the EPA should determine what level of validation is necessary for pivotal regulatory science so that it can be consistently applied.

The TCEQ applauds the EPA's intention to make regulatory science more transparent.

References

United States Department of Health and Human Services (HHS). 2012. Guidance regarding methods for deidentification of protected health information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Washington, DC: HHS.

Institute of Medicine (IOM). 2015. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. Committee on Strategies for Responsible Sharing of Clinical Trial Data; Board on Health Sciences Policy; Institute of Medicine. Washington (DC): National Academies Press (US); 2015 Apr 20.

Message

From: Hawkins, CherylA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D917BEE23E774E0DBB05CE06D694985E-HAWKINS, CHERYLA]
Sent: 8/16/2018 6:53:38 PM
To: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]
Subject: FW: Two controls assigned to OSP that should be transferred to OSA for response
Attachments: RE: CMS New Assignment - Wanda Bess - AX-18-000-9983; RE: CMS New Assignment - Wanda Bess - AX-18-000-9922

Hi Tom,

I will send the scans of the letters over to the docket and Thomas should prepare the standard hardcopy response letters.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Deener, Kathleen
Sent: Thursday, August 16, 2018 2:39 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Cc: Doa, Maria <Doa.Maria@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>; Matchen, Irving <Matchen.Irving@epa.gov>; Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: Two controls assigned to OSP that should be transferred to OSA for response

Tom and Cheryl –

Attached are the two controls that were assigned to OSP but that should probably be reassigned to OSA to respond to. Additionally, these comments will need to be put into the docket, and I think you all have been handling that.

Irving – can you get these reassigned to OSA for the response?

Thanks,
Kacee

Kacee Deener, MPH
Deputy Director, Office of Science Policy
Office of Research and Development
US Environmental Protection Agency
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deener.kathleen@epa.gov

Message

From: Bess, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78B77015C0D34FC69CC6B4043F2A58A7-BESS, WANDA]
Sent: 8/13/2018 7:02:10 PM
To: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Nathan Gentry [gentry.nathan.epa@gmail.com]
CC: Gentry, Nathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8f7a2857a234d06b785cc36c73fdddd-Gentry, Nathan]; Harty, Kathi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be2770ce4ae4aeda939f0a2ba7a6e2f-Harty, Kath]
Subject: RE: CMS New Assignment - Wanda Bess - AX-18-000-9922
Attachments: AX-18-000-9922.pdf

Hi Kathleen,
Per attachment

Thank you,
Wanda Bess, Technical Editor
Contractor, LSI
Correspondence Office
U.S. EPA Office of Research and Development
Ronald Reagan Building, #41151
202.564.5243
Bess.wanda@epa.gov

-----Original Message-----
From: Deener, Kathleen
Sent: Monday, August 13, 2018 2:59 PM
To: Nathan Gentry <gentry.nathan.epa@gmail.com>
Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>; Harty, Kathi <Harty.Kathi@epa.gov>; Bess, Wanda <bess.wanda@epa.gov>
Subject: RE: CMS New Assignment - Wanda Bess - AX-18-000-9922

Thanks Nathan. Kathi or Wanda - could you provide me with a copy of the incoming letter for this control?

Thanks so much.

Kacee Deener, MPH
Deputy Director, Office of Science Policy Office of Research and Development US Environmental Protection Agency
(ph) 202.564.1990 | (mobile) 202.510.1490 deener.kathleen@epa.gov

-----Original Message-----
From: Nathan Gentry [mailto:gentry.nathan.epa@gmail.com]
Sent: Monday, August 13, 2018 1:43 PM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>
Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>; Harty, Kathi <Harty.Kathi@epa.gov>; Bess, Wanda <bess.wanda@epa.gov>
Subject: Re: CMS New Assignment - Wanda Bess - AX-18-000-9922

Personal Matters / Ex. 6 If you just need it printed out so you can look at it, Kathi or Wanda should be able to help you out.

> On Aug 13, 2018, at 12:26 PM, Deener, Kathleen <Deener.Kathleen@epa.gov> wrote:
>
> Hi Nathan - are you by chance able to access this control for us? Personal Matters / Ex. 6
Personal Matters / Ex. 6
>
> Thanks,
>
> Kacee Deener, MPH
> Deputy Director, Office of Science Policy Office of Research and
> Development US Environmental Protection Agency
> (ph) 202.564.1990 | (mobile) 202.510.1490 deener.kathleen@epa.gov
>
> -----Original Message-----
> From: cmsadmin@epa.gov [mailto:cmsadmin@epa.gov]
> Sent: Friday, August 10, 2018 4:24 PM

> To: Deener, Kathleen <Deener.Kathleen@epa.gov>; Matchen, Irving
> <Matchen.Irving@epa.gov>; Drumm, Heather <Drumm.Heather@epa.gov>;
> Wilson, Theodore <wilson.theodore@epa.gov>
> Subject: CMS New Assignment - Wanda Bess - AX-18-000-9922
>
> Control AX-18-000-9922 has been assigned to your office on 8/10/18 4:23 PM by Wanda Bess. Please go to the CMS webpage to view the details of the control.
>
> Summary Information -
> Control Number: AX-18-000-9922
> Control Subject: Strengthening Transparency in Regulatory Science
> From: Donn, Marjory M.
>
>
> Note: This Email was automatically generated. Please do not attempt to respond to it. You can access this control at https://cms.epa.gov/cms. Questions or comments concerning CMS should be directed to CMS Support at 202-564-4985 or CMS Information@epa.gov.

Personal Matters / Ex. 6

August 3, 2018

Current Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Dear Sir or Madam:

I am writing about EPA's Proposed Rule:
"Strengthening Transparency in Regulatory Science."
As the EPA develops regulations governing clean air, clean water and exposure to toxic substances and pesticides, it needs to include all valid, peer-reviewed studies, even if their underlying data sets cannot be released to the public. I believe that the proposed rule's premise is faulty, because it excludes studies whose data is not publicly available. The proposed rule should be withdrawn.

I object to the fact that the scientific community was not consulted as the proposed rule was being prepared. Certainly, at least the EPA's own Science Advisory Board should be consulted.

Thank you.

Sincerely,

Margery M. Donn

Margory M. Donn

OFFICE OF THE
2018 AUG 10 AM 10:29
EXECUTIVE SECRETARIAT

CAPITAL DISTRICT NY 120
08 AUG 2018 PM 3 L

Current Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

AUG 10 2018

20460-

FCL 2122330

Personal Matters / Ex. 6

M. Nunn

Message

From: Bess, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78B77015C0D34FC69CC6B4043F2A58A7-BESS, WANDA]
Sent: 8/15/2018 12:38:59 PM
To: Deener, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]
CC: Harty, Kathi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be2770ce4ae4aeda939f0a2ba7a6e2f-Harty, Kath]
Subject: RE: CMS New Assignment - Wanda Bess - AX-18-000-9983
Attachments: AX-18-000-9983.pdf

Good morning Kathleen,
Sure. Per attachment.

Thank you,
Wanda Bess, Technical Editor
Contractor, LSI
Correspondence Office
U.S. EPA Office of Research and Development
Ronald Reagan Building, #41151
202.564.5243
Bess.wanda@epa.gov

-----Original Message-----
From: Deener, Kathleen
Sent: Wednesday, August 15, 2018 8:37 AM
To: Harty, Kathi <Harty.Kathi@epa.gov>; Bess, Wanda <bess.wanda@epa.gov>
Subject: FW: CMS New Assignment - Wanda Bess - AX-18-000-9983

Hi Kathi and Wanda - I'm so sorry to bother you with this, but would you mind sending us this control also?

Irving will be back in the office next week, and he'll be able to access these for us.

Thanks,

Kacee Deener, MPH
Deputy Director, Office of Science Policy Office of Research and Development US Environmental Protection Agency
(ph) 202.564.1990 | Personal Matters / Ex. 6 deener.kathleen@epa.gov

-----Original Message-----
From: cmsadmin@epa.gov [mailto:cmsadmin@epa.gov]
Sent: Wednesday, August 15, 2018 8:27 AM
To: Deener, Kathleen <Deener.Kathleen@epa.gov>; Matchen, Irving <Matchen.Irving@epa.gov>; Drumm, Heather <Drumm.Heather@epa.gov>; Wilson, Theodore <wilson.theodore@epa.gov>
Subject: CMS New Assignment - Wanda Bess - AX-18-000-9983

Control AX-18-000-9983 has been assigned to your office on 8/15/18 8:27 AM by Wanda Bess. Please go to the CMS webpage to view the details of the control.

Summary Information -
Control Number: AX-18-000-9983
Control Subject: Docket ID NO. EPA-HQ-OA-2018-0259 - EPA Proposed Rule: Strengthening Transparency in Regulatory Science
From: Pecnik, Richard

Note: This Email was automatically generated. Please do not attempt to respond to it. You can access this control at https://cms.epa.gov/cms. Questions or comments concerning CMS should be directed to CMS Support at 202-564-4985 or CMS Information@epa.gov.

Gernatt
13870 Taylor Hollow Rd.
Collins, NY 14034
716-532-3371
716-532-9000 (fax)
www.gernatt.com

August 8, 2018

Andrew R. Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: EPA Proposed Rule: Strengthening Transparency in Regulatory Science. 83 Fed. Reg. 18,768 (Apr. 30, 2018). Docket Number EPA-HQ-OA-2018-0259.

Dear Administrator Wheeler,

I am writing to you on behalf of Gernatt Asphalt Products, Inc. and it's 200+ employees from southwestern New York State, as members of the National Stone, Sand & Gravel Association (NSSGA). We support the above-referenced rule which will strengthen transparency in regulatory science. As active sand and gravel miners, we are intimately familiar with the myriad of existing Federal environmental regulations that govern our operations. We are also keenly aware of the importance of a healthy environment, which supports our business by providing products and jobs now, and for the future of our children and Country.

Our goal has always been to operate within the regulatory framework of whatever entity we are working within, not merely to avoid the legal ramifications of non-compliance, but also in the spirit that sound environmental regulation keeps the playing field level for everyone in the industry while promoting sustainability. The products we supply are imperative to the infrastructure that supports the well-being of every citizen and business in this Country. Many people do not make the connection between a sound and stable aggregate mining industry and our vibrant, safe, and progressive way of life. These folks assume our industry is inherently a detriment to the environment, resulting in long-term negative impacts. As a result, popular sentiment is often that more regulation of industry like ours is not only needed, but somehow heroic. This is simply not true.

That is why it is extremely important for regulations to be thoroughly vetted for their need, effectiveness, and beneficial result before they're imposed on industry like ours. The proposed transparency rule will help ensure that only scientifically sound regulatory initiatives are considered for implementation, saving producers from poorly thought out, knee-jerk type of regulations that result from over-reaction.

As an active member of the NSSGA, we fully support their comments on this issue. Please consider those comments, and our position as stated above, when considering this rule. Thank you.

Sincerely,

Richard Pecnik

Richard Pecnik
Regulatory Affairs
Gernatt Asphalt Products, Inc.

Gernatt
13870 TAYLOR HOLLOW RD.
COLLINS, NEW YORK 14034

ADDRESS SERVICE REQUESTED

FIRST-CLASS

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0001162046 AUG 09 2018
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FCL2119233

Andrew R. Wheeler, Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

AUG 14 2018

ED_002389_00028935-00002

Message

From: Staff_OSA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BE69B6688A614CA39759D52CA5716EF3-OSA]
Sent: 8/15/2018 6:53:41 PM
To: St. John, Joseph [StJohnJ@ag.louisiana.gov]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: RE: Comment of 11 State Attorneys General ISO EPA's Proposal to Strengthen Transparency in Regulatory Science

Dear Mr. St. John,

Thank you for your interest regarding the US EPA proposed rule "Strengthening Transparency in Regulatory Science" (https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science).

Your ensure your letter is included, it has been forwarded to the docket located at https://www.regulations.gov/docket?D=EPA-HQ-OA-2018-0259.

Sincerely,

Tom Sinks, Ph.D.
Director, Office of the Science Advisor

From: St. John, Joseph [mailto:StJohnJ@ag.louisiana.gov]
Sent: Wednesday, August 15, 2018 10:30 AM
To: Bolen, Brittany <bolen.brittany@epa.gov>; Staff_OSA <Staff_OSA@epa.gov>
Subject: Comment of 11 State Attorneys General ISO EPA's Proposal to Strengthen Transparency in Regulatory Science

Ms. Bolen and Mr. Sinks:

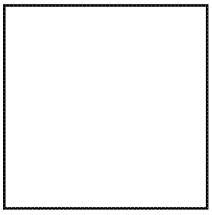
On behalf of the Attorneys General of Louisiana, Alabama, Arkansas, Indiana, Kansas, Nebraska, Oklahoma, South Carolina, Texas, Utah, and Wisconsin, please see the attached comment in support of EPA's Proposal to Strengthen Transparency in Regulatory Science. An electronic copy was submitted on regulations.gov, and a hardcopy with attached exhibits is being sent to EPA's docket center.

Best regards,
Scott St. John

Joseph Scott St. John
Deputy Solicitor General
Office of Attorney General Jeff Landry
Tel: (225) 485-2458
stjohnj@ag.louisiana.gov
www.AGJeffLandry.com

From: no-reply@regulations.gov [mailto:no-reply@regulations.gov]
Sent: Wednesday, August 15, 2018 9:24 AM

To: St. John, Joseph
Subject: Your Comment Submitted on Regulations.gov (ID: EPA-HQ-OA-2018-0259-0001)



Please do not reply to this message. This email is from a notification only address that cannot accept incoming email.

Your comment was submitted successfully!

Comment Tracking Number: 1k2-94v2-zrbz

Your comment may be viewable on Regulations.gov once the agency has reviewed it. This process is dependent on agency public submission policies/procedures and processing times. Use your tracking number to find out the status of your comment.

Agency: Environmental Protection Agency (EPA)
Document Type: Rulemaking
Title: Strengthening Transparency in Regulatory Science
Document ID: EPA-HQ-OA-2018-0259-0001

Comment:
On behalf of the Attorneys General of Louisiana, Alabama, Arkansas, Indiana, Kansas, Nebraska, Oklahoma, South Carolina, Texas, Utah, and Wisconsin, please see the attached comment in support of EPA's Proposal to Strengthen Transparency in Regulatory Science. A hardcopy with attached exhibits is being sent to EPA's docket center.

Uploaded File(s):

- 2018.08.15 Comment Letter re Transparency in Science (FINAL FOR FILING).pdf

This information will appear on Regulations.gov:

None of the information will appear on Regulations.gov

This information will not appear on Regulations.gov:

Submitter's Representative: Jeff Landry
Government Agency Type: State
Government Agency: Office of the Louisiana Attorney General

For further information about the Regulations.gov commenting process, please visit https://www.regulations.gov/faqs.

If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

Message

From: Nanishka Albaladejo [nalbaladejo@scainc.com]
Sent: 7/23/2018 3:15:21 PM
To: Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere1144e76]; Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]
Subject: Public Comment - July 17 Hearing Files
Attachments: Copies of Oral Testimonies.z1p; Docket Box Submissions.z1p; Formatted for Public Viewing.z1p; Origingal Hardcopies Sheets.z1p; July 17 PH Final Registration List.xlsx

Morning Cheryl,

My apologizes. Attached are revised folders. Please let me know if you still have trouble viewing them. Thank you.

Nanishka (Nan) Albaladejo
LEED Green Associate/Environmental Scientist
1414 Raleigh Rd., Ste. 450
Chapel Hill, NC 27517
Office: (919) 484-0222, ext 959
Direct: (984) 243-3959
nalbaladejo@scainc.com
www.scainc.com
SC&A

From: Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Sent: Monday, July 23, 2018 10:58 AM
To: Nanishka Albaladejo <nalbaladejo@scainc.com>; Perry, Dale <Perry.Dale@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>
Cc: Sinks, Tom <Sinks.Tom@epa.gov>; Joanne O'Loughlin <joloughlin@scainc.com>; Phil Norwood <pnorwood@scainc.com>
Subject: RE: Public Comment - July 17 Hearing (1 file)

Hi Nan,

EPA mail tends to block zip files. So what we've received is txt files that say the zip files have been blocked. If you change the .zip to .zzz on the file and try resending, we might receive them. We will just change the .zzz to .zip after we receive them.

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Nanishka Albaladejo [mailto:nalbaladejo@scainc.com]
Sent: Thursday, July 19, 2018 4:54 PM
To: Perry, Dale <Perry.Dale@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>
Cc: Sinks, Tom <Sinks.Tom@epa.gov>; Joanne O'Loughlin <joloughlin@scainc.com>; Phil Norwood <pnorwood@scainc.com>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Subject: Public Comment - July 17 Hearing (1 file)

Good afternoon,

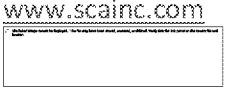
Attached is a condensed (zipped) public comments folder that includes scanned copies of oral testimonies submitted, scanned copies of written comments submitted to the docket box, final speaker, attendee and press lists, scanned copies of the original check-in/sign-in sheets.

Please note that I plan to follow up with the court reporters to see if they received any copies (while at the hearing) that were not provided to us (or that we are missing).

Please let me know if you have any questions or concerns.

Thank you and have a great day.

Nanishka (Nan) Albaladejo
LEED Green Associate/Environmental Scientist
1414 Raleigh Rd., Ste. 450
Chapel Hill, NC 27517
Office: (919) 484-0222, ext 959
Direct: (984) 243-3959
nalbaladejo@scainc.com
www.scainc.com



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Count Summary

Mornning Session, 8am-12pm	43	
Afternoon Session, 12pm-4pm	44	
Evening Session, 4pm-8pm	4	
Total Speakers	91	(includes 3 EO)
Total Nonspeakers	57	
Total Press	9	
TOTAL No. of Attendees	157	

Public Hearing - Strengthening Transpar

Morning Session - Final List of Spea

1201 Constitution Ave. NW | WJC East E

Assigned Speaker No.	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
1	4E+05	5/30/2018 12:06	5/30/2018 12:06	5/30/2018 12:06	0	184.28.17.34	0	Ted	Steichen
2	4E+05	6/26/2018 11:35	6/26/2018 11:35	6/26/2018 11:35	0	184.51.101.6	0	Jodi	Feld
3	4E+05	5/29/2018 10:19	5/29/2018 10:19	5/29/2018 10:19	0	184.28.17.36	0	Robert	Sussman
4	4E+05	5/25/2018 12:29	5/25/2018 12:29	5/25/2018 12:29	0	184.51.151.5	0	Andrew	Rosenberg
5	4E+05	6/18/2018 9:20	6/18/2018 9:20	6/18/2018 9:20	0	184.51.101.7	0	Daniel	Greenbaum
6	4E+05	6/20/2018 17:29	6/20/2018 17:29	6/20/2018 17:29	0	184.28.17.24	0	Jennifer	McPartland
7	4E+05	6/18/2018 17:39	6/18/2018 17:39	6/18/2018 17:39	0	184.51.101.6	0	David	Michaels
8	4E+05	5/25/2018 10:35	5/25/2018 10:35	5/25/2018 10:35	0	23.35.150.28	0	Paul	Billings
9	4E+05	6/27/2018 22:59	6/27/2018 22:59	6/27/2018 22:59	0	184.51.101.6	0	Gary	Timm
10	4E+05	6/7/2018 14:47	6/7/2018 14:47	6/7/2018 14:47	0	184.51.101.7	0	Tyler	Smith
11	4E+05	6/11/2018 17:16	6/11/2018 17:16	6/11/2018 17:16	0	184.51.151.5	0	Eugenia (Jeannie)	Economos
12	4E+05	6/7/2018 13:53	6/7/2018 13:53	6/7/2018 13:53	0	184.28.17.34	0	Anne	LeHuray
13	4E+05	5/25/2018 11:31	5/25/2018 11:31	5/25/2018 11:31	0	23.62.239.20	0	Diana	Van Vleet
14								John	Auerbach
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17	4E+05	5/31/2018 15:02	5/31/2018 15:02	5/31/2018 15:02	0	184.51.101.6	0	Peter	Lurie
18	4E+05	6/27/2018 8:58	6/27/2018 8:58	6/27/2018 8:58	0	184.28.17.24	0	Jamie	Wells
19	4E+05	6/26/2018 20:16	6/26/2018 20:16	6/26/2018 20:16	0	184.51.101.6	0	Ami	Zota
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21	4E+05	6/20/2018 16:22	6/20/2018 16:22	6/20/2018 16:22	0	184.28.17.34	0	Laura	Bloomer
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23	4E+05	5/25/2018 10:58	5/25/2018 10:58	5/25/2018 10:58	0	184.28.17.24	0	Joanne	Zurcher
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26	4E+05	5/25/2018 16:02	5/25/2018 16:02	5/25/2018 16:02	0	184.51.101.7	0	Ann	Mesnikoff
27	4E+05	6/27/2018 7:45	6/27/2018 7:45	6/27/2018 7:45	0	184.51.151.5	0	Roy	Gamse

28	4E+05	6/28/2018 13:29	6/28/2018 13:29	6/28/2018 13:29	0	184.51.101.7	0	Jennifer	Sass
29	4E+05	5/30/2018 20:18	5/30/2018 20:18	5/30/2018 20:18	0	184.51.101.6	0	Paul	Miller
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32	4E+05	6/2/2018 16:37	6/2/2018 16:37	6/2/2018 16:37	0	23.216.10.36	0	Erica	Bardwell
33								Jennifer	Reaves
34	4E+05	5/25/2018 10:42	5/25/2018 10:42	5/25/2018 10:42	0	184.51.101.7	0	Molly	Rauch
35	4E+05	5/29/2018 15:29	5/29/2018 15:29	5/29/2018 15:29	0	184.28.17.24	0	Barbara	Gottlieb
36	4E+05	5/30/2018 18:45	5/30/2018 18:45	5/30/2018 18:45	0	184.51.101.6	0	Lyndsay	Alexander
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38	4E+05	6/1/2018 12:30	6/1/2018 12:30	6/1/2018 12:30	0	184.51.101.7	0	Liz	Borkowski
39	4E+05	5/25/2018 10:51	5/25/2018 10:51	5/25/2018 10:51	0	23.35.150.15	0	Janice	Nolen
40	4E+05	5/31/2018 12:08	5/31/2018 12:08	5/31/2018 12:08	0	184.51.101.7	0	Albert	Donnay
41	4E+05	6/7/2018 15:30	6/7/2018 15:30	6/7/2018 15:30	0	184.28.17.34	0	Mona	Sarfaty
No Show	4E+05	5/31/2018 8:09	5/31/2018 8:09	5/31/2018 8:09	0	184.28.17.34	0	Harvey	Fernbach MD MPH

Assigned Speaker Letter	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
A								Paul	Tonko
B	4E+05	7/11/2018 17:23	7/11/2018 17:23	7/11/2018 17:23	0	184.51.101.7	0	Suzanne	Bonamici

ency in Regulatory Science

kers | July 17, 2018

Building, Room 1153

Organization	City and State or Province	Country	Email Address	Phone
American Petroleum Institute	Washington DC	USA	steichent@api.org	##########
New York State Office of the Attorney General	New York	USA	jodi.feld@ag.ny.gov	##########
Safer Chemicals Healthy Families	Washington DC	USA	Personal Matters / Ex. 6	##########
Union of Concerned Scientists' Center for Science and Democracy	Cambridge, MA	USA	arosenberg@ucsusa.org	##########
Health Effects Institute	Boston, Massachusetts	USA	dgreenbaum@healtheffects.org	##########
Environmental Defense Fund	Washington, DC	USA	jmcpartland@edf.org	##########
George Washington University School of Public Health	Washington, DC	USA	Personal Matters / Ex. 6	##########
American Lung Association	Washington	USA	Paul.Billings@lung.org	##########
Environmental Protection Network	Herndon, VA	USA	Personal Matters / Ex. 6	##########
Earthjustice	New York, NY	USA	tsmith@earthjustice.org	##########
Farmworker Association of Florida	Apopka, FL	USA	farmworkerassoc@aol.com	##########
Pavement Coatings Technology Council	Alexandria, Virginia	USA	alehuray@pavementcouncil.org	##########
American Lung Association	Washington	USA	diana.vanvleet@lung.org	##########
Trust for America's Health		USA		
Hunton Andrews Kurth	Washington DC	USA	jstanko@hunton.com	##########
Center for Science in the Public Interest	Washington, DC	USA	plurie@cspinet.org	##########
American Council on Science and Health	Washington DC	USA	jamie@acsh.org	##########
The George Washington University	Washington, DC	USA	azota@gwu.edu	##########
Environmental Defense Fund	Washington, D.C.	USA	ssarang@edf.org	##########
Harvard Law School	Cambridge, MA	USA	Personal Matters / Ex. 6	##########
Children's Environmental Health Network	Washington, DC	USA	Personal Matters / Ex. 6	##########
National Environmental Health	Denver, CO	USA	JZurcher@neha.org	##########
Environmental Defense Fund	Washington	USA	mendo@edf.org	##########
Environmental Defense Fund	D.C.	USA	jxie@edf.org	##########
Environmental Law & Policy Center	Washington	USA	amesnikoff@elpc.org	##########
EPN	Arlington, VA	USA	Personal Matters / Ex. 6	##########

Natural Resources Defense Council	Washington DC	USA	jsass@nrdc.org	##########
NESCAUM	Boston, MA	USA	pmiller@nescaum.org	##########
Natural Resources Defense Council	Washington, DC	USA	mmckinzie@nrdc.org	##########
Consultant	Atlanta GA	USA	Personal Matters / Ex. 6	##########
The reality-based community	Arlington	USA	Personal Matters / Ex. 6	##########
Moms Clean Air Force		USA		
Moms Clean Air Force	Washington DC	USA	mrauch@momscleanairforce.org	##########
Physicians for Social Responsibility	Washington, DC	USA	bgottlieb@psr.org	##########
American Lung Association	Washington	USA	lyndsay.alexander@lung.org	##########
American Lung Association	Fairfax, VA	USA	laura.bender@lung.org	##########
Jacobs Institute of Women's Health (at Milken Institute School of Public Health, George Washington University)	Washington, DC	United States	borkowsk@gwu.edu	##########
American Lung Association	Washington, DC	USA	Janice.Nolen@Lung.org	##########
Donnay Detoxicology LLC	Hyattsville MD	USA	albert@donnaydetox.com	##########
Program on Climate and Health	Fairfax, Virginia	USA	Personal Matters / Ex. 6	##########
Physicians for Social Responsibility	Bethesda , Maryland	USA		##########

Organization	City and State or Province	Country	Email Address	Phone
U.S. Representative from New York's 20th congressional district	New York			
U.S. House of Representatives, Oregon First Congressional District	Beaverton, Oregon	U.S.	maxine.sugarman@mail.house.gov	##########

Public Hearing - Strengthening Tra

Afternoon Session - Final List

1201 Constitution Ave. NW | W

Assigned Speaker No.	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
1	4E+05	6/8/2018 10:01	6/8/2018 10:01	6/8/2018 10:01	0	23.212.53.68	0	Pamela	Miller
2	4E+05	5/25/2018 10:37	5/25/2018 10:37	5/25/2018 10:37	0	184.28.17.34	0	Elizabeth Ann Glass	Geltman
3	4E+05	6/13/2018 16:45	6/13/2018 16:45	6/13/2018 16:45	0	23.62.239.21	0	Patricia	Koman
4	4E+05	5/25/2018 16:14	5/25/2018 16:14	5/25/2018 16:14	0	184.51.101.6	0	Alexis	Andiman
5	4E+05	5/25/2018 16:11	5/25/2018 16:11	5/25/2018 16:11	0	184.51.101.6	0	Alexis	Andiman
6	4E+05	7/6/2018 15:34	7/6/2018 15:34	7/6/2018 15:34	0	184.28.17.24	0	Sarah	Kogel-Smucker
7	4E+05	7/2/2018 13:41	7/2/2018 13:41	7/2/2018 13:41	0	184.28.17.34	0	John	Doherty
8	4E+05	6/26/2018 12:52	6/26/2018 12:52	6/26/2018 12:52	0	184.51.101.7	0	Trisha	Sheehan
9	4E+05	5/30/2018 17:48	5/30/2018 17:48	5/30/2018 17:48	0	23.35.150.36	0	James	Duffy
10	4E+05	6/29/2018 16:51	6/29/2018 16:51	6/29/2018 16:51	0	23.212.53.72	0	Erika	Rosen
11	4E+05	7/2/2018 9:21	7/2/2018 9:21	7/2/2018 9:21	0	184.51.101.6	0	Gretchen	Goldman
12	4E+05	7/11/2018 17:15	7/11/2018 17:15	7/11/2018 17:15	0	184.51.101.7	0	Maggie	Flaherty
13	4E+05	7/11/2018 12:21	7/11/2018 12:21	7/11/2018 12:21	0	184.51.101.7	0	Adam M.	Finkel
14	4E+05	6/5/2018 11:03	6/5/2018 11:03	6/5/2018 11:03	0	184.28.17.34	0	Augusta	Wilson
15	4E+05	7/2/2018 9:22	7/2/2018 9:22	7/2/2018 9:22	0	184.51.101.6	0	David	Coursen
16	4E+05	7/10/2018 20:08	7/10/2018 20:08	7/10/2018 20:08	0	184.51.101.6	0	Abigail	Omojola
17	4E+05	5/29/2018 12:06	5/29/2018 12:06	5/29/2018 12:06	0	23.35.150.15	0	Alan	Lockwood
18	4E+05	6/29/2018 13:16	6/29/2018 13:16	6/29/2018 13:16	0	184.51.101.6	0	Elizabeth	Woolford
19	4E+05	7/3/2018 10:51	7/3/2018 10:51	7/3/2018 10:51	0	23.62.239.21	0	Paul	Allwood
20	4E+05	7/2/2018 14:23	7/2/2018 14:23	7/2/2018 14:23	0	23.62.239.21	0	John	Stine
21	4E+05	6/14/2018 23:29	6/14/2018 23:29	6/14/2018 23:29	0	184.51.101.6	0	Virginia	Ruiz
22	4E+05	6/28/2018 12:48	6/28/2018 12:48	6/28/2018 12:48	0	184.51.101.7	0	Karen	Mongoven
23	4E+05	6/8/2018 11:09	6/8/2018 11:09	6/8/2018 11:09	0	184.51.101.7	0	Steve	Milloy
24	4E+05	6/13/2018 15:02	6/13/2018 15:02	6/13/2018 15:02	0	23.212.53.68	0	Steve	Milloy
25	4E+05	6/14/2018 22:15	6/14/2018 22:15	6/14/2018 22:15	0	184.28.17.24	0	Meredith	McCormack
26	4E+05	7/7/2018 17:37	7/7/2018 17:37	7/7/2018 17:37	0	184.51.101.6	0	Olivia	Bartlett

27	4E+05	7/9/2018 14:23	7/9/2018 14:23	7/9/2018 14:23	0	184.51.101.7	0	Dan	Byers
28	4E+05	6/15/2018 12:13	6/15/2018 12:13	6/15/2018 12:13	0	184.51.101.7	0	Antonia	Herzog
29	4E+05	7/6/2018 11:31	7/6/2018 11:31	7/6/2018 11:31	0	184.28.17.34	0	Tess	Dernbach
30	4E+05	7/2/2018 11:51	7/2/2018 11:51	7/2/2018 11:51	0	184.28.17.24	0	Mary	Angly
31	4E+05	6/25/2018 16:42	6/25/2018 16:42	6/25/2018 16:42	0	184.28.17.24	0	Brenda	Munive
32	4E+05	6/19/2018 8:50	6/19/2018 8:50	6/19/2018 8:50	0	184.28.17.24	0	George	Thurston
33	4E+05	6/15/2018 12:11	6/15/2018 12:11	6/15/2018 12:11	0	184.51.101.6	0	Brittany	Meyer
34	4E+05	5/25/2018 11:08	5/25/2018 11:08	5/25/2018 11:08	0	23.62.239.20	0	Adam M.	Spanier
35	4E+05	5/25/2018 12:30	5/25/2018 12:30	5/25/2018 12:30	0	184.51.101.6	0	Sean	Moulton
36	4E+05	5/25/2018 13:13	5/25/2018 13:13	5/25/2018 13:13	0	184.51.101.6	0	Andrew	Bergman
37A	4E+05	7/12/2018 11:33	7/12/2018 11:33	7/12/2018 11:33	0	184.51.101.7	0	Emma	Gildesgame
38A								Jyotsna	Pandey
39A								Patricia	Koman
40A								Peter	Ferrara
41A	4E+05	7/13/2018 13:50	7/13/2018 13:50	7/13/2018 13:50	0	184.51.101.6	0	Elizabeth	Hitchcock
42A								Benjamin	Kirby
43A	4E+05	7/12/2018 11:11	7/12/2018 11:11	7/12/2018 11:11	0	184.51.101.7	0	Mahealani	Daniels

Assigned Speaker Letter	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
C								Dan	Lipinski

nsparency in Regulatory Science

of Speakers | July 17, 2018

/JC East Building, Room 1153

Organization	City and State or Province	Country	Email Address	Phone
Alaska Community Action on Toxics	Anchorage, Alaska	USA	pamela@akaction.org	##########
CUNY School of Public Health	New York	USA	elizabeth.geltman@sph.cuny.edu	##########
University of Michigan	Ann Arbor	USA	Personal Matters / Ex. 6	##########
Earthjustice	New York, NY	USA	aandiman@earthjustice.org	##########
on the behalf of Devon Hall, Rural Empowerment Association for Community		USA		
Office of the Attorney General for the District of Columbia	Washington, DC	USA	sarah.kogel-smucker@dc.gov	##########
Independent Toxicologist	Oakton, VA	USA	lakinplace@gmail.com	##########
Moms Clean Air Force	Haddon Heights, NJ	USA	tsheehan@momscleanairforce.org	##########
Clean Air Task Force	Boston, Ma	USA	jduffy@catf.us	##########
on the behalf of Lynn Goldman, George Washington University	Washington, DC	USA	erikarosen@email.gwu.edu	##########
Union of Concerned Scientists	Washington, DC	USA	ggoldman@ucsusa.org	##########
League of Conservation Voters	Ukiah, California	USA	mflaherty@lcv.org	##########
University of Michigan School of Public	Pennington NJ	USA	afinkel@upenn.edu	##########
Climate Science Legal Defense Fund	New York	USA	awilson@csldf.org	##########
Environmental Protection Network		USA		
Breast Cancer Prevention Partners	San Francisco, CA	USA	aomojola@rabengroup.com	##########
Physicians for Social Responsibility	Oberlin	USA	ahl@buffalo.edu	##########
National Parks Conservation Association	Arlington	USA	ewoolford@npca.org	##########
Minnesota Department of Health	St. Paul, MN	USA	paul.allwood@state.mn.us	##########
Minnesota Pollution Control Agency	St. Paul, MN	USA	john.stine@state.mn.us	##########
Farmworker Justice	Washington, DC	USA	vruiz@farmworkerjustice.org	##########
National Association of Clean Air Agencies	Washington, DC	USA	kmongoven@4cleanair.org	##########
JunkScience.com	Potomac, MD	USA	Personal Matters / Ex. 6	##########
On the behalf of John Dunn, No Affiliation	Brownwood, Texas	USA	Personal Matters / Ex. 6	##########
American Thoracic Society	Baltimore, MD	USA	mmccor16@jhmi.edu	##########
Do The Most Good	Bethesda, MD	USA	Personal Matters / Ex. 6	##########

U.S. Chamber of Commerce Global Energy Institute	Washington	USA	dbyers@uschamber.com	##########
Physicians for Social Responsibility	Washington, DC	USA	aherzog@psr.org	##########
EarthJustice		USA	tdernback@earthjustice.org	##########
Physicians for Social Responsibility	Washington DC	USA	Personal Matters / Ex. 6	##########
Physicians for Social Responsibility	Washington DC	USA	bmunive@psr.org	##########
International Society of Environmental Epidemiology	Tuxedo	USA	george.thurston@nyu.edu	##########
Michael J. Fox Foundation for Parkinson's Research	Washington	USA	bmeyer@michaeljfox.org	##########
American Academy of Pediatrics		USA		
Project on Government Oversight	Broomall, PA	USA	Personal Matters / Ex. 6	##########
Project on Government Oversight	Washington, D.C.	USA	Personal Matters / Ex. 6	##########
National Parks Conservation Association	New Haven, CT	USA	emma.gildesgame@yale.edu	##########
American Institute of Biological Sciences	Washington, DC		jpandey@aiba.org	##########
on the behalf of Tracey Woodruff, UCSF				
Heartland Institute			Personal Matters / Ex. 6	##########
Safer Chemicals Healthy Families	Washington, DC	US	lizhitchcock@saferchemicals.org	##########
on the behalf of John Hall, Center for Regulatory Reasonableness				
The League of Conservation Voters	Kaneohe, Hawaii	United States of America	mdaniels@lcv.org	(808)778-0944

Organization	City and State or Province	Country	Email Address	Phone
U.S. Representative for Illinois's 3rd congressional district	Illinois	USA		

Public Hearing - Strengthening T

Evening Session - Final Li

1201 Constitution Ave. NW

Assigned Speaker No.	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
1	4E+05	5/30/2018 18:10	5/30/2018 18:10	5/30/2018 18:10	0	184.51.101.7	0	Karl	Shipps
2	4E+05	7/13/2018 13:13	7/13/2018 13:13	7/13/2018 13:13	0	184.28.17.34	0	Kimberly	White
3	4E+05	5/31/2018 8:56	5/31/2018 8:56	5/31/2018 8:56	0	184.28.17.24	0	Walter	Tsou
4								Mark	Mitchell

Transparency in Regulatory Science

List of Speakers | July 17, 2018

| WJC East Building, Room 1153

Organization	City and State or Province	Country	Email Address	Phone
Representing Self	New Carrollton, MD	USA	Personal Matters / Ex. 6	##########
American Chemistry Council	Washington, DC	USA	kimberly_white@americanchemistry.com	##########
Philadelphia Physicians for Social Responsibility	Philadelphia, PA	United States	walter@psrphila.org	##########
National Medical Association			mmitchell@enviro-md.com	##########

Public Hearing - Strengthening Trai

Final List of Attende

1201 Constitution Ave. NW | W

Count	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
1*	420951	6/7/2018 14:45	6/7/2018 14:45	6/7/2018 14:45	0	184.51.101.7	0	Carrie	Apfel
2								John	Bobka
3								Tom	Brennan
4								*[Name Illegible]*	*Broder*
5								Vincent	Cogliano
6*	429433	7/3/2018 13:01	7/3/2018 13:01	7/3/2018 13:01	0	184.28.17.24	0	Joanne	Collins
7*	420163	6/5/2018 14:01	6/5/2018 14:01	6/5/2018 14:01	0	184.51.101.7	0	Timia	Crisp
8								Bridgid	Curry
9								Ian	DeValliere
10								Mark	Drajem
11*	424711	6/19/2018 12:50	6/19/2018 12:50	6/19/2018 12:50	0	184.51.101.7	0	Ligia	Duarte Botelho
12*	441757	7/12/2018 9:22	7/12/2018 9:22	7/12/2018 9:22	0	184.51.101.7	0	David	Dunlap
13								Grayson	Feist
14*	438245	7/10/2018 9:30	7/10/2018 9:30	7/10/2018 9:30	0	184.51.101.6	0	Rebecca	Fowler
15								Eve	Garthner
16	420901	6/7/2018 13:30	6/7/2018 13:30	6/7/2018 13:30	0	184.28.17.24	0	Kelly	Good
17*	430325	7/6/2018 12:38	7/6/2018 12:38	7/6/2018 12:38	0	184.51.101.6	0	Ruth	Greenspan Bell
18*	429549	7/3/2018 15:22	7/3/2018 15:22	7/3/2018 15:22	0	184.28.17.24	0	Meredith	Haines
19								Fred	Hauchman
20								Bob	Hotes
21*	438679	7/10/2018 13:36	7/10/2018 13:36	7/10/2018 13:36	0	184.51.101.7	0	Sebastian	Irby
22								Kysia	Jones
23								Miles	Keogh
24*	423189	6/14/2018 12:28	6/14/2018 12:28	6/14/2018 12:28	0	23.79.240.10	0	Yogin	Kothari
25*	443557	7/12/2018 18:47	7/12/2018 18:47	7/12/2018 18:47	0	23.215.15.34	0	Kevin	Letterly
26*	420965	6/7/2018 14:55	6/7/2018 14:55	6/7/2018 14:55	0	184.51.101.6	0	Angela	Logomasini
27								Kamala	Lyon
28								Kelli	McPhail

29								Sam	Miller
30								Christina	Motilall
31*	420813	6/7/2018 10:17	6/7/2018 10:17	6/7/2018 10:17	0	184.51.101.7	0	Ryan	Mowrey
32								Caryn	Muellerleile
33								Zoe	Need
34*	421613	6/10/2018 20:35	6/10/2018 20:35	6/10/2018 20:35	0	184.28.17.34	0	Anna	Normand
35								Alison	Parker
36								Dhara	Patel
37*	423047	6/14/2018 10:11	6/14/2018 10:11	6/14/2018 10:11	0	184.51.151.5	0	Mel	Peffers
38*	438613	7/10/2018 13:19	7/10/2018 13:19	7/10/2018 13:19	0	184.51.101.7	0	Mikayla	Pellerin
39								Jack	Rayburn
40*	425083	6/20/2018 10:21	6/20/2018 10:21	6/20/2018 10:21	0	184.51.101.7	0	Kathleen	Roberts
41*	425709	6/21/2018 14:40	6/21/2018 14:40	6/21/2018 14:40	0	184.28.17.34	0	Eric	Rosenfield
42								Julia	Rowe
43								Keith	Rushing
44*	440327	7/11/2018 12:57	7/11/2018 12:57	7/11/2018 12:57	0	184.51.101.7	0	Eunice	Salcedo
45*	442753	7/12/2018 15:29	7/12/2018 15:29	7/12/2018 15:29	0	23.79.240.10	0	Seema	Schappelle
46*	440075	7/11/2018 11:14	7/11/2018 11:14	7/11/2018 11:14	0	23.35.150.15	0	Racquel	Segall
47								Nicole	Shao
48								Frank	Shipps
49*	428291	6/29/2018 9:19	6/29/2018 9:19	6/29/2018 9:19	0	184.28.17.24	0	Diana	Smith
50								Latosha	Thomas
51*	420411	6/6/2018 9:13	6/6/2018 9:13	6/6/2018 9:13	0	184.51.101.6	0	Jeanne	VanBriesen
52								Brianna	VanNoy
53*	428363	6/29/2018 11:56	6/29/2018 11:56	6/29/2018 11:56	0	184.28.17.34	0	Margaret	Wang
54								Kara	Watkins
55								Emma	Wheeler
56*	428991	7/2/2018 13:03	7/2/2018 13:03	7/2/2018 13:03	0	23.62.239.20	0	Eleanor	Wintersteen
57*	443947	7/13/2018 7:56	7/13/2018 7:56	7/13/2018 7:56	0	184.51.101.6	0	Chris	Zarba

* Indicates onsite registrant

nsparency in Regulatory Science

ɛes | July 17, 2018

/JC East Building, Room 1153

Organization	City and State or Province	Country	Email Address	Phone
Earthjustice	Washington, DC	USA	capfel@earthjustice.org	(202) 667-4500
William & Mary Law School			jrbobka@email.wm.edu	
US EPA			brennan.thomas@epa.gov	(202) 564-6953
[Organization illegible]				
US EPA			cogliano.vincent@epa.gov	(202) 564-4313
HRI Science and Environment Group	Reston VA	USA	Personal Matters / Ex. 6	(585) 703-1121
American Geophysical Union	Washington, DC	USA	tcrisp@agu.org	(202) 777-7485
US EPA, OP			curry.bridgid@epa.gov	(202) 565-2567
USCE			idevalliere@uschamber.com	(202) 624-7864
NRDC				
B&C Consortia Management, LLC	Washington, DC	USA	lbotelho@bc-cm.com	(202) 833-6583
KII	Washington, DC	USA	david.dunlap@kochind.com	(202) 879-8511
EVA				
Climate Science Legal Defense Fund	New York, NY	USA	rfowler@csldf.org	(503) 347-4727
Earthjustice			egarther@earthjustice.org	
Carnegie Mellon University	Philadelphia, PA	USA	Personal Matters / Ex. 6	(717) 669-3201
Environmental Protection Network	Washington	USA		(202) 361-2409
HRI Science and Environment	Vienna, VA	USA		(703) 242-1026
US EPA			hauchman.fred@epa.gov	(202) 564-3151
US EPA				
Environmental Protection Network	Washington DC	USA	Personal Matters / Ex. 6	(910) 338-6543
US EPA				
NACAA			mkeogh@4cleanair.org	(202) 624-7864
Union of Concerned Scientists	Washington	USA	ykothari@ucsusa.org	(202) 331-5665
Assoc. of State Drinking Water Admin.	Arlington	USA	kletterly@asdwa.org	(703) 812-9507
Competitive Enterprise Institute	Washington, DC	USA	alogomasini@cei.org	(703) 944-8141
University of California			kamala.lyon@ucdc.edu	(202) 974-6312
Embassy of Canada				

MTR				
US EPA			motilall.christina@epa.gov	(202) 564-1287
The Fertilizer Institute	Washington D.C	USA	rmowrey@tfi.org	(202) 515-2723
US EPA, OP			muellerleile.caryn@epa.gov	(202) 564-2855
US EPA				
American Geosciences Institute	Alexandria	USA	anormand@americangeosciences.org	(337) 692-3071
US EPA			parker.alison@epa.gov	(202) 564-6058
UCLA Fielding, School of Public Health			dppatel@g.ucla.edu	(317) 514-7329
US EPA	Washington, DC	USA	peffers.mel@epa.gov	(202) 564-8786
Environmental Protection Network	Washington, DC	USA	Personal Matters / Ex. 6	(717) 504-2839
trust for America's Health			jrayburn@tfah.org	202) 223-9870 ext. 28
B&C Consortia Management, LLC	Washington, DC	USA	kroberts@bc-cm.com	(202) 833-6581
OMB	Washington, DC	USA	erosenfield@omb.eop.gov	(202) 395-7755
University of California				
Earthjustice				
AFSCME	Washington, DC	USA	esalcedo@afscme.org	(559) 396-7351
US EPA	Washington DC	USA	schappelle.seema@epa.gov	(202) 564-8006
IAFF	Washington, DC	USA	rsegall@iaff.org	(202) 824-1573
US EPA			shao.nicole@epa.gov	(202) 564-6779
Dominican Friars			Personal Matters / Ex. 6	(202) 607-3707
Herndon-Reston Indivisible Science and Environment Group	Reston, Va	USA	Personal Matters / Ex. 6	(703) 715-0027
US EPA			thomas.latosha@epa.gov	(202) 564-2621
Carnegie Mellon University	Pittsburgh	USA	jeanne@cmu.edu	(412) 268-4603
George Washington University			bnvannoy@gwu.edu	(937) 902-6359
National Parks Conservation Association	Washington DC	USA	mwang@npca.org	(415) 847-5706
BCPP			kwatkins@rabengroup.com	(202) 466-8585
Constituent			Personal Matters / Ex. 6	(252) 241-7657
MIT	Helena, MT	USA	eleanorw@mit.edu	(406) 459-3225
None	Annapolis, MD	USA	Personal Matters / Ex. 6	(410) 980-9487

Public Hearing - Strengthening Transpare

Press/Media List | July

1201 Constitution Ave. NW | WJC East

Count	SID	Submitted Time	Completed Time	Modified Time	Draft	IP Address	UID	First Name	Last Name
1								Sam	Brock
2								Sylvia	Carignan
3								Francie	Diep
4								Maria	Hegstad
5								Emily	Holden
6								Ellen	Knickmeyer
7	445025	7/13/2018 16:26	7/13/2018 16:26	7/13/2018 16:26	0	184.51.101.6	0	Jeffrey	Mervis
8	447967	7/14/2018 19:39	7/14/2018 19:39	7/14/2018 19:39	0	184.51.101.6	0	Sean	Reilly
9								Esther	Whieldon

ncy in Regulatory Science

17, 2018

t Building, Room 1153

Organization	City and State or Province	Country	Email Address	Phone
Argus Media			sam.brock@argusmedia.com	
Bloomberg Environment			scarignan@bloombergenvironment.com	
Pacific Standard			fdiep@psmag.com	
Inside EPA			mhegstad@iwpnews.com	
Politico			eholden@politico.com	
AP			eknickmeyer@ap.org	
Science	Washington, DC	USA	jmervis@aaas.org	##########
E&E News	Washington, DC	USA	sreilly@eenews.net	##########
S&P Global			esther.whieldon@spglobal.com	

Strengthening Transparency in Regulatory Science Public Hearing Registration

Submission Details (7-16-18)

SID	Submitted Time
429329	7/3/2018 10:51
417361	5/25/2018 16:14
428957	7/2/2018 11:51
420951	6/7/2018 14:45
431291	7/7/2018 17:37
417289	5/25/2018 13:13
419189	6/1/2018 12:30
424963	6/19/2018 21:06
435583	7/9/2018 14:23
428861	7/2/2018 9:22
429019	7/2/2018 13:41
418513	5/30/2018 17:48
422787	6/13/2018 15:02
440195	7/11/2018 12:21
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6/7/2018 14:45	6/7/2018 14:45	0	184.51.101.7	0	Carrie	Apfel
7/7/2018 17:37	7/7/2018 17:37	0	184.51.101.6	0	Olivia	Bartlett
5/25/2018 13:13	5/25/2018 13:13	0	184.51.101.6	0	Andrew	Bergman
6/1/2018 12:30	6/1/2018 12:30	0	184.51.101.7	0	Liz	Borkowski
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6/13/2018 15:02	6/13/2018 15:02	0	23.212.53.68	0	john	dunn
7/11/2018 12:21	7/11/2018 12:21	0	184.51.101.7	0	Adam M.	Finkel
7/11/2018 17:15	7/11/2018 17:15	0	184.51.101.7	0	Maggie	Flaherty
6/7/2018 14:11	6/7/2018 14:11	0	184.51.101.6	0	Christina	Franz
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5/25/2018 10:37	5/25/2018 10:37	0	184.28.17.34	0	Elizabeth Ann Glass	Geltman
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7/6/2018 11:31	7/6/2018 11:31	0	184.28.17.34	0	Chris	Heaney
6/15/2018 12:13	6/15/2018 12:13	0	184.51.101.7	0	Antonia	Herzog
7/6/2018 15:34	7/6/2018 15:34	0	184.28.17.24	0	Sarah	Kogel-Smucker
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6/14/2018 22:15	6/14/2018 22:15	0	184.28.17.24	0	Meredith	McCormack
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6/5/2018 11:03	6/5/2018 11:03	0	184.28.17.34	0 Augusta	Wilson
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7/13/2018 14:15	7/13/2018 14:15	0	184.51.101.7	0 Roy	Gamses
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7/12/2018 16:50	7/12/2018 16:50	0	184.51.101.7	0 John	Hall
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7/13/2018 13:50	7/13/2018 13:50	0	184.51.101.6	0 Elizabeth	Hitchcock
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7/11/2018 17:23	7/11/2018 17:23	0	184.51.101.7	0 Suzanne	Bonamici
6/6/2018 11:13	6/6/2018 11:13	0	184.51.101.6	0 Adam	Carpenter
5/25/2018 15:57	5/25/2018 15:57	0	184.51.151.5	0 Kara	Cook
5/31/2018 12:08	5/31/2018 12:08	0	184.51.101.7	0 Albert	Donnay
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5/25/2018 9:35	5/25/2018 9:35	0	184.51.101.6	0	Vijay	Limaye
5/31/2018 15:02	5/31/2018 15:02	0	184.51.101.6	0	Peter	Lurie
6/29/2018 11:13	6/29/2018 11:13	0	184.51.101.6	0	Matthew	McKinzie
6/20/2018 17:29	6/20/2018 17:29	0	184.28.17.24	0	Jennifer	McPartland
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6/15/2018 9:18	6/15/2018 9:18	0	184.51.101.6	0	Devon	Payne-Sturges
6/14/2018 10:11	6/14/2018 10:11	0	184.51.151.5	0	Mel	Peffers
7/10/2018 13:19	7/10/2018 13:19	0	184.51.101.7	0	Mikayla	Pellerin
6/28/2018 22:10	6/28/2018 22:10	0	184.28.17.34	0	George	Penny
6/4/2018 17:08	6/4/2018 17:08	0	184.51.101.7	0	Rachel	Plett
7/9/2018 9:48	7/9/2018 9:48	0	184.28.17.24	0	Sunny	Qiao
7/12/2018 12:45	7/12/2018 12:45	0	184.51.101.7	0	Randy	Rabinowitz
7/7/2018 0:02	7/7/2018 0:02	0	184.51.101.6	0	Jennifer	Reaves

7/14/2018 19:39	7/14/2018 19:39	0	184.51.101.6	0	Sean	Reilly
7/12/2018 18:44	7/12/2018 18:44	0	23.215.15.34	0	Alan	Roberson
6/20/2018 10:21	6/20/2018 10:21	0	184.51.101.7	0	Kathleen	Roberts
7/6/2018 12:39	7/6/2018 12:39	0	184.51.101.6	0	Michelle	Roos
7/13/2018 15:13	7/13/2018 15:13	0	184.51.101.7	0	Erika	Rosen
6/21/2018 14:40	6/21/2018 14:40	0	184.28.17.34	0	Eric	Rosenfield
7/11/2018 12:57	7/11/2018 12:57	0	184.51.101.7	0	Eunice	Salcedo
7/10/2018 9:52	7/10/2018 9:52	0	184.51.101.7	0	Lauren	Schapker
7/12/2018 15:29	7/12/2018 15:29	0	23.79.240.10	0	Seema	Schappelle
7/3/2018 10:08	7/3/2018 10:08	0	184.51.101.7	0	Stephanie	Schlea
7/11/2018 11:14	7/11/2018 11:14	0	23.35.150.15	0	Racquel	Segall
7/11/2018 19:34	7/11/2018 19:34	0	184.51.101.7	0	Joanna	Slaney
7/12/2018 9:56	7/12/2018 9:56	0	184.51.101.7	0	Kristine	Smith
6/29/2018 9:19	6/29/2018 9:19	0	184.28.17.24	0	Diana	Smith
6/26/2018 16:09	6/26/2018 16:09	0	184.51.101.7	0	Lucky	Tran
6/6/2018 9:13	6/6/2018 9:13	0	184.51.101.6	0	Jeanne	VanBriesen
7/13/2018 12:29	7/13/2018 12:29	0	184.28.17.24	0	Scott	Waldman
6/29/2018 11:56	6/29/2018 11:56	0	184.28.17.34	0	Margaret	Wang
7/2/2018 13:03	7/2/2018 13:03	0	23.62.239.20	0	Eleanor	Wintersteen
6/28/2018 20:12	6/28/2018 20:12	0	184.51.101.6	0	mark	wright
7/6/2018 12:39	7/6/2018 12:39	0	184.51.101.6	0	George	Wyeth
6/18/2018 14:35	6/18/2018 14:35	0	184.51.101.7	0	Christopher	Yarosh
6/4/2018 7:34	6/4/2018 7:34	0	184.51.101.7	0	RP	Yeager
7/13/2018 7:56	7/13/2018 7:56	0	184.51.101.6	0	Chris	Zarba
7/6/2018 5:52	7/6/2018 5:52	0	184.51.101.6	0	Chris	Zarba

Organization	City and State or Province
Minnesota Department of Health	St. Paul, MN
Earthjustice	New York, NY
Physicians for Social Responsibility	Washington DC
Earthjustice (cancelled speaking, but will attend)	Washington, DC
Do The Most Good	Bethesda, MD
Project on Government Oversight	Washington, D.C.
Jacobs Institute of Women's Health (at Milken Institute School of Public Health, George Washington University)	Washington, DC
Moms Clean Air Force	Chevy Chase, MD
U.S. Chamber of Commerce Global Energy Institute	Washington
Union of Concerned Scientists (registration changed from Michael Halpern, mhalpern@ucsusa.org on 7-16-2018)	Washington, DC
INdependent Toxicologist	Oakton, VA
Clean Air Task Force	Boston, Ma
none	Brownwood, Texas
University of Michigan School of Public Health	Pennington NJ
League of Conservation Voters	Ukiah, California
American Chemistry Council	Washington, DC
American Academy of Pediatrics	Washington, DC
CUNY School of Public Health	New York
Union of Concerned Scientists (registration changed from Vivian Change, vchang@ucsusa.org on 7-16-2018)	Washington, DC
University of Pittsburgh Graduate School of Public Health	Pittsburgh, PA
Rural Empowerment Association for Community Help	Duplin County, North Carolina
Johns Hopkins Bloomberg School of Public Health	Baltimore, MD
Physicians for Social Responsibility	Washington, DC
Office of the Attorney General for the District of Columbia	Washington, District of Columbia
University of Michigan	Ann Arbor
Physicians for Social Responsibility	Oberlin
American Thoracic Society	Baltimore, MD
Michael J. Fox Foundation for Parkinson's Research	Washington
Alaska Community Action on Toxics (requested change from 4pm-8pm slot to 12-4pm)	Anchorage, Alaska
JunkScience.com	Potomac, MD
National Association of Clean Air Agencies	Washington, DC
Project On Government Oversight	Broomall, PA
Physicians for Social Responsibility	Washington DC
Physicians for Social Responsibility Philadelphia	Philadelphia
Breast Cancer Prevention Partners	San Francisco, CA
George Washington University	Washington, DC
Farmworker Justice	Washington, DC

EDF	Takoma Park, Maryland
Health Care Without Harm	Reston, Virginia
Minnesota Pollution Control Agency	St. Paul, MN
#WTMAPVigil	Washington, DC
International Society of Environmental Epidemiology	Tuxedo
Climate Science Legal Defense Fund	New York
NPCA	Arlington
The League of Conservation Voters	Kaneohe, Hawaii
Environmental Protection Network (cancelled 7-16-18, taking John Bachmann's place in 8am-noon session)	Arlington, VA
National Parks Conservation Association	New Haven, CT
Center for Regulatory Reasonableness	Washington DC
FreedomWorks Foundation	District of Columbia
Safer Chemicals Healthy Families	Washington, DC
United States citizenry	Germantown, MD
Earthjustice (cancelled on 7/12/18)	New York, NY
Environmental Health Strategy Center	Portland, ME
Physicians Committee for Responsible Medicine	Washington, DC
private citizen	Silver Spring, MD
Representing Self (email address updated)	New Carrollton, MD
American State Litter Scorecard (cancelled on 7/16/18)	Clarksburg, MD 20871
American Petroleum Institute	Washington
Philadelphia Physicians for Social Respo	Philadelphia, PA
Environmental Defense Fund	Rockville, Maryland
American Chemistry Council	Washington, DC
UCSF	CA
Self	Washington,DC
American Lung Association	Washington
The reality-based community	Arlington
American Lung Association	Fairfax, VA
American Lung Association	Washington
Harvard Law School	Cambridge, MA
U.S. House of Representatives, Oregon First Congressional District (scheduled to speak at 8:35)	Beaverton, Oregon
American Water Works Association	Washington DC
US PIRG	Houston, TX
Donnay Detoxicology LLC	Hyattsville MD
Farmworker Association ofFlorida (requested change from 12-4pm time slot to 8am-noon)	Apopka, FL
EDF	Washington
New York State Office of the Attorney General	New York
Physicians for Social Responsibility	Bethesda , Maryland
EPN (registration changed from John Bachmann, johnbachmann@bellsouth.net, 919 942-5928 on 7-16-2018)	Arlington, VA

Johns Hopkins Bloomberg School of Public Health (cancelled on 7-11-18)	Baltimore
Physicians for Social Responsibility	Washington, DC
Health Effects Institute	Boston, Massachusetts
Pavement Coatings Technology Council	Alexandria, Virginia
Natural Resources Defense Council	New York, New York
Center for Science in the Public Interest	Washington, DC
Natural Resources Defense Council (NRDC)	Washington, DC
Environmental Defense Fund	Washington, DC
Consultant	Atlanta GA
Environmental Law & Policy Center	Washington
George Washington University School of Public Health	Washington, DC
Self	Silver Spring
NESCAUM (registration changed from Kathy Kinsey, kkinsey@nescaum.org, 617-259-2704 on 7-5-2018)	Boston, MA
American Lung Association	Washington, DC
Children's Environmental Health Network (CEHN)	Washington, DC
Moms Clean Air Force	Washington DC
Trust for America's Health	Washington, DC
Democracy	Cambridge, MA
Environmental Defense Fund	Washington, D.C.
Program on Climate and Health	Fairfax, Virginia
NRDC	Washington DC
Moms Clean Air Force	Haddon Heights, NJ
Earthjustice	New York, NY
Hunton Andrews Kurth	Washington DC
American Petroleum Institute (request time slot as early as possible)	Washington DC
Safer Chemicals Healthy Families	Washington DC
Environmental Protection Network	Herndon, VA
American Lung Association	Washington
American Council on Science and Health (registration changed from Hank Campbell, hank@acsh.org on 7-16-2018)	Washington DC
Environmental Defense Fund	D.C.
The George Washington University	Washington, DC
National Environmental Health Association (registration changed from David Dyjack on 7-11-18)	Denver, CO
None	Alexandria
Union of Concerned Scientists	Washington, D.C.
Mrs.	Silver Spring
Eastman Chemical Company	Crown Point, IN
HRI Science and Environment Group	Reston VA
American Geophysical Union	Washington, DC
GW Center for Regulatory Studies	D.C.
B&C Consortia Management, LLC	Washington, DC

KII	Washington, DC
Research!America	Arlington
American Chemistry Council	Washington , DC
N/A	North Garden
Climate Science Legal Defense Fund	New York, NY
Chemical Watch	Washington, DC
The Procter & Gamble Company	Cincinnati, Ohio
Noblis	Reston, VA
Carnegie Mellon University	Philadelphia, PA
do not wish to answer	Washington, DC
Environmental Protection Network	Washington
HRI Science and Environment	Vienna, VA
ACC	Washington, DC
Hazen Consulting Support and S	Annapolis
Inside EPA	Arlington, VA
Safer Chemicals Healthy Families	Washington, DC
Environmental Protection Network	Washington DC
Healthy Legacy Coalition	Minnesota
Fluvanna Democratic Committee	Troy
National Academies	Washington DC
Union of Concerned Scientists	Washington
California Small Business Alliance	Anaheim, CA
Assoc. of State Drinking Water Admin.	Arlington
NYT	Washington
New York Times	Washington
Competitive Enterprise Insitute	1310 L Street, NW, #700, Washington, DC 200(
Shell Oil Company	Houston, TX
AAAS	Washington, DC
Science	Washington, DC
Ocean Conservancy	Washington
The Fertilizer Insitute	Washington D.C
Global Automakers	Washington
Eastman Chemical Company	Lancaster, PA
American Geosciences Institute	Alexandria
Assoc. of State Drinking Water Admin.	Arlington
Assoc. of State Drinking Water Admin.	Arlington
American Institute of Biological Sciences	Washington, DC
UMD	University Park
EPA	Washington
Environmental Protection Network	Washington D.C.
	1946 Washington
RSM	Washington DC
National Parks Conservation Association	Washington D.C.
OSH Law Project	Washington DC
Mom's Clean Airforce Maryland	Hyattsville Maryland

E&E News	Washington, D.C.
Assoc. of State Drinking Water Admin.	Arlington
B&C Consortia Management, LLC	Washington, DC
Environmental Protection Network	Bronx, NY
The George Washington University	Washington, DC
OMB	Washington, DC
AFSCME	Washington, DC
National Ground Water Association	Washington
US EPA	Washington DC
Association of Metropolitan Water Agencies	Washington
IAFF	Washington
Environmental Defense Fund	Washington, D.C.
Bureau of Reclamation	Washington, DC
Herndon-Reston Indivisible Science and Environment Group	reston, Va
March for Science	New York, New York
Carnegie Mellon University	Pittsburgh
E&E News	Washington, DC
National Parks Conservation Association	Washington DC
MIT	Helena, MT
self	washington DC
Environmental Protection Network	Washington
American Chemical Society	Washington, D.C.
FDA	Silver Spring, MD
None	Annapolis, MD
None	Annapolis Maryland

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US	raymond.yeager@fda.hhs.gov
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USA	

Phone	Do you wish to speak?	Time slot
651-201-5711	Yes	12pm-4pm
2128457394	Yes	12pm-4pm
5122840712	Yes	12pm-4pm
(202) 667-4500	No	12pm-4pm
2407515599	Yes	12pm-4pm
609-577-3752	Yes	12pm-4pm
994-0034	Yes	12pm-4pm
206-697-2064	Yes	12pm-4pm
2022558780	Yes	12pm-4pm
202-340-0171	Yes	12pm-4pm
703 620 3473	Yes	12pm-4pm
8022337967	Yes	12pm-4pm
325 7846697	Yes	12pm-4pm
202-406-0042	Yes	12pm-4pm
(707) 391-9636	Yes	12pm-4pm
202-249-6406	Yes	12pm-4pm
2023478600	Yes	12pm-4pm
2023204520	Yes	12pm-4pm
2023315672	Yes	12pm-4pm
4124179611	Yes	12pm-4pm
(910) 296-1180	Yes	12pm-4pm
443-287-4989	Yes	12pm-4pm
202-587-5224	Yes	12pm-4pm
202-724-9727	Yes	12pm-4pm
7347640552	Yes	12pm-4pm
7162350035	Yes	12pm-4pm
4437172708	Yes	12pm-4pm
2026384101	Yes	12pm-4pm
(907) 222-7714	Yes	12pm-4pm
240-205-1243	Yes	12pm-4pm
202-624-7864	Yes	12pm-4pm
3015202563	Yes	12pm-4pm
9096812092	Yes	12pm-4pm
2157490960	Yes	12pm-4pm
5046102043	Yes	12pm-4pm
202-994-5179	Yes	12pm-4pm
2022935420	Yes	12pm-4pm

2023873509	Yes	12pm-4pm
510-543-8196	Yes	12pm-4pm
651-757-2014	Yes	12pm-4pm
2023523217	Yes	12pm-4pm
845-731-3564	Yes	12pm-4pm
646-820-6490	Yes	12pm-4pm
7035779743	Yes	12pm-4pm
(808)778-0944	Yes	4pm-8pm
703-532-5648 (home)	Yes	4pm-8pm
7812485417	Yes	4pm-8pm
202-463-1166	Yes	4pm-8pm
4252836512	Yes	4pm-8pm
202794-8755	Yes	4pm-8pm
3019165590	Yes	4pm-8pm
(212) 845-7376	Yes	4pm-8pm
207-699-5796	Yes	4pm-8pm
202-717-8677	Yes	4pm-8pm
3017404976	Yes	4pm-8pm
202-781-3012	Yes	4pm-8pm
202-521-1489	Yes	4pm-8pm
2026828568	Yes	4pm-8pm
2675195299	Yes	4pm-8pm
(240) 994-5575	Yes	4pm-8pm
202-249-6707	Yes	4pm-8pm
4154763198	Yes	4pm-8pm
202-294-4860	Yes	4pm-8pm
2024817668	Yes	8am-12pm
410-369-6865	Yes	8am-12pm
202-715-3457	Yes	8am-12pm
2027853355	Yes	8am-12pm
2814684836	Yes	8am-12pm
202-225-0855	Yes	8am-12pm
202-326-6126	Yes	8am-12pm
405-613-0970	Yes	8am-12pm
410-889-6666	Yes	8am-12pm
407-886-5151	Yes	8am-12pm
661-714-1654	Yes	8am-12pm
2124168477	Yes	8am-12pm
3013451919	Yes	8am-12pm
702 532-5648	Yes	8am-12pm

9082275103	Yes	8am-12pm
202-587-5225	Yes	8am-12pm
6174882331	Yes	8am-12pm
(703) 299-8470	Yes	8am-12pm
6086988938	Yes	8am-12pm
202-777-8334	Yes	8am-12pm
202-289-6868	Yes	8am-12pm
202-387-3500	Yes	8am-12pm
404-310-2889	Yes	8am-12pm
2023758296	Yes	8am-12pm
3018061333	Yes	8am-12pm
4437656701	Yes	8am-12pm
617-259-2016	Yes	8am-12pm
202-715-3444	Yes	8am-12pm
2025434033	Yes	8am-12pm
202-744-4790	Yes	8am-12pm
2022239870	Yes	8am-12pm
617-301-8010	Yes	8am-12pm
202 572 3526	Yes	8am-12pm
2407434174	Yes	8am-12pm
202-289-2362	Yes	8am-12pm
9178631009	Yes	8am-12pm
(212) 845-7376	Yes	8am-12pm
2029551529	Yes	8am-12pm
202-682-8568 (request time slot as early as possible	Yes	8am-12pm
202-716-0118	Yes	8am-12pm
703-946-1305	Yes	8am-12pm
7032209467	Yes	8am-12pm
202-543-1174	Yes	8am-12pm
2023873556	Yes	8am-12pm
202-994-9289	Yes	8am-12pm
2022706193	Yes	8am-12pm
8136386008	No	
2023315663	No	
3014383389	No	
423-229-8716	No	
5857031121	No	
2027777485	No	
4802020373	No	
2028336583	No	

202-879-8511	No
6109551832	No
2022496712	No
4342442691	No
5033474727	No
2028034192	No
5132060066	No
7036102042	No
7176693201	No
9082780519	No
202-361-2409	No
7032421026	No
202-249-6440	No
4439240191	No
7034168541	No
2027948755	Yes
9103386543	No
6126233666	No
4342426393	
202 334 3066	No
2023315665	No
(714) 778-0763	No
7038129507	No
202 862 0448	No
202 862 0448	No
7039448141	No
832-337-9857	No
2023266725	No
202.326.7012	No
2402157047	No
202-515-2723	No
2026505547	
717-666-9607	No
3376923071	No
7038129507	No
7038129507	No
2026281500 x225	No
3017796622	No
202-564-8786	No
7175042839	No
2022442142	No
31647707005	No
6073798873	No
2022564080	No
2029107768	No

2024460433	No
7038129507	No
202-833-6581	No
6463616928	No
2534951412	No
2023957755	No
5593967351	No
2028889151	No
2025648006	No
202-331-2820	No
202-824-1573	No
202-258-6640	No
2025130557	No
703-715-0027	No
2123053689	No
4122684603	No
2024460419	No
4158475706	No
406-459-3225	No
3014425841	No
301-633-6361	No
2028726274	No
301-796-6742	No
4109809487	No
4109809487	No

Statement of Lynn R. Goldman, MD, MS, MPH

July 17, 2018

Submitted to: the US Environmental Protection Agency
Comments on EPA Proposed Rule: "Strengthening Transparency in Regulatory Science"

I am a pediatrician and an epidemiologist and have been Dean of the Milken Institute School of Public Health at the George Washington University since 2010. From 1993 through 1998, I served as Assistant Administrator for Toxic Substances at the US Environmental Protection Agency leading what is now known as the Office of Chemical Safety and Pollution Prevention. While serving in that position, I was responsible for the implementation of the nation's pesticide and chemicals laws. I am a member of the National Academy of Medicine. My comments represent my expertise as an environmental health scientist, and a former EPA official, and not the views of any one organization.

This NPRM suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as the scientific community, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision-making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking, thus freezing EPA's risk assessment processes in the future and breaking the important separation between risk assessment and risk management that has been fundamental to science based decision-making.

Lack of Justification for the Proposed Rule:

First, why does EPA think that this proposed rule is necessary? No justification is given in the preamble. In 2013, our paper in *Environmental Health Perspectives* documented the use of the Information Quality Act for requests for raw data.[1] We found little evidence for unfulfilled demand for more access to raw data. If, during that ten year period, EPA had accumulated datasets for all raw data for all dose response assessments that had been conducted, it would have been a tremendous waste in terms of 1) *delays* in EPA conducting assessments until data

[1] Goldman, L.R. and Silbergeld, E.K. Assuring access to data for chemical evaluations. Environ Health Perspect, 121(2):149-52, 2013.

were obtained; 2) *costs* to the academic community in preparing datasets and extensive meta data files for EPA for all of their studies; 3) *expenditure* of agency staff resources in EPA compelling the submission of the data from academics; and 4) *EPA staffing and funds* for establishing and maintaining systems to house, protect and make available the raw data.

The proposal ignores the "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences[2] and the National Toxicology Program[3]. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments. As a corollary, they have never concluded that scientific findings should be disregarded if "raw data" for dose response assessments are not available.

Costly to EPA and the Research Community

While at EPA I learned that risk assessment activities at EPA are extensive; not only the flagship IRIS program, but several regulatory programs are actively engaged in performing more than 1,000 risk assessments per year (a 1996 estimate). Such assessments are required under a number of EPA's statutes, for example: premarket notification for chemicals; assessments of priority air standards; pesticide tolerances; drinking water MCLs; and assessment of existing chemicals risks. The burdens for these assessments under the proposed rule are likely to be considerable. The proposal does not consider, across hundreds of assessments performed annually, the costs to the U.S. EPA and researchers, the significant time and paperwork burdens for researchers, and major regulatory delays that will occur when EPA is waiting for data to be made publicly available, which may not ever happen. It does not address how EPA could compel the submission of such data in the context of weak regulatory authority for research conducted in the past; studies not funded by the U.S. government; and/or research conducted abroad. It seems unaware of the Paperwork Reduction Act that tilts against information gathering from private parties. The U.S. EPA is further constrained by industry confidential business information (CBI) claims for regulatory testing data under U.S. chemical and pesticide laws; even when the EPA receives raw data from industry, it provides only data summaries to the public. For whatever data it could obtain, EPA would have to establish a public data repository for this information that would securely house not only the data (especially personal health information and/or CBI) but also a number of unique meta data elements required to understand the data.

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[2] National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. https://doi.org/10.17226/25086.

[3] Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. 2014. Systematic review and evidence integration for literature-based environmental health science assessments. Environ Health Perspect 122:711–718; http://dx.doi.org/10.1289/ehp.1307972

Risk of Disclosure of Personal Information for Human Subjects

To manage risks of disclosure of sensitive human data, the EPA would have to perform checks to assure that no personal health information would be in public data sets. We live in a day when not only name&date of birth, name&address, social security number and/or medical record number can be used to identify person but when massive quantities of "big data" are on the web. Most recently, the renowned geneticist Craig Venter and colleagues reported identified persons using their genetic code alone.[4]

Sound Science Will be Excluded from EPA Regulatory Decisions

The predictable result of this proposal is that EPA will be forced to exclude studies that should be included in a systematic review. For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base of knowledge underpinning EPA's decisions. While the NPRM includes a provision for the EPA to waive this requirement, it provides no clear criteria for such waivers and appears to be a process that would allow arbitrary and capricious application of the proposed rule.

Reversal of EPA Science Policy and Precedents

The proposal seems to attempt, via a single rulemaking, to overturn years of well-thought EPA science policy guidelines and precedents in the selection and application of dose-response models for toxicity assessment. It misrepresents the recommendations of prior expert reviews such as the so-called NAS "Silver Book"[5] and the Bi-Partisan Commission review[6]. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. The NPRM seems to naively assume that single studies are used to inform risk assessors of the possible shape of dose response curves. That was true at one time, but today, the first step of the dose-response modeling process is to evaluate all of the scientific information to gain a biological understanding of how each type of toxicity or response (adverse effect) occurs, the "mode of action". This is not done via modelling of raw data from a single study. When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens. According to the NAS "Silver Book", often noncancer

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[4] "Here, we show that phenotypic prediction from WGS data can enable reidentification without any further information being shared. If conducted for unethical purposes, this approach could compromise the privacy of individuals who contributed their genomes into a database. In stratified analyses, we see that risk of reidentification correlates with variability of the cohort. Although sharing of genomic data is invaluable for research, our results suggest that genomes cannot be considered fully deidentifiable and should be shared by using appropriate levels of security and due diligence." From: Christoph Lippert, Riccardo Sabatini, M. Cyrus Maher, Eun Yong Kang, Seunghak Lee, et al. Genomics of physical traits, PNAS Sep 2017, 201711125; DOI: 10.1073/pnas.1711125114

[5] National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. https://doi.org/10.17226/12209.

[6] Bipartisan Commission. Improving the Use of Science in Regulatory Policy, Washington, DC. 2009

effects (such as, lead and other neurotoxic substances) also have no practically identifiable thresholds. More fundamentally, this NPRM for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that may be dubious today but certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

Conclusion

In conclusion, the proposed rule would cause significant delays in how EPA uses science to make hundreds of regulatory decisions every year. It would overturn years of precedent, as well as advice from scientific experts outside of EPA. It would be burdensome, for the agency and researchers alike.

I strongly urge the EPA Administrator (1) not to use the agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community.

What is at stake is no less than the public's confidence in the integrity of EPA's science and decisions.

Comments on EPA Proposed Rule
Strengthening Transparency in Regulatory Science

Abigail Omojola, Breast Cancer Prevention Partners

My name is Abigail Omojola and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would *not* serve to provide the public with greater "confidence in and understanding of" EPA's regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard *not* to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule's requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would provide.

An example of the kind of study this proposed rule could eliminate from the EPA's regulatory process is the National Institute of Environmental Health Sciences' Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing

breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.

This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publicly available. This is particularly true for vulnerable communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research. The competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to *prevent* this devastating disease. This proposal takes a hard step away from that goal.

Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.

Testimony of Physicians for Social Responsibility

1111 14th Street NW
Washington DC 20005

Re: Proposed Rule: Strengthening Transparency in Regulatory Science
Docket ID: EPA-HQ-OA-2018-0259
Presented by: Alan H. Lockwood, MD, FAAN, FANA
Date: July 17, 2018
Location: U.S. Environmental Protection Agency Headquarters
William Jefferson Clinton East Building, Main Floor Room 1153
1201 Constitution Avenue NW
Washington, D.C. 20460

Thank you for this opportunity to speak on behalf of Physicians for Social Responsibility (PSR). I am a board-certified neurologist and an elected fellow of the American Neurological Association and the American Academy of Neurology, and Professor Emeritus of Neurology at the University at Buffalo. PSR is a 501(c)(3) scientific and educational organization headquartered in Washington DC with over 30,000 physicians, medical students, and others across the country. Our mission is to protect human life from the gravest threats to health and survival.

We submit this testimony in strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposed rule would change the standards for the inclusion of studies used by the Agency and lead to the abolition or weakening of virtually all protections under the purview of the Agency.

Under the misleading veil of "transparency," the proposed rule could force investigators to invade the confidentiality of research participants and make confidential and private data open to all. A similar concern was voiced by the current SAB writing, "there are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests ..." The rule could replace evidence-based decision-making with arbitrary determinations based on political considerations.

Peer-reviewed research has led to important gains in health:

Air pollution. The CAA protects us from air pollution and is arguably the most health-protective law in effect. I have written extensively about this in The Silent Epidemic[1]. Peer-reviewed studies link air pollutants with leading causes of death in the US including heart disease, stroke, and respiratory diseases. Additional studies link particulates to Alzheimer's disease and Type II Diabetes. Seminal studies include:

- The Harvard Six Cities Study that involved 8,111 adults followed for between 14 and 16 years showing a clear link between pollution and mortality[2].
- The Women's Health Initiative study involving 65,893 post-menopausal women that demonstrated a link between particulates, and cardiovascular disease and stroke mortality[3].
- I attended closely to the study of 1,705 neurologist-confirmed strokes showing that a transient increase in $PM_{2.5}$ was associated with a statistically significant increase in strokes even though levels were within limits "generally considered safe" by the EPA[4].

A congressionally mandated report prepared by the EPA projected that by 2020 CAA provisions will

save two trillion dollars per year in adverse health impacts[5]. Many savings will positively impact the budgets of state and federal agencies at a time of ballooning deficits.

Safe drinking water. EPA rules provide significant protection for the developing brains of children by establishing limits on lead. Lead impairs brain development and has adverse effects on behavior and cognition. Other data link arsenic levels in drinking water to Type II diabetes and cancer.

Natural gas production. Natural gas production, particularly "fracking" harms health due to human proximity to wells, pumping stations, and contamination of water supplies and contributes to climate change.

Protecting privacy. Protecting the privacy of research participants is a keystone of biomedical research and one with which I have had years of personal experience as a member then chairman of the Buffalo VA institutional review board. Peer-reviewed journals require authors to affirm their adherence to federal privacy protections as a pre-condition for publication. This standard should not be abolished.

PSR's mission is to "to protect human life from the gravest threats to health and survival." To protect the scientific integrity of the EPA and protect health we oppose the deceptively named proposal, "Strengthening Transparency in Regulatory Science."

On behalf of Physicians for Social Responsibility

Alan H. Lockwood MD, FAAN, FANA

Emeritus Professor of Neurology and Nuclear Medicine
University at Buffalo, Senior Scientist, Past President, and Member, Board of Directors, PSR
Physicians for Social Responsibility, 1111 14th St NW Suite 700, Washington, DC 20005

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5. U.S. Environmental Protection Agency Office of Air and Radiation. The Benefits and Costs of the Clean Air Act:1990 to 2020.

I'm Andrew Bergman, and I'm speaking today as the special environmental advisor at the Project On Government Oversight, but I'm also currently a Ph.D. student in applied physics at Harvard University.

While the proposed "Strengthening Transparency in Regulatory Science" rule uses the words "transparency" and "reproducibility" to project lofty goals, it's real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process. I'm here today to urge EPA to withdraw this rule.

My colleague, Sean Moulton, has just addressed ~~will focus on~~ how the proposed rule conflicts with the EPA's regulatory process, and the statutory requirements underlying that process, but the rule will also have a direct impact on how the EPA approaches science.

The rule fails to properly address its two key considerations that will have a major impact on how it is implemented. First, the rule states that data relied on in making regulations must be made publically available, but it doesn't suggest a mechanism for how personally identifiable information or confidential business information would be handled.

This is an incredibly important issue, as so many studies that EPA uses rely on this type of confidential data. Yet it's reasonable to conclude from the rule that, if it goes into effect, the EPA will no longer be able to use most longitudinal human health studies to craft public safeguards, even though those studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity. Instead, they will be left with industry studies that more often use animal test subjects, which don't have any personal privacy concerns.

Second, while the rule refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' reproducibility, which has a wholly different meaning in a scientific context. But because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule intends the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings.

The Agency uses many studies, however, such as those that link leaded gasoline to brain damage in children or a study that found a link between fine particulate air pollution and premature deaths, that examine dangerous real world exposures and cannot, of course, be safely repeated. Just because they can't—or shouldn't—be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future.

Without knowing the details of how these two provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. We can conclude that the result will be that large swaths of studies will be arbitrarily ruled out for use in future rulemakings.

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially. The CBO found that a policy very similar to the proposed rule, when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding—a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary."

The three judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all.

Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation.

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule.

Thank you for your time and for the opportunity to comment on this important proposal.

EPA Hearing Oral Statement on the Proposed Rule, Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259 - July 17th, 2018

My name is Antonia Herzog and I am a scientist with a doctorate in Physics. I work in the Environment and Health Program at Physicians for Social Responsibility, a nonprofit organization based in Washington, DC with chapters in multiple states across the country and over thirty thousand members and activists around the country. Our mission is to protect human life from the gravest threats to health and survival; we number environmental pollution among those key threats.

PSR would like to express its strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." This proposed rule could arbitrarily exclude many important scientific studies—including thousands of public health and epidemiological studies—that the agency uses to make informed policy decisions regarding major public health and environmental laws. While it pretends to be about "transparency", the policy actually will limit the agency's ability to use the best available science thereby weakening protections for public health and the environment. In essence it could censor and block much of the peer reviewed scientific research that has allowed us to address many serious environmental health threats over the decades.

EPA's proposed rule would place crippling restrictions on the use of data the Agency would accept in the rulemaking process by ultimately requiring investigators to divulge personal information about the participants in research studies. Scientific studies that failed to meet this criterion would not be acceptable to the Agency. At present, this kind of information must be kept confidential according to the generally accepted rules that govern the conduct of research that must be adhered to by agencies of the federal government and institutions that receive federal funds.

As an example, the Clean Air Act, a bedrock environmental law that protects us from dangerous air pollutants, is such a critical health protection that would be endangered under this proposed rule because it relies on a longitudinal epidemiologic study of thousands of individuals. This includes the National Ambient Air Quality Standards (NAAQS) in the Clean Air Act. These standards address six major classes of common air pollutants, including standards for fine

particles (PM 2.5), and are the backbone of the U.S. air quality management system.

The Clean Air Act specifies that new or revised NAAQS be based on scientific criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." EPA has relied largely on community epidemiology and controlled human studies in establishing the specific pollutant levels and averaging times for NAAQS. If these studies were excluded by the EPA restrictions it would greatly reduce the availability of information that has proved to be significant in assessing the consistency and coherence of the evidence upon which the standards are based and would certainly weaken the scientific basis for maintaining or strengthening the current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby, putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.

PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science."

Brittany Meyer - Michael J Fox Foundation for Parkinson's Research
EPA "Transparency Rule" Testimony as prepared for oral delivery
07/17/2018

My name is Brittany Meyer and I am the Associate Director of Public Policy at the Michael J. Fox Foundation for Parkinson's Research. I am here on behalf of the nearly one – million people with Parkinson's disease in the United States who rely on the Environmental Protection Agency to safeguard their health and inform them about potential hazards in the environment.

Over the past ten years, we've learned a lot about the mechanisms of Parkinson's disease and now know that the condition is caused by both genetic and environmental factors. It is now very clear that when coupled with a genetic risk factor, exposure to several chemicals, most notably solvents and certain pesticides, can trigger the disease. Just eight weeks ago, a study out of Canada suggested low-level exposure to pesticides disrupts cells in a way that mimics the effects of mutations known to cause Parkinson's.[1] More research is needed to fully understand the mechanisms at work and how to prevent them.

Many of the studies used to identify risk factors for Parkinson's disease are investigated via large population based epidemiology studies and will be impacted by EPA's proposal. I am going to highlight one clear example- though along with my health and science colleagues here today, we can provide hundreds of examples of studies that could impacted.

A 2009 study used GPS to estimate participants' well-water contamination exposure from agricultural pesticides. The results showed that consuming water from a private well located in an area with historical pesticide use resulted in an increased risk of Parkinson's disease.[2] Due to the nature of wells — typically serving a relatively limited number of people within a very small radius — the detail needed to perform the study renders proper de-identification impossible. All one needs to know is that a certain person lives near a particular well along with a demographic detail such as their age, gender, race, etc., and privacy is at great risk.

Data from studies like this cannot be de-identified to the degree needed to protect patient's identification while still providing the amount of specificity needed to help a scientist trying to replicate the results. Obtaining consent is not a solution. Some people make the choice to not disclose their Parkinson's diagnosis for a variety of reasons including privacy concerns, fear of prejudice or retaliation at work, and others. It is simply unreasonable to put people in the position of outing their diagnosis or to decline to participate in a study that could someday find a cure for their condition. Additionally, people who are willing to sign away their privacy and those who are not are different in ways we cannot predict or control for in study analysis.

The Michael J. Fox Foundation believes in open, reliable, and replicable science. We fund approximately 90 million dollars in research per year and hold our funded scientists to the highest standards. Our contracts require studies to be peer reviewed and most require data to be

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[1] Stykel, Morgan G. et al. "Nitration Of Microtubules Blocks Axonal Mitochondrial Transport In A Human Pluripotent Stem Cell Model Of Parkinson's Disease". *The FASEB Journal*, 2018, p. fj.201700759RR. FASEB, doi:10.1096/fj.201700759rr. Accessed 17 July 2018.

[2] Gatto, Nicole M. et al. "Well-Water Consumption And Parkinson'S Disease In Rural California". *Environmental Health Perspectives*, vol 117, no. 12, 2009, pp. 1912-1918. *Environmental Health Perspectives*, doi:10.1289/ehp.0900852. Accessed 17 July 2018.

as available as possible while protecting precious health data. We echo the call of our fellow public health groups here today and the nearly seventy public health, science, academic, and medical groups who signed on to a joint statement calling for the rule to be abandoned for the sake of science and for our health. Thank you.

CLEAN AIR TASK FORCE

Comments of James Duffy, Clean Air Task Force, Associate Attorney
at Strengthening Transparency in Regulatory Science Public Hearing
July 17, 2018, Washington DC

Good afternoon, my name is James Duffy and I am an associate attorney with Clean Air Task Force. CATF seeks to help safeguard against the worst impacts of climate change by working to catalyze the rapid global development and deployment of low carbon energy and other climate-protecting technologies, through research and analysis and public advocacy leadership.

EPA's Proposal, at best, is a solution in search of a problem – the Agency has failed to identify a need for further review of the already, extensively peer-reviewed public health and environmental science it uses in decision-making. Nor has it made the case that underlying health data must be made more public that current statutes and practice allow. The only thing transparent about the Proposal, is that it is an attempt to undermine EPA's use of the "best available science" by placing arbitrary limits on the ability to consider the best studies.[1] As the professor cited multiple times in the Proposal recently said, if the Proposal is finalized, "science will be practically eliminated from all decision-making processes," so that public health and environmental "regulation would then depend … on opinion and whim."[2]

Banning the use of fully peer-reviewed studies because their underlying data must be kept confidential would eliminate the consideration of vital information in critical public health decision-making. That is not only unnecessary, it also represents a significant shift in decades-long policy, without justification.[3] As the D.C. Circuit has held when considering this very question: "requiring agencies to obtain and publicize the data underlying the studies on which they rely would be impractical and unnecessary."[4] Congress has clearly spoken, moreover, mandating that Agencies must consider *all* relevant science.[5]

It is well understood, and has been for decades, that many of the most important public health studies are those based on actual patient information. Because that information must be kept highly confidential, and because making even some of the patient's details public would allow them to be identified, the information must be kept private.[6]

But that does not mean those studies can't be - or haven't been - verified. For example, the Harvard Six-Cities Studies, linking fine particulate matter and mortality, have been extensively re-analyzed by independent institutions, including by researchers under the auspices of the Health Effects Institute. This reanalysis confirmed the studies essential findings while keeping confidential the underlying data.[7]

There are already several ways in which the public can access the studies that EPA uses, and in some cases their underlying data, without the release of confidential information - including the Freedom of Information Act, which provides an avenue to request raw data, including a process ensuring that sensitive data is protected.

The Proposal puts EPA in the untenable position of either violating its mandate to consider all relevant science or violating confidentiality laws.

Additionally, the Proposal is impermissibly scattershot, vague and confusing. It is insufficiently formed to allow for meaningful comment – it seems more like a request for ideas about how to discredit the best available science, than for how to make it more accessible.[8] For example, the Proposal claims that it is consistent with the Data Quality Act and HIPAA, as well as various Executive Orders, but each of these contains checks on the release of confidential information. In fact, the longstanding OMB Guidelines, stemming from the Data Quality Act, recognize peer review as a *per se* marker of objectivity, and the Harvard Six Cities Studies reanalysis as the gold standard for reproducibility.[9]

Finally, in violation of Executive Order 12,866, the Proposal fails to perform any analysis regarding the impact this rulemaking could have on the environment, public health or science generally - or even on what it would cost to implement. Because the Agency does not have authority to undertake this effort, and because it would undermine consideration of relevant science in its public health and environmental rulemakings, it should be abandoned.

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[1] Bob Sussman, "EPA's Flawed 'Secret Science' Plan Puts Good Science at Risk," BLOOMBERG BNA (May 21, 2018), *available at*: https://www.bna.com/practitioner-insights-epas-n57982092715/.

[2] John P. A. Ioannidis, *All science should inform policy and regulation*, 15 PLOS MED. 5 (May 3, 2018).

[3] EPA has long held that "whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications." EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (Nov. 29, 2016) (emphasis added).

[4] *Am. Trucking Ass'ns v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2001); *Coal. of Battery Recyclers Ass'n* v. EPA, 604 F.3d 613, 623 (D.C. Cir. 2010) (same).

[5] 5 U.S.C. § 553(c) (requiring "consideration of the relevant matter presented"). *Hercules, Inc. v. EPA*, 938 F.2d 276, 289 (D.C. Cir. 1991)(rejecting "the EPA's action because it reads into the statute a drastic limitation that nowhere appears in the words Congress chose and that, in fact, directly contradicts the unrestricted character of those words.").

[6] National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties*, at 11 (2002), *available at*: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing.

[7] *Id.* at 11-12

[8] *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977).

[9] 67 Fed. Reg. 8,452, 8,456 (Feb. 22, 2002).

As a retired EPA toxicologist, I know first hand the frustrations of having to deal with epidemiological reports. However, I believe epidemiological reports are valuable but more critical initial review is needed. Today I hope to present a path forward.

The animal studies required to support the registration of a pesticide follow strict, quality assurance, good laboratory practices, ethics and reporting standards. Multiple layers of primary and secondary reviewers are identified and sign the review documents.

Epi reports have a mixed bag of standards for GLP, quality assurance, ethics and reporting. They are often accepted at their face value without documentation of independent review. There is no way to verify the procedures or results presented and the EPA reviewers are not identified.

This is unfair to the public!

Historically, I would like to mention two situations where a more critical initial evaluation would have prevented social or medical problems.

The first is the book "The Kallikak Family" published in 1912 by Henry Goddard. This book was the foundation of "eugenics" and was "well received" at first but serious social consequences resulted. However, closer examination revealed that much of the interviewing reflected the biases of the interviewers. Goddard later regretted writing the book.

The other is the association of vaccinations with autism that could not be verified. The publisher retracted the original

publication. However, within the past year there was an increase in measles in Minnesota because people feared autism from vaccinations.

With the concepts of disparity in the review of animal versus epidemiological studies and the need to provide a more critical initial review of epi reports, I am proposing that:

An Epidemiology Peer Review Council with the goal of creating a transparent document reflecting a thorough review be established by EPA. This Council will consist of six independent sub-committees with relevant experts as follows:

1. **Ethics**: All aspects of assuring the personal safety and identities of the individuals in the cohorts are protected. Will state clearly why individual protected personal data is or is not needed to make a decision.
2. **Endpoint evaluation:** Relevant experts knowledgeable about the endpoint will discuss factors like how many in a cohort are needed to make a meaningful difference. Identify what is known about how this endpoint can be altered by environment and any known chemicals.
3. **Exposure evaluation**
4. **Statistical evaluation**
5. **Analytical Chemistry**
6. **Animal Toxicity and Structure Activity Correlations**

Each sub-committee will articulate why additional date are or are not needed.

The Council will consist of qualified individuals from EPA, FDA or other agencies and consultants as needed. The Council will consider the reports of the six sub-committees and make their

recommendations especially with regard to additional data needed to support transparent regulatory decisions.

The report of the Council will append each of the six sub-committee reports as well as any dissenting opinions.

The Council owns the decisions and since all responsible individuals will be identified, the report is thus transparent. SAPs may further review the Council report.

In conclusion, controversies associated with epidemiological reports may not be eliminated but the Council should contribute to minimizing these controversies.

John D. Doherty, Ph.D.
(DABT 1982-2017)
email: Personal Email / Ex. 6

Statement of Lynn R. Goldman, MD, MS, MPH

July 17, 2018

Submitted to: the US Environmental Protection Agency
Comments on EPA Proposed Rule: "Strengthening Transparency in Regulatory Science"

I am a pediatrician and an epidemiologist and have been Dean of the Milken Institute School of Public Health at the George Washington University since 2010. From 1993 through 1998, I served as Assistant Administrator for Toxic Substances at the US Environmental Protection Agency leading what is now known as the Office of Chemical Safety and Pollution Prevention. While serving in that position, I was responsible for the implementation of the nation's pesticide and chemicals laws. I am a member of the National Academy of Medicine. My comments represent my expertise as an environmental health scientist, and a former EPA official, and not the views of any one organization.

This NPRM suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as the scientific community, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision-making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking, thus freezing EPA's risk assessment processes in the future and breaking the important separation between risk assessment and risk management that has been fundamental to science based decision-making.

Lack of Justification for the Proposed Rule:

First, why does EPA think that this proposed rule is necessary? No justification is given in the preamble. In 2013, our paper in *Environmental Health Perspectives* documented the use of the Information Quality Act for requests for raw data.[1] We found little evidence for unfulfilled demand for more access to raw data. If, during that ten year period, EPA had accumulated datasets for all raw data for all dose response assessments that had been conducted, it would have been a tremendous waste in terms of 1) *delays* in EPA conducting assessments until data

[1] Goldman, L.R. and Silbergeld, E.K. Assuring access to data for chemical evaluations. Environ Health Perspect, 121(2):149-52, 2013.

were obtained; 2) *costs* to the academic community in preparing datasets and extensive meta data files for EPA for all of their studies; 3) *expenditure* of agency staff resources in EPA compelling the submission of the data from academics; and 4) *EPA staffing and funds* for establishing and maintaining systems to house, protect and make available the raw data.

The proposal ignores the "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences[2] and the National Toxicology Program[3]. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments. As a corollary, they have never concluded that scientific findings should be disregarded if "raw data" for dose response assessments are not available.

Costly to EPA and the Research Community

While at EPA I learned that risk assessment activities at EPA are extensive; not only the flagship IRIS program, but several regulatory programs are actively engaged in performing more than 1,000 risk assessments per year (a 1996 estimate). Such assessments are required under a number of EPA's statutes, for example: premarket notification for chemicals; assessments of priority air standards; pesticide tolerances; drinking water MCLs; and assessment of existing chemicals risks. The burdens for these assessments under the proposed rule are likely to be considerable. The proposal does not consider, across hundreds of assessments performed annually, the costs to the U.S. EPA and researchers, the significant time and paperwork burdens for researchers, and major regulatory delays that will occur when EPA is waiting for data to be made publicly available, which may not ever happen. It does not address how EPA could compel the submission of such data in the context of weak regulatory authority for research conducted in the past; studies not funded by the U.S. government; and/or research conducted abroad. It seems unaware of the Paperwork Reduction Act that tilts against information gathering from private parties. The U.S. EPA is further constrained by industry confidential business information (CBI) claims for regulatory testing data under U.S. chemical and pesticide laws; even when the EPA receives raw data from industry, it provides only data summaries to the public. For whatever data it could obtain, EPA would have to establish a public data repository for this information that would securely house not only the data (especially personal health information and/or CBI) but also a number of unique meta data elements required to understand the data.

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[2] National Academies of Sciences, Engineering, and Medicine. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press. https://doi.org/10.17226/25086.

[3] Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. 2014. Systematic review and evidence integration for literature-based environmental health science assessments. Environ Health Perspect 122:711–718; http://dx.doi.org/10.1289/ehp.1307972

Risk of Disclosure of Personal Information for Human Subjects

To manage risks of disclosure of sensitive human data, the EPA would have to perform checks to assure that no personal health information would be in public data sets. We live in a day when not only name&date of birth, name&address, social security number and/or medical record number can be used to identify person but when massive quantities of "big data" are on the web. Most recently, the renowned geneticist Craig Venter and colleagues reported identified persons using their genetic code alone.[4]

Sound Science Will be Excluded from EPA Regulatory Decisions

The predictable result of this proposal is that EPA will be forced to exclude studies that should be included in a systematic review. For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base of knowledge underpinning EPA's decisions. While the NPRM includes a provision for the EPA to waive this requirement, it provides no clear criteria for such waivers and appears to be a process that would allow arbitrary and capricious application of the proposed rule.

Reversal of EPA Science Policy and Precedents

The proposal seems to attempt, via a single rulemaking, to overturn years of well-thought EPA science policy guidelines and precedents in the selection and application of dose-response models for toxicity assessment. It misrepresents the recommendations of prior expert reviews such as the so-called NAS "Silver Book"[5] and the Bi-Partisan Commission review[6]. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. The NPRM seems to naively assume that single studies are used to inform risk assessors of the possible shape of dose response curves. That was true at one time, but today, the first step of the dose-response modeling process is to evaluate all of the scientific information to gain a biological understanding of how each type of toxicity or response (adverse effect) occurs, the "mode of action". This is not done via modelling of raw data from a single study. When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens. According to the NAS "Silver Book", often noncancer

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[4] "Here, we show that phenotypic prediction from WGS data can enable reidentification without any further information being shared. If conducted for unethical purposes, this approach could compromise the privacy of individuals who contributed their genomes into a database. In stratified analyses, we see that risk of reidentification correlates with variability of the cohort. Although sharing of genomic data is invaluable for research, our results suggest that genomes cannot be considered fully deidentifiable and should be shared by using appropriate levels of security and due diligence." From: Christoph Lippert, Riccardo Sabatini, M. Cyrus Maher, Eun Yong Kang, Seunghak Lee, et al. Genomics of physical traits, PNAS Sep 2017, 201711125; DOI: 10.1073/pnas.1711125114

[5] National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. https://doi.org/10.17226/12209.

[6] Bipartisan Commission. Improving the Use of Science in Regulatory Policy, Washington, DC. 2009

effects (such as, lead and other neurotoxic substances) also have no practically identifiable thresholds. More fundamentally, this NPRM for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that may be dubious today but certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

Conclusion

In conclusion, the proposed rule would cause significant delays in how EPA uses science to make hundreds of regulatory decisions every year. It would overturn years of precedent, as well as advice from scientific experts outside of EPA. It would be burdensome, for the agency and researchers alike.

I strongly urge the EPA Administrator (1) not to use the agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community.

What is at stake is no less than the public's confidence in the integrity of EPA's science and decisions.

Testimony of Walter Tsou, MD, MPH
Executive Director of Physicians for Social Responsibility Philadelphia. July 17, 2018

My name is Dr. Walter Tsou. I serve as Executive Director of Philadelphia Physicians for Social Responsibility and a past president of the American Public Health Association. Thank you for the opportunity to testify on "Strengthening Transparency in Regulatory Science". As many of my colleagues have noted today, while the goal of transparency in how studies are conducted and the ability to reproduce scientific results are important, it can offer a politically motivated Administration a convenient excuse for eliminating or ignoring scientific studies that may go against the wishes of a powerful industry group. All one has to do is demand the data sets be handed over for "further scrutiny" or demand that the study be repeated before basing a regulation on the study in question.

The very nature of longitudinal public health studies where health and toxins intersect are by design, large, expensive and require years or decades before results are found. Sample sizes can often number in the tens of thousands to millions of data points and may need to be collected over many years before a statistically significant finding is identified. For example, Curry, et al studied in Pennsylvania babies who lived within 1 kilometer of active fracking wells. She had to review over 1.1 million birth records before demonstrating the relationship between living close to gas wells and low birth weight babies. Because these studies are so big, they are often too expensive to repeat. In our state of Pennsylvania, scientific research on fracking is actively stymied or suppressed. In a state where billions are made on gas drilling, only one part time contractor at the Health Department collects data on health complaints from fracking. Those who do have health complaints have to sign non-disclosure agreements and not cooperate with any research in order to get life saving water to drink. This extortion practice is common in the industry in order to suppress any health studies on the dangers of fracking. If the transparency regulation was in place, all health studies on fracking would be simply not considered because the research could not be conducted due to non disclosure agreements.

Today there is no reputable scientist that doesn't believe in the harmful effects of smoking. The health studies on smoking were 15 years in the making before the Surgeon General released his landmark report. And except for a handful of EPA administrators, there is no reputable scientist who doesn't believe that climate change is real and is man made. The studies on climate change and health have been known since Exxon wrote about it in 1977. If these transparency rules were in place when the EPA was founded, smoking would still be in airplanes and no one would have heard of "greenhouse gases" or "global warming", the greatest threat to our planet's existence.

Since the founding of the EPA, independent scientific research has been the foundational basis of your mission. Science is the cross before the corporate devil. This transparency rule would destroy the confidential nature of research and make the burden of conducting research more difficult and expensive. Finally, the real purpose of these rules is to reverse regulations on industries who have been harmful to public health. We should let science speak the truth and the EPA should hear from all scientific studies, not just the ones the industry wants you to listen to. Thank you.

July 17, 2018

Public Testimony to US EPA

RE: Proposal to "Strengthen Transparency in Regulatory Science"

FROM : Albert Donnay, MS, MHS, Donnay Detoxicology LLC, albert@donnaydetox.com

My name is Albert Donnay, and my comments are based on experience gained from over 40 years of working on regulatory science as an environmental health engineer and toxicologist, as a research scientist, public health activist, clinician, consultant, and peer-reviewer for academic journals, environmental groups, and government agencies at all levels, including EPA.

EPA's proposal to "Strengthen Transparency in Regulatory Science" does not include any examples of regulations that have been undermined by a lack of such transparency, so I'd like remind to everyone of what is at stake, and what happened the first time EPA, Congress and environmental groups had to decide whether it was ok to base regulatory standards on published scientific studies whose archives were no longer available for review. They got the answer right then, and I hope they'll get it right again now.

It was May 1983, and EPA was about to publish a new NAAQS for carbon monoxide based on 9 studies by a distinguished cardiologist at the VA, Dr. Aronow, when the Washington Post reported that he had been barred by FDA a year earlier for submitting a "wave of false medical experiments" after he admitted "fudging" his lab reports in human drug studies. Although EPA's head of Air Quality Planning and Standards said the agency had "no reason to believe anything was wrong" with Aronow's CO studies--whose data Aronow claimed "Are excellent and can't be questioned"--EPA nevertheless appointed a special team of agency and outside scientists to review his work "when we read that Aronow had done some kooky things."

A month later, the Post reported the shocking results under the headline "EPA Probe criticizes a study used in air-quality standard." The team "could not resolve the issue of possible falsification of data" because "no data were available"--Aronow told them he had discarded the archives of all his CO studies after first storing them in his garage and then offering it to EPA because "they didn't want it."

The investigators noted "considerable concerns about the validity of the results reported.... Raw data were lost or discarded, adequate records were not maintained, available data were of poor quality, quality control was non-existent"--while Aronow's published results were consistently too good to be true. They found it "rather remarkable" that in 10 years of research his papers showed "not even one missing data point." They concluded that EPA "cannot rely on Dr. Aronow's data due to the

concerns we have noted" and recommended that the agency commission new research to attempt to replicate Aronow's findings. Congressional hearings and a GAO investigation followed, after which Administrator Ruckelshaus agreed that EPA would not rely on any of Aronow's studies in future rulemakings, but only on studies whose archives were still available for review.

In coordination with the California air Resources Board and the Health Effects Institute, EPA commissioned a series of new controlled human exposure studies on CO. and since 1994 has based the CO NAAQS exclusively on just 6 of them, all of which published their individual results in de-identified form so they would be available for public review in perpetuity. And it is a good thing they did since all the larger archives of these studies were eventually discarded by their authors without being offered to EPA. This history shows that EPA can and should base regulations solely on studies whose methods and data are available for review.

To base regulations on studies that can't be re-analyzed is not science and there is no need for it. Even federal rules that are based only on older epidemiology studies–like the last PM NAAQS rule in 2013 that cited just six—could and should be based on more recent research that better reflect current air quality. Over 500 studies a year are now published on particulate epidemiology and many are in high quality journals that require authors to make all their de-identified data and methods available-- at least to reviewers if not to all readers via the posting of supplemental material.

Given EPA's interest in basing regulations on more transparent research, EPA should start requiring all of the researchers it funds, both intramural and extramural, to publish their results in such journals. Hopefully this will prompt less rigorous journals that don't require the posting of supplemental material to update their policies.

The Aronow scandal shows EPA cannot rely exclusively on traditional peer-review to detect misconduct. He duped reviewers at 11 leading journals as well as EPA staff and their scientific advisors on the CASAC who also reviewed his studies before recommending that 9 be cited as the basis for the CO NAAQS. Unfortunately, despite all this publicity, none of Aronow's CO studies were retracted and EPA has started citing them again, most recently in its 2010 Integrated Science Assessment of the CO literature. EPA's proposal to strengthen transparency in regulatory science could stop this from happening again, which is why I support it and encourage my colleagues to do so as well.

# # #

Dr. Andrew Rosenberg Union of Concerned Scientists

Good morning. I am Dr. Andrew Rosenberg, Director of the Center for Science and Democracy at the Union of Concerned Scientists. We advocate for the role of science in public policy. I am here today to ask that you rescind this proposed rule because it would only restrict EPA's ability to use the best available science to fulfill its mission of protecting public health and the environment, while doing nothing to improve transparency in decision-making.

First and foremost, this proposal is fatally flawed because it provides almost no justification or analysis of the impacts of the proposed change in policy. There is no cost benefit analysis of the rule with respect to the agency and external researchers, nor how it would affect EPA's mission-critical work.

Additionally, the proposal would effectively prevent the EPA from using many kinds of scientific studies vital to its decision-making. This includes, but is not limited to, studies that rely on personal health data, confidential business information, intellectual property, or older studies where the authors or data sources may not be accessible. Without the ability to use this scientific information, EPA would be unable to meet its mission and statutory obligations . This proposal would make it significantly harder for EPA to use the best available science to protect the public, including from:

- Harmful emissions of hazardous air pollutants, particulate matter and ozone
- Exposure to dangerous chemicals in commerce
- Drinking water contaminated with toxic chemicals such as PFAS or lead

Further, CBO has calculated that such restrictions would substantially increase costs and burdens to an agency that is already experiencing budget cuts, reorganizations, and understaffing, thus undermining the ability of EPA to make decisions based on science.

The proposed rule could also prevent the agency from addressing the impacts of dangerous chemicals at low concentrations where direct measurements are very difficult. This would have the effect of leaving Americans unprotected even when there was clear indication of harms to human health.

I have over 30 years of experience in government service, academia, and non-profit leadership. I have authored or reviewed 100s of peer reviewed scientific papers. As part of my government service, I worked as a scientist and in a policy position at a regulatory agency. In universities as a faculty member and dean. I understand how agencies use science in policymaking, how research at universities is conducted, and how these entities incorporate best practices of transparency into their scientific work. As a frequent peer reviewer I do not review the raw data for studies, since that would tell me little. I review the research questions, the methods, the summarized data, the results and conclusions in order to assess the quality of the work. EPA's proposed rule would do nothing to improve transparency for scientists, policy-makers or the public. Crafting the rule without consulting with the scientific community is a fatal error for this proposal. Even the agency's own Science Advisory Board has noted the need to consult with scientists in any further development of this proposal.

A further fatal flaw is that the proposed rule would replace scientific evidence with political judgement. The rule would grant the EPA administrator broad authority to exclude individual studies or entire decisions from being subject to its provisions. Decisions on what science to rely on should be made by the agency's scientific experts based on established criteria for best available science.

Five minutes is not enough time to cover all of the problems with this proposal. At best, this proposed rule is a misguided attempt at transparency. At worst, it is a backdoor attempt to prevent EPA from protecting public health.

UCS supports real transparency reforms . We support scientific integrity policies that prevent political interference in scientific analyses and reporting. We do not believe researchers should be put in the absurd position of choosing between protecting study participant privacy or informing the EPA 's efforts to protect public health and safety.

On behalf of the Union of Concerned Scientists and our 500,000 supporters I urge the EPA not to move forward with this rulemaking and to continue to allow the agency's scientists and policy analysts to use the best science available to inform their work.

EPA Hearing on Transparency in Data July 17, 2018
Testimony of Anne Mellinger-Birdsong, MD, MPH, FAAP

Hello. Thank you for allowing me to speak today. My name is Anne Mellinger-Birdsong. I am a Fellow of the American Academy of Pediatrics and a specialist in environmental public health. I have worked at city, county, state, and federal public health agencies and at Indian Health Service facilities.

I am here to speak in opposition to this proposed rule and to state that this proposed rule is unnecessary and would harm EPA's ability to evaluate health impacts of environmental pollutants. It should not be finalized or implemented.

This proposal has wording that makes it appear noble and well meaning. But it is a wolf in sheep's clothing. This proposal will severely hamper EPA's ability to use past and future research on health effects of human exposure to environmental chemicals and toxicants.

Both the Health Insurance Portability and Accountability Act (HIPAA)(1) and 45 CFR 46 Federal Regulations on Protection of Human Subjects(2) address privacy as a concern of people who participate in research.

It is not as simple as redacting data personally identifiable information redacted, as EPA officials stated when announcing this proposed rule. If the database is open to the public, it not only has to have personal identifiers redacted, it also has to not include information that can be used to figure out who a person is that participates in a study. For example, studies that examine air pollution contain research on heart attacks. If the data contains information about person X, age Y, in town A, who had a heart attack in July 2015, that might be sufficient information to identify who person X was. So even though the data does not contain name, birthdate, medical record number or other personal identifiers, people could still use the data to figure out who person X is. Therefore HIPAA and Human Subjects rules would prevent this data from being publicly available, and this rule would prohibit this study from being used.

All environmental studies require information on exposure to the substance or chemical being studied. Many studies do this by using residence zip code or census tract. Studies also use information on travel or commuting routes, school, or work locations. So again, residence data combined with age group data and disease information (asthma attack, hospital admission, etc.) could be used to identify people in studies. Some studies look at death due to exposures, others look at illness, symptoms, or hospital admissions of living people. Living people require more protections of their identity than studies of deceased people. Studies of children have even more human subjects protections.

People who participate in studies have concerns about the trustworthiness of the researchers and institutions, as noted by Carter et al in British Medical Journal (3). They also have concerns that private companies will not use their health data for marketing or other purposes that might be considered exploitive.

And as noted by Damschroder et al in Social Science & Medicine (4), people's trust in the researchers was the most powerful determinant of the kind of control they want over their medical records.

This proposed rule would eliminate consideration of many major studies on the health impacts of environmental pollutants. An example of one would be the 6 Cities study of air pollution and mortality published in 1993 (5). Probably the Children's Health Study conducted in southern California (6) would also be eliminated.

It would also likely decrease people's willingness to participate in future studies of environmental exposures, due to concerns about trust and privacy.

This rule is unnecessary. There are already HIPAA compliant and IRB approved methods to transfer data between researchers so that studies can be evaluated and verified, and to determine if findings can be replicated.

This rule would severely hamper EPA's ability to use already published scientific studies. It would also severely hamper future research on health effects of environmental exposures.

So I ask: why was a rule was proposed that would eliminate use of scientific studies and hamper future research, when the rule is completely unnecessary. This rule should not be finalized or implanted.

I will end with a quote by Carnegie Mellon University engineering professor M. Granger Morgan, who chaired EPA's Science Advisory Board under Republican President George W. Bush. He said the policy 'is an attempt by people who aren't interested in using science to find the truth "to raise doubts about what at this stage is very clearly established and well-reviewed science."'(7)

Anne Mellinger-Birdsong, MD, MPH, FAAP
Personal Email / Ex. 6
Personal Email / Ex. 6

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Comments of Barbara Gottlieb
to the U.S. Environmental Protection Agency
Concerning "Strengthening Transparency in Regulatory Science"
Docket ID No. EPA-HQ-OA-2018-0259

July 17, 2018

Good morning. My name is Barbara Gottlieb. I am the director for environment and health at Physicians for Social Responsibility, a physician-led, nationwide organization that works to protect human life from the gravest threats to health and survival. I'm here to express Physicians for Social Responsibility's opposition to the proposed rule, "Strengthening Transparency in Regulatory Science."

The U.S. EPA plays a critical role in keeping our nation and our families safe from environmental exposures that can cause illness and death. We thank you for that – and we count on you for it. Because your role is vital to our health and well-being, the nation relies on you to formulate and enforce the most effective protections possible, based on the best available science. The medical and scientific studies that underlie the EPA's decisions must be objective, vetted, and present a full and accurate assessment of the threats to health posed by the pollutants under study.

To provide those full and accurate assessments, studies need to relate exposure levels to actual health outcomes in real human beings, and to amass large data bases so that researchers can draw valid conclusions.

In order to have reliable data and large sample sizes, researchers frequently study the records of patients treated in hospitals. Hospital records, of course, include personal identifiers, and disclosure of those identifiers would violate privacy and confidentiality laws. Thus, the best available data for many health studies cannot be – in the literal sense – fully and openly shared.

However, to refuse to consider scientific studies simply because they include personal identifiers would be a great mistake. First of all, it is not necessary. Reviewers wanting to reproduce a study in order to validate it can arrange to have confidential access to key data. Furthermore, scientists can assess the merits of published research without seeing its data directly by considering such publicly released features as the study's research design, the methods used for data collection and analysis, and comparisons with previous results.

Furthermore, to exclude credible peer-reviewed scientific studies because the personal identifiers cannot be released under the law, is to exclude from the EPA's consideration many important and valid studies. This would greatly hamper our ability to understand the impacts of serious, even deadly, environmental pollutants. Several of my colleagues will testify later today to the potential impact of this proposed rule on our understanding of pollutants from coal-fired power plants, and children's exposure to lead in drinking water. I would like to bring your attention several other studies that also might be lost to consideration, yet are vitally important. These are studies that reveal statistical correlations between exposure to emissions from hydraulic fracturing ("fracking") for oil and gas, and serious impacts on health. I will mention three:

1. A study by University of Pennsylvania and Columbia University researchers and published in 2015 in the journal *PLoS ONE*, found that drilling and fracking activity was associated with increased rates of hospitalization in Pennsylvania. The study examined hospitalization data between 2007 and 2011 and found that inpatient prevalence rates surged for people living near shale gas wells, in regard to hospitalizations for cardiology, neurology, cancer, skin conditions, and urological problems. In communities with the most wells, the rate of cardiology hospitalizations was 27 percent higher than in control communities with no fracking.[1] These findings obviously are of great concern; we would not want them to be lost to the EPA as it considers regulation of emissions from fracking sites and infrastructure. Yet because the data include patients' names, diagnoses and addresses, this valuable study could under the proposed rule be excluded from EPA consideration.

2. Another study conducted in Pennsylvania, this one between 2005 and 2012, found that living near fracking operations significantly increases asthma attacks. This study was conducted by researchers at Johns Hopkins University and was based on a study of 35,000 medical records of people with asthma in north and central Pennsylvania.[2] Again, 35,000 medical records. This is just the sort of study that we want EPA to base its health-protective regulations on: a robust and objective database, conducted by researchers at a respected institution and published in the *Journal of the American Medical Association Internal Medicine*. Yet should the proposed rule be adopted, this study could be disallowed because its 35,000 medical records cannot easily and efficiently be stripped of personal identifiers.

3. One final study. This study, by the Johns Hopkins Bloomberg School of Public Health and other researchers, used data from the Geisinger Health System on 9,384 pregnant women and their 10,496 newborns between January 2009 and January 2013. Looking at 40 counties in north and central Pennsylvania, the researchers developed an index for proximity to fracking wells based on distance from the women's homes, stage of drilling and depth of wells dug, and the amount of gas that was produced at those wells during the pregnancies. They found that pregnant women who lived near active fracking operations in Pennsylvania were at a 40 percent

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[1] Jemielita T., Gerton G. L., Neidell, M., Chillrud S., Yan B., Stute, M., . . . Panettieri, Jr., R. A. (2015), Unconventional gas and oil drilling is associated with increased hospital utilization rates. PLoS ONE 10(7), e0131093. doi: 10.1371/journal.pone.0131093

[2] Rasmussen, S. G., Ogburn, E. L., McCormack, M., Casey, J. A., Bandeen-Roche, K. Mercer, D. G., & Schwartz, B. S. (2016). Association between unconventional natural gas development in the Marcellus Shale and asthma exacerbations. JAMA Internal Medicine. Advance online publication. doi: 10.1001/jamainternmed.2016.2436

increased risk of giving birth prematurely.[3] Let me remind us that premature birth is the leading cause of infant death in the United States. So we're talking about health data that indicate that fracking operations could put newborn babies at risk of death. This study was published in the peer-reviewed journal *Epidemiology*.

Our country, our families, should have the benefit of these studies to assess the health implications of unconventional oil and gas development activities. Similarly, we should have the benefit of many robust scientific studies, on a range of critical health issues, that use data that cannot be released publicly in full because it includes personal identifiers. To exclude that body of peer-reviewed research findings would be to weaken the scientific record and undercut the accuracy and the strength of EPA's regulatory process. For that reason, Physicians for Social Responsibility opposes the proposed rule, "Strengthening Transparency in Regulatory Science." Thank you.

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[3] Casey, J. A., Savitz, D. A., Rasmussen, S. G., Ogburn, E. L., Pollak, J., Mercer, D. G., & Schwartz, B. S. (2016). Unconventional natural gas development and birth outcomes in Pennsylvania, USA. Epidemiology 27(2), 163–172. doi: 10.1097/EDE.0000000000000387

STATEMENT OF ROBERT SUSSMAN ON EPA's PROPOSED RULE ON TRANSPARENCY IN REGULATORY SCIENCE -- July 17, 2018

My name is Bob Sussman. I'm a former EPA official in the Clinton and Obama Administrations and am now a consultant and attorney. I'm here today representing Safer Chemicals Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use every day.

I believe that EPA proposal we are discussing today is flawed and misconceived. In the name of "transparency," it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The unspoken premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on human health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of study results.

Study reports typically explain the protocols used to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of such effects, and any unusual occurrences that may affect interpretation of the results. This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk. In its narrow focus on a single criterion for study acceptability, the proposal departs from this comprehensive, multi-faceted approach for determining the "best available science" to inform decision-making.

In principle, no one disputes the benefits of improving access to underlying data for research on chemicals and pollutants. The goals of "open science" have received support from several organizations and leading scientific journals and

research institutions have adopted practices and policies to maximize data access. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data. Analyzing House legislation that would impose similar obligations on EPA, the Congressional Budget Office and EPA staff concluded that the costs of implementation would be at least $250 million a year. Moreover, rather than devoting time and effort to assuring access to underlying data, EPA staff may follow the path of least resistance and simply drop many studies from consideration, shrinking the body of scientific evidence on which decisions are based.

Even with diligent effort by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. For epidemiology and other studies of human cohorts, privacy protections will often block release of individual medical records. Industry-conducted studies may contain confidential business information (CBI) required to be withheld by law. For studies based on human exposure measurements, replication may be impossible because exposure conditions have changed. Studies attempting to capture the impacts of one-time events like spills or plant explosions will also be inherently unreproducible. And for older studies predating digital technology, retrieving full study records may be difficult or impossible.

The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis where "compliance is impracticable." But an exemption process will add to the considerable cost and effort required to implement the proposed rule and may result in disputes and even litigation over whether exemptions are justified.

Is the damage it will inflict on the quality and timeliness of EPA science justified by the benefits of the proposed rule? EPA leaders have painted a bleak picture of

EPA reliance on "secret science" developed behind "closed doors" "based on data that has been withheld from the American people." But is this the reality?

EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record, even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review. And members of the regulatory community are free at any time to replicate studies they deem flawed or to independently seek access to underlying data and reanalyze them. In short, the "problem" that the proposed rule seeks to fix is largely imaginary.

In conclusion, the Agency's leadership needs to fundamentally rethink this proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize this deeply problematic and unnecessary proposal.

HEI

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Comments of Daniel Greenbaum, President
Health Effects Institute (HEI)
July 17, 2018

HEI Comments on Proposed Rule EPA–HQ–OA–2018–0259; FRL–9977–40–ORD

HEI is pleased to have the opportunity to present these brief oral comments. We are preparing and will submit more detailed written comments

1. HEI has a longstanding commitment to the principles being addressed by this proposal: producing science of the highest integrity and quality, with special attention to issues of reproducibility and transparency. This includes:

    - Rigorous research and statistical design – Subject to competition, continuous oversight, data quality assurance audits, and more
    - Extensive efforts to test all findings against a wide range of different statistical techniques and assumptions
    - Intensive and independent peer review, with *all* results published
    - An active *Data Access Policy* for nearly 20 years to ensure access to underlying data for all HEI-funded studies.

2. Reproducibility is a critical challenge for science: can the results of an important study be reproduced? In HEI's view the most effective way to test the reproducibility and validity of scientific results is not necessarily to simply reproduce the same results in the same data sets -- because that also reproduces all the weaknesses and limitations of the original study. Rather, it is most important to answer the question: *Are the results consistent when tested in other independent studies*:

    - That use new and different data not affiliated with the original studies?
    - Have different investigators applying the same and/or alternative statistical techniques?
    - And test the sensitivity of the results against a wide range of possible other explanations, e.g. smoking behavior, socioeconomic status, access to medical care, and more.

3. In a limited number of cases, where there are not comparable studies in other datasets, it may be useful to gain access to the original study data and analytic codes to allow for independent evaluation: *Can the original results be replicated? And are they robust to a wide range of alternative assumptions, models and potential confounders?*

- This is the approach that HEI applied in its independent, rigorous reanalysis of the Harvard Six Cities and American Cancer Society Studies (see attached description of the Reanalysis):
- This approach can – and did – provide comprehensive assurance of the quality, integrity, and validity of the original results
- However, this is a highly cost-intensive and time-consuming endeavor which should only be applied in cases where there are one or just a few studies in a given area.

4. HEI also agrees with the continuing need to enhance transparency and data access, but would note that these issues are not new, and have been addressed now for over 15 years by administrations from both parties and by the scientific community:

    - This has included Guidelines for the Information Quality Act adopted by the Office of Information and Regulatory Affairs (OIRA) in 2002, numerous actions by the scientific community and journals to enhance access, and most recently the requirements for enhanced data access across the Federal Government promulgated by the Office of Science and Technology Policy (OSTP) in February 2013
    - We would strongly urge EPA to review the progress already made under these several major initiatives, and to carefully consider whether or not there are additional efforts that could further enhance transparency, *before* proceeding with a final rule.

5. Finally, access to private medical information is essential to conducting high quality and reproducible air quality and health research:

    - There are of course longstanding federal rules for protecting the privacy of individual medical information of the subjects of studies (HIPPA, Common Rule, etc.)

    - Gaining access to data from older studies may be difficult, given the privacy commitments that were made to study subjects in the past.

    - However, there *are* today several means to make such data available to investigators with appropriate privacy protections (e.g. Medicare, Federal Research Data Centers) and many investigators have been taking advantage of these.

    - Although it is possible, as some have suggested, to create a "depersonalized" data set by stripping all personal identifiers, such as address, date of birth, etc.
        - *It is not possible to conduct a high-quality air pollution and health study without knowing the locations of those being studied*, i.e. where they live, and what are the sources and levels of their air pollution exposure?

Thank you for this opportunity to testify – we look forward to submitting our detailed written comments and would welcome the opportunity to further assist EPA in these efforts to ensure the widest array of quality science is available for decisions.

ATTACHMENT: The HEI Reanalysis Statement

HEALTH EFFECTS INSTITUTE

STATEMENT

Synopsis of the Particle Epidemiology Reanalysis Project

BACKGROUND

Epidemiologic work conducted over several decades has suggested that long-term residence in cities with elevated ambient levels of air pollution from combustion sources is associated with increased mortality. Subsequently, two prospective cohort studies, the Six Cities Study (as reported in Dockery et al 1993) and the American Cancer Society (ACS) Study (as reported in Pope et al 1995) estimated that annual average all-cause mortality increased in association with an increase in fine particles (all particles less than 2.5 μm in median aerodynamic diameter [$PM_{2.5}$]).

As part of the Six Cities Study, Dockery and colleagues (1993) had prospectively followed a cohort of 8,111 adult subjects in northeast and midwest United States for 14 to 16 years beginning in the mid-1970s. The authors found that higher ambient levels of fine particles and sulfate (SO_4^{2-}) were associated with a 26% increase in mortality from all causes when comparing the most polluted to the least polluted city, and that an increase in fine particles was also associated with increased mortality from cardiopulmonary disease. The relative risks in all-cause mortality were associated with a difference (or range) in ambient fine particle concentrations of 18.6 μg/m^3 and a difference of ambient sulfate concentrations of 8.0 μg/m^3, comparing the least polluted city to the most polluted city.

In the much larger ACS Study, Pope and colleagues (1995) followed 552,138 adult subjects in 154 US cities beginning in 1982 and ending in 1989 (3 cities did not overlap between the 151 and 50 cities studied, resulting in a total of 154 cities). Again, higher ambient levels of fine particles were associated with increased mortality from all causes and from cardiopulmonary disease in the 50 cities for which fine particle data were available (sampled from 1979 to 1983). Higher ambient sulfate levels were associated with increased mortality from all causes, cardiopulmonary disease, and lung cancer in the 151 cities for which sulfate data were available (sampled from 1980 to 1982). The difference between all-cause mortality in the most-polluted city and the least-polluted city was 17% and 15% for fine particles and sulfate, respectively (with a range of 24.5 μg/m^3 for fine particles and of 19.9 μg/m^3 for sulfate).

Both of these studies came under intense scrutiny in 1997 when the EPA used the results to support new National Ambient Air Quality Standards for fine particles and to maintain the standards for particles less than 10 μm in median aerodynamic diameter (PM_{10}) already in effect. Members of Congress and industry, the scientific community and others interested in regulation of air quality scrutinized the studies' methods and their results. Some insisted that any data generated using federal funding should be made public. Others argued that these data had been gathered with assurances of confidentiality for the individuals who had agreed to participate and that the concept of public access to federally funded data did not take into account the intellectual property rights of the investigators and their supporting institutions. To address the public controversy, Harvard University and the ACS requested that the Health Effects Institute organize an independent reanalysis of the data from these studies. Both institutions agreed to provide access to their data to a team of analysts to be selected by HEI through a competitive process.

APPROACH

To conduct the reanalysis, the HEI Board of Directors, with support from the EPA, industry, Congress, and other stakeholders, appointed an Expert Panel chaired by Dr Arthur Upton from the University of Medicine and Dentistry of New Jersey and former Director of the National Cancer

This Statement, prepared by the Health Effects Institute, is a summary of a research project conducted by the Reanalysis Team, led by Dr Daniel Krewski at the University of Ottawa. The following Special Report contains the detailed Investigators' Report (Summary, Introduction, and Parts I and II), Commentary on the project prepared by a special panel of the Institute's Health Review Committee, and Comments on the Reanalysis Project by the Original Investigators (Drs Douglas W Dockery, C Arden Pope III et al).

Institute. The Expert Panel selected competitively a Reanalysis Team—led by Dr Daniel Krewski of the University of Ottawa—and oversaw all aspects of the team's work. They were assisted in their oversight efforts by a broad-based Advisory Board of knowledgeable stakeholders and scientists who, in the project's early stages, provided extensive advice to the Expert Panel on the key questions to be analyzed. The final results of the Reanalysis Team were intensively and independently peer reviewed by a Special Panel of the HEI Health Review Committee, which was chaired by Dr Millicent Higgins of the University of Michigan.

The overall objective of what became the Particle Epidemiology Reanalysis Project was to conduct a rigorous and independent assessment of the findings of the Six Cities and ACS Studies of air pollution and mortality. This objective was met in two parts. In *Part I: Replication and Validation*, the Reanalysis Team sought to replicate the original studies via a quality assurance audit of a sample of the original data and to validate the original numeric results. In *Part II: Sensitivity Analyses*, they tested the robustness of the original analyses to alternate risk models and analytic approaches.

RESULTS AND IMPLICATIONS

PART I: REPLICATION AND VALIDATION

- An extensive audit of the study population data for both the Six Cities and ACS Studies and of the air quality data in the Six Cities Study revealed the data to be of generally high quality with a few exceptions. In both studies, a few errors were found in the coding and inclusion of certain subjects; when those subjects were included in the analyses, they did not materially change the results as originally reported. Because the air quality data used in the ACS Study could not be audited, a separate air quality database was constructed for the sensitivity analyses described in Part II.
- The Reanalysis Team was able to replicate the original results in both studies using the same data and statistical methods as used by the Original Investigators. The Reanalysis Team confirmed the original point estimates: For the Six Cities Study, they reported the relative risk of mortality from all causes associated with an increase in fine particles of 18.6 $\mu g/m^3$ as 1.28, close to the 1.26 reported by the Original Investigators. For the ACS Study, the relative risk of mortality from all causes associated with an increase in fine particles of 24.5 $\mu g/m^3$ was 1.18 in the reanalysis, close to the 1.17 reported by the Original Investigators.

PART II: SENSITIVITY ANALYSES

Once the original results of the studies had been validated, the Reanalysis Team sought to test an array of different models and variables to determine whether the original results would remain robust to different analytic assumptions.

- First, the Reanalysis Team used the standard Cox model used by the Original Investigators and included variables in the model for which data were available from both original studies but had not been used in the published analyses (eg, physical activity, lung function, marital status). The Reanalysis Team also designed models to include interactions between variables. None of these alternative models produced results that materially altered the original findings.
- Next, for both the Six Cities and ACS Studies, the Reanalysis Team sought to test the possible effects of fine particles and sulfate on a range of potentially susceptible subgroups of the population. Although different subgroups did show some variation in their estimated effects, the results were not statistically significant with one exception. The estimated effects of fine particles did appear to vary with educational level; the association between an increase in fine particles and mortality tended to be higher for individuals without a high school education than for those who had completed high school or for those with more than a high school education.
- In the ACS study, the Reanalysis Team tested whether the relationship between ambient concentrations and mortality was linear. They found some indications of both linear and nonlinear relationships, depending upon the analytic technique used, suggesting that the

issue of concentration-response relationships deserves additional analysis.

- In the Six Cities Study where data were available, the Reanalysis Team tested whether effect estimates changed when certain key risk factors (smoking, body mass index, and air pollution) were allowed to vary over time. One of the criticisms of both original studies has been that neither analyzed the effects of change in pollutant levels over time. In general, the reanalysis results did not change when smoking and body mass index were allowed to vary over time. The Reanalysis Team did find for the Six Cities Study, however, that when the general decline in fine particle levels over the monitoring period was included as a time-dependent variable, the association between fine particles and all-cause mortality dropped substantially, but the effect continued to be positive and statistically significant.
- Using its own air quality dataset constructed from historical data to test the validity of the original ACS air quality data, the Reanalysis Team found essentially the same results.
- Any future analyses using the sulfate data should take into account the impact of artifactual sulfate. Sulfate levels with and without adjustment differed by about 10% for the Six Cities Study. Both the original ACS Study air quality data and the newly constructed dataset contained sulfate levels inflated by approximately 50% due to artifactual sulfate. For the Six Cities Study, the relative risks of mortality were essentially unchanged with adjusted or unadjusted sulfate. For the ACS Study, adjusting for artifactual sulfate resulted in slightly higher relative risks of mortality from all causes and cardiopulmonary disease compared with unadjusted data. The relative risk of mortality from lung cancer was lower after the data had been adjusted.
- Because of the limited statistical power to conduct most sensitivity analyses for the Six Cities Study, the Reanalysis Team conducted the majority of its sensitivity analyses using only the ACS Study dataset with 154 cities. In that dataset, when a range of city-level (ecologic) variables (eg, population change, measures of income, maximum temperature, number of hospital beds, water hardness) were included in the analyses, the results generally did not change. Two exceptions were that associations for both fine particles and sulfate were reduced when city-level measures of population change or sulfur dioxide were included in the model.
- A major contribution of the Reanalysis Project is the recognition that both pollutant variables and mortality appear to be spatially correlated in the ACS Study dataset. If not identified and modeled correctly, spatial correlation could cause substantial errors in both the regression coefficients and their standard errors. The Reanalysis Team identified several methods for dealing with this, all of which resulted in some reduction in the estimated regression coefficients. The full implications and interpretations of spatial correlations in these analyses have not been resolved and appear to be an important subject for future research.
- When the Reanalysis Team sought to take into account both the underlying variation from city to city (random effects) and the spatial correlation between cities, only sulfur dioxide as a city-level variable continued to decrease the originally reported associations between mortality and fine particles or sulfate. This effect was more pronounced for sulfate.
- When the Reanalysis Team conducted spatial analyses of sulfur dioxide, the association between sulfur dioxide and mortality persisted after adjusting for sulfate, fine particles, and other variables.
- As a result of these extensive analyses, the Reanalysis Team was able to explain much of the variation between cities, but some unexplained city-to-city variation remained.

CONCLUSIONS

The Reanalysis Team designed and implemented an extensive and sophisticated series of analyses that included a set of new variables, all the gaseous copollutants, and the first attempts to apply spatial analytic methods to test the validity of the data and the results from the Six Cities Study and the ACS Study. Overall, the reanalyses assured the quality of the original data, replicated

the original results, and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality.

At the same time, the reanalyses did extend and challenge our understanding of the original results in several important ways.

- The Reanalysis Team identified a possible modifying effect of education on the relation between air quality and mortality in that estimated mortality effects increased in the subgroup with less than high school education.
- The use of spatial analytic methods suggested that, when the analyses controlled for correlations among cities located near one another, the associations between mortality and fine particles or sulfate remained but were diminished.
- An association between sulfur dioxide and mortality was observed and persisted when other possible confounding variables were included; furthermore, when sulfur dioxide was included in models with fine particles or sulfate, the associations between these pollutants (fine particles and sulfate) and mortality diminished.

In reviewing these results, the Special Panel of the HEI Health Review Committee identified the following factors to consider when interpreting the results from the Reanalysis Team.

- The inherent limitations of using only six cities, understood by the Original Investigators, should be taken into account when interpreting results of the Six Cities Study.
- The Reanalysis Team did not use data adjusted for artifactual sulfate for most alternative analyses. When they did use adjusted sulfate data, relative risks of mortality from all causes and cardiopulmonary disease increased. This result suggests that more analyses with adjusted sulfate might result in somewhat higher relative risks associated with sulfate.
- Findings from spatial analyses applied to the ACS Study data need to be interpreted with caution; the spatial adjustment may have overadjusted the estimated effect for regional pollutants such as fine particles and sulfate compared with the effect estimates for more local pollutants such as sulfur dioxide.
- After the Reanalysis Team completed its spatial analyses, residual spatial variation was still noticeable; this finding suggests that additional studies might further refine our understanding of the spatial patterns in both air pollution and mortality.
- No single epidemiologic study can be the basis for determining a causal relation between air pollution and mortality.

In conclusion, the Reanalysis Team interpreted their findings to suggest that increased relative risk of "mortality may be attributed to more than one component of the complex mix of ambient air pollutants in urban areas in the United States". The Review Panel concurs. In the alternative analyses of the ACS Study cohort data, the Reanalysis Team identified relatively robust associations of mortality with fine particles, sulfate, and sulfur dioxide, and they tested these associations in nearly every possible manner within the limitations of the datasets. Future investigations of these issues will enhance our understanding of the effect of combustion-source air pollutants (eg, fine particles, sulfate, and sulfur dioxide) on public health.

Harvey Fernbach, M.D., MPH
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Subject Environmental Protection Agency 07/17/2018.

"Strengthening, Transparency and Regulatory Science."

EPA-HQ-00-2018-25

I am Dr. Harvey Fernbach, a member of the national board of Physicians for Social Responsibility. Thank you for the opportunity to present my perspective on "Strengthening, Transparency and Regulatory Science." I agree with the strong opposition to this proposal expressed in the 06/01/2018 joint letter of the American Academy of Pediatrics and American College of Obstetrics and Gynecology to former administrator Pruitt as well the 05/31/2018 testimony to the EPA's Science Advisory Board by Lynn Goldman, M.D., formerly of EPA and now Dean of the GW School of Public Health.

The proposal's title is disingenuous since its purpose is clearly aimed at impeding the EPA from getting more peer reviewed environmental studies in a world that is creating a huge number of new chemicals for industry household products and pharmaceuticals. Why would the EPA's political leadership not want to add to the studies? I know they are on the "drill baby drill" ilk, but why would they want to expose themselves and the public to possible adverse health effects of these

new pollutants? Additionally, why is the EPA curtailing the activities of their staff scientists who are so experienced? The public is angered about these negative activities which is turning the Environmental Protection Agency into a misnomer. Perhaps this is why the former head of the EPA was so security conscious.

Many of us here are also interested in transparency in this regulatory agency! For example, the agency knows all the studies of climate change/global warming that has led almost 100 percent of climate scientists to conclude human activity is a significant cause of this development. What is not clear is the derivation of this shameful madness to pollute, make seas rise, melt glaciers, cause animal extinction, raise CO2 level, bring on extreme weather, human migration from crop failures, existential threat to human life and as reported by the Pentagon, more wars.

How can the President and the EPA's leaders knowing the human suffering they are inflicting through their pretend denial keep on doing it? Perhaps the motivation to cause such irreversible sickness and destruction is a cruelty that goes beyond simply wanting to help the fossil fuel industry. Sooner or later, we will see the EPA's terrible behavior as a crime against humanity or at best, depraved indifference.

I urge and plead with the EPA to come to its senses, apologize and get back to their true noble mission and make up for lost time. It is not yet too late!

Harvey Fernbach, M.D., MPH
Physicians for Social Responsibility
National Board

This transcription was made from a recording of the voice of Harvey Fernbach, M.D. and forwarded for signature by Superior/ld on 07/13/2018.

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Proposed Rule "Strengthening Transparency in Regulatory Science"

Docket No. EPA-HQ-2018-0259

Comments from
Janice Nolen, MA
National Assistant vice President, Policy
American Lung Association

July 17, 2018

Thank you for the opportunity to provide comments. My name is Janice Nolen and I am the National Assistant Vice President for Policy for the American Lung Association. The American Lung Association turns 114 years old this year. For more than a century, we have fought to save lives by protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society and they were looking to create a huge database of ordinary Americans who would be willing to provide them with confidential information about their health and medical experiences and would allow them to track for years to come. I was so pleased that two men from my church choir in Nashville agreed to participate. They completed the forms and other paperwork, and became two of the more than half a million participants in the Cancer Prevention Study II.

Fast forward a few decades and I learned that their data were now part of a landmark study—the American Cancer Society study--that revealed the risks to human health from breathing air pollution that I and my colleagues at the Lung Association were working hard to clean up. Their data and private health and medical data from hundreds of thousands of others were pointing the way to the need to clean up emissions from power plants, from diesel engines and fuels and many other sources. I never dreamed when my mother-in-law first made her request that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution. None of us then would have ever dreamed that the information these two men provided would have helped to identify and underline the threat to human life posed by the microscopic particles in the air we breathe.

Furthermore, that study and the Harvard 6 Cities study became examples of not only groundbreaking research, but of how questions about that research can be, reviewed and resolved without having to lose the entire study. Unfortunately, that is an example that this proposal clearly fails to acknowledge.

These two studies with decades-old patient data, and others in the long list of studies that found evidence of harm from industrial emissions or unique events that no one or hopes to replicate—like gulf oil spills— clearly appear to be targets of this proposed rule. Studies that have long been targets of industry polluters and their allies remain so in this proposal.

Once published, these studies raised alarms in the public health community about the increased likelihood of premature death from particulate matter in widespread parts of the nation. The studies raised alarms within industries about the increased likelihood that their polluting sources would have to clean up their emissions. Industry kicked in the messaging developed by the tobacco industry to

challenge the science using the same arguments we have in this proposal. I have in my office a page from a 1999 U.S. News and World Report article on the challenges to these studies that could have been written this year.

Scientists are working to become more transparent in their research. More researchers use publicly available information. But some studies cover populations that are so limited in size or specialized in their characteristics that those data should not be posted on the web for all the world to see. Anyone who has an account on Facebook should have a visceral knowledge of how important keeping confidential data confidential can be.

Meanwhile, EPA could readily review historical data and studies in ways that respect patient confidentiality and the gifts of data from people like my two choir member friends.

So far, EPA has failed to show any reason that changes are needed in the current system. Failed in its own transparency on this issue in fact, since EPA has not sought SAB review of this and not provided sufficient rationale for why EPA needs this change, much less how they would use this rule going forward.

We request EPA to withdraw this proposal. Thank you.

U.S. Environmental Protection Agency

Public Hearing on the Proposed "Strengthening Transparency in Regulatory Science" Rule

July 17, 2018

Testimony of Jodi Feld
Chief Scientist
Environmental Protection Bureau
Office of New York State Attorney General
Barbara D. Underwood

Testimony of Jodi Feld on EPA's Proposed "Strengthening Transparency in Regulatory Science" Rule

Good day. My name is Jodi Feld; I am Chief Scientist with the New York Office of the Attorney General's Environmental Protection Bureau. I am one of seven full-time scientists at the office; the only state Attorney General's office in the nation that employs on-staff scientists.

On behalf of New York Attorney General Barbara D. Underwood, I thank you for the opportunity to speak on the proposal by the Environmental Protection Agency (EPA) to limit use of science by the Agency in developing regulations.

While Attorney General Underwood with other Attorneys General will be submitting extensive, detailed comments on the proposal at a later date, I would like to provide brief comments on it today on her behalf.

* * *

Ostensibly proposed to strengthen the foundation of EPA's regulatory actions, the "Strengthening Transparency in Regulatory Science" proposal would do the opposite. It would exclude from EPA decision-making relevant, probative scientific studies, models, and other information that have been validated by peer review simply because not all underlying data are available to the public.

The Office of the New York Attorney General strongly opposes the proposal. It is vague, poorly reasoned, deeply flawed, and violates fundamental legal requirements for a valid rulemaking.

The proposal broadly and squarely conflicts with core EPA statutory duties, violating the very federal laws the Agency is required to uphold.

Moreover, it is bad science. Owing to its total absence of independent scientific input, the proposal departs abruptly from the best practices of the scientific community and ignores the well-established reasons why public sharing of all study data is not possible.

The result of the proposed rule would be to profoundly weaken EPA's science, its regulatory decision-making, and, ultimately, its protection of public health and the environment in New York and elsewhere across the nation.

Congress and the courts have rejected virtually identical efforts to limit EPA's use of science. We urge EPA to abandon this damaging, misguided effort as well.

The Proposed Rule is Bad Science

As mentioned previously, as far as we are able to determine, the proposed rule was developed with a total absence of independent scientific input. It is perhaps unsurprising, then, that as a scientific matter; the rule also makes very little sense.

The fundamental premise of the proposed rule is that only studies for which the underlying data are publicly available are valid for decision-making.

However, the proposal offers no rationale for this premise, nor evidence that EPA's current approach to selecting studies for decision-making is resulting in scientifically unsound regulations – or those that are overly protective of public health and the environment.

Hence, at its core, the proposal is a solution in search of a problem.

Enforcing "transparency" as the paramount determinative of scientific validity at EPA would represent an abrupt and unprecedented break from well-established best practices of the scientific community.

The scientific community recognizes what the proposal ignores: that there are often very good reasons – such as the protection of personal privacy and confidentiality, and proprietary interests and property rights – why some research data simply cannot be made fully available to the public.

Within the scientific community, the validity of research are judged on multiple grounds, including how well studies are designed, how clearly data are collected, how carefully analyses are described, and how thoroughly findings of related studies are cited.

In other words, within the scientific community, studies are validated through rigorous expert peer-review – they are not summarily judged invalid and discarded simply because all underlying data cannot be fully shared.

The Proposed Rule Would Directly Harm States and our Residents

EPA asserts that the proposed rule would not affect states, so there are no federalism implications. Nothing could be further from the truth.

EPA standards and regulations are of fundamental importance to states, and actions that affect these standards and regulations directly impact us.

For example, EPA standards – such as National Ambient Air Quality Standards – not only form the backbone of New York's efforts to ensure the quality of our air, water, and

land, and protect the health, safety, and welfare of our residents, but also serve as a backstop to prevent pollution from out-of-state sources from undercutting our efforts.

Further, many states' environmental laws and regulations explicitly adopt EPA standards, or at the very least, require an express justification for any deviation.

Even those states – such as New York – that are not statutorily required to apply federal standards may not always have the institutional capacity to develop their own standards and thus, must rely on the standards set by EPA.

As such, the proposed rule – which would undermine EPA standards and regulations by undermining their scientific basis – would likely have direct, damaging impacts on New York and other states' ability to protect the health and environment of their residents.

These impacts would be felt most starkly by our most vulnerable – the young, the elderly, and the sick – and those living in communities that have borne a disproportionate share of environmental hazards, including communities of color and low-income communities.

The Proposed Rule Is Unfounded and Unsupported, and Contrary to Federal Law

The proposed rule's direct and damaging impact on New York and the residents of our state is aggravated by the proposal's failure to meet the most fundamental of legal requirements for a valid rulemaking.

The proposal is exceedingly vague, creating many more questions than it answers. For example, the actual parameters of the rule are unclear, the alternatives under consideration are open-ended, and critical information, such as its actual cost, is entirely missing.

Further, few of the statutory provisions cited in the proposal actually support EPA's ability to pick and choose among valid scientific information, studies, and techniques in its formation of environmental standards and modeling. None authorizesfba precluding consideration of probative, relevant studies.

In fact, no federal environmental statute so much as suggests that EPA can ignore the "latest" or "best" or "appropriately designed and conducted" scientific studies whenever the underlying data are not public.

By limiting EPA's access to the latest, best available, and generally accepted science, the proposed rule would violate the very federal laws that EPA is required to uphold.

For example, the Safe Drinking Water Act – which, among other things, serves to protect children from lead poisoning – mandates that EPA develop rules based on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."

Besides the Safe Drinking Water Act, the proposal violates specific provisions of the Clean Water and Air Acts, CERCLA, TSCA, and EPCRA, at the very least.

Disturbingly, the proposed rule's only exception to the exclusion of studies for which underlying data are not publically available is wholly at the EPA Administrator's discretion. The rule would allow the Administrator – without standardized, objective, or even science-based criteria – to determine on a case-by-case basis that compliance is "impracticable" where making data publically available is "not feasible."

Clearly, such an insular, open-ended exemption "process" is ready-made for arbitrariness, if not misuse and abuse.

Independent Scientific Organizations Do Not Support the Proposal

The strongest indicator that the proposal is flawed as a matter of science is the overwhelmingly negative reception it has received from the scientific community.

In fact, we are not aware of a single major independent scientific organization that has expressed support for the proposal.

The American Association for the Advancement of Science stated, "[t]his proposal appears to be an attempt to remove valid and relevant scientific evidence from the rule-making process."[1]

The editors of the several prestigious journals, including Science, Nature, and the Proceedings of the National Academy of Sciences, issued a joint statement in response to the proposal in which they stated, "[e]xcluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."[2]

Incredibly, EPA's own scientific advisors – the Scientific Advisory Board – were not consulted by the Agency on the rule. (SAB members became aware of the rule only when it was announced by then-Administrator Pruitt announced at a press event).

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[1] American Association for the Advancement of Science. AAAS Statement on EPA Administrator's Plan to Disallow Use of Scientific Evidence in Decision-Making. (April 20, 2018).
[2] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel, and Deborah Sweet. Joint Statement on EPA Proposed Rule and Public Availability of Data. Science. (April 30, 2018).

The SAB subsequently wrote to the then-Administrator observing that the proposed rule deals with "a number of scientific issues that would benefit from expert advice and comment from the SAB."[3]

The advisory group's letter urged the Agency to "request, receive, and review" scientific advice from the SAB before moving further ahead with the proposed rule.

The Proposal Should Be Withdrawn And EPA Should Consult With Scientific Organizations On Agency Science Needs

The State of New York believes that the proposal is vague, ill-supported, and deeply flawed; it broadly and squarely conflicts with core EPA statutory duties, and is directly contrary to federal law.

Coupled with the Administrator's directive prohibiting EPA grant recipients from serving on scientific advisory panels, the proposal appears to reflect a deliberate effort to undermine well-founded Agency scientific practices – which is particularly egregious given EPA's critical mission and its responsibilities to the residents of New York and other states across our nation.

In May, the New York Attorney General, joined by seven other Attorneys General, wrote to then-Administrator Pruitt, expressing strong opposition to the proposed rule and calling for it to be withdrawn.

Today, the State of New York renews our call to withdraw the proposed rule to Acting Administrator Wheeler.

After withdrawing the proposed rule, if the Acting Administrator is genuinely interested in the "transparency" of science at EPA, he should familiarize himself with the many ongoing efforts within EPA, the federal government, and the scientific community itself to promote transparency and data sharing. He should then work with independent scientific organizations – such as the National Academy of Sciences – to both support and build on these efforts.

On behalf of Attorney General Underwood, I thank you for your time and attention, and for providing me an opportunity to speak on this important matter.

[3] Letter from SAB Chair Michael Honeycutt to Administrator Pruitt (June 28, 2018).

Testimony of
Molly Rauch, MPH
Public Health Policy Director
Moms Clean Air Force
on
July 17, 2018
for
Censored Science Hearing
Docket Identification No. [EPA-HQ-EPA-HQ-OA-2018-0259]
at
EPA Headquarters
William Jefferson Clinton East Building, Main Floor
Room 1153
1201 Constitution Avenue NW., Washington, DC 20460
Public Hearing Testimony

Hello, my name is Molly Rauch and I am Public Health Policy Director with Moms Clean Air Force. Thank you for this opportunity to offer comment. On behalf of more than one million members of Moms Clean Air Force, I am here today to strongly oppose the administration's attempts to censor the science used in public health decision making.

This intentionally misleading proposal is being sold by EPA leadership as an effort to increase "transparency." But the facts suggest that the real motivation is simply to sweep under the rug the scientific evidence disfavored by polluting companies. The proposal would prevent EPA from using studies that are based on personal medical data, thereby eliminating some of the most important long-term epidemiological studies investigating the impacts of pollution on public health. Hundreds of scientists have spoken out against this proposal.

Indeed, this flimsy proposal was designed without adequate input from the scientific community, according to members of EPA's own Scientific Advisory Board. It was rushed through the regulatory process, and was originally proposed with a gallingly short public comment period, suggesting an intention of casting less light on the rulemaking process, not more. For a proposal that posits a sweeping change in the health-based rulemaking that is the foundation of the EPA, it was quite the sleight of hand.

As a public health expert who has been closely following EPA's rulemaking process for more than a decade, it is evident that this proposal is a cynical ploy to bolster polluting industries that don't like the results of longitudinal research.

Who does this benefit? Who really benefits from this charade? Not the families everywhere who want to breathe clean air and drink clean water. Not frontline communities dealing with multiple pollution exposures from many industrial sources. Not the millions of children with asthma across the country whose disease can be worsened by small changes in air quality day to day. Not the elderly, and those with underlying health problems, whose likelihood of being admitted to the hospital, of having a stroke, of having a heart attack, of dying – could depend on the levels of particulate pollution in the air. It does not benefit these people.

I have a master's in Public Health. One of the most valuable things I learned in graduate school was how to evaluate the reliability of epidemiological studies. We learned the importance of considering many different criteria. Whether the raw data was available to me was never grounds for automatically discounting the credibility of research. The idea that an entire library of studies would be rejected, based simply on that one external criteria, represents a crude approach, to put it kindly.

We also learned about the ironclad importance of treating study subjects ethically and with respect. All research on humans must be approved by an Institutional Review Board, which prioritizes the privacy and consent of the study subject. There are laws about this. When study subjects are disrespected, terrible things can happen. There's a reason that we had to learn about the Tuskegee study of untreated syphilis in African American men. We cannot go back to a time when the study subject is a mere pawn in someone else's game. Treating study subjects ethically requires protecting their privacy.

Finally, we studied the tactics of polluting industries, and their shameful legacy of attempting to undermine science. Whether it was the tobacco industry or the lead industry, we learned about the deliberate, expensive, decades-long campaigns to protect corporate profits – and meanwhile, people were literally dying as a result. This is

an old story. We've heard it before. Today, we are hearing that story again. Public health professionals are trained to recognize this story, and call it out.

This proposal is an excuse to hamstring researchers, weaken public health protections, and pad the profits of polluting industries.

As a public health professional, as a mother, and on behalf of Moms Clean Air Force and our more than one million members, I strongly urge the EPA to stop this radical proposal – for the health and safety of all Americans.

The Medical Society Consortium
ON CLIMATE & HEALTH

Respected EPA panelists and fellow citizens. My name is Mona Sarfaty. I am a physician trained in family medicine and public health; I practiced primary care medicine and taught medical and public health students in three different academic medical centers over a 35-year period. Today, I direct a program in Climate and Health at George Mason University in Fairfax, Virginia. I also direct a Consortium of physician societies called the Medical Society Consortium for Climate and Health whose 550,000 members are more than half the doctors in the U.S. The Consortium seeks to inform the public and policymakers about the health harms of climate change and the health benefits of climate solutions. I am submitting the formal comment of the Consortium in written form in a separate document.

The Environmental Protection Agency (EPA) is proposing to change the rules that dictate what evidence must be considered as the basis for protecting the public's health. As a physician who spent a summer in Southern California during college and didn't see Mount Wilson looming in front of me for the entire first week I spent there because of the smog, I am incredulous. I remember well the pain in my chest when attempting to play tennis on those smoggy days.

This was the early 70's at a time when a Republican president was creating the EPA. Now, 50 years hence, tremendous evidence has accumulated that validates my symptoms and the negative effect that unhealthy air has on people who must breath it. After that summer, as a practicing physician, I took care of people with asthma and chronic lung disease who were at greater risk on bad air days. So it is shocking to me that the EPA would propose putting aside huge amounts of thoroughly reviewed evidence on the causal connections between air pollution and poor health claiming that the basis for the conclusions were "secret".

Today, I lead a Consortium comprised of the country's largest medical societies whose doctor members are highly concerned about the health harms of climate change. The similarities between the current EPA willingness to disregard established science about the connection between carbon dioxide and global warming and the willingness to disregard solid evidence about the impact of air pollution on health are glaring. Despite overlapping evidence from every country in the world and the entire U.S. climate-science enterprise, the EPA leadership does not accept or recognize reality.

To all of us whose lives are dedicated to helping people get and stay healthy, there is a "secret" lurking in the science of air pollution and global warming. It is not what we have long known about how burning fossil fuels creates waste products that damage and inflame our lungs. This has been validated by voluminous overlapping research studies. The secret is not that carbon emissions from burning fossil fuels are warming our climate, exacerbating the health harms of air pollution, and causing other dangers to our health--from heatwaves, wildfires, pollen production, and storms. The secret is hiding in plain sight: fighting air pollution is the greatest public health opportunity of our time. Reducing polluting fumes and emissions from fossil fuels will rapidly improve our health and fight climate change.

When an EPA's not-so-secret agenda is to promote fossil fuels, two things follow: 1) the fact that fossil fuels are the major contributor to both air pollution and global warming must be undermined or denied; and, 2) the research that documents this reality and how it harms our health must be attacked. It's not hard to see that the approach is to mislead people by wrapping these attacks in rhetoric that is alternatively scary ("secret science") and high-minded ("transparency"). We are told that the rationale for the new proposed "strengthening transparency standard" is that individual medical records included in research were "secret". In fact, like all medical records, they were confidential; and they remain so.

The record shows that this same argument of "secrecy" against scientific studies has been used by polluting industries going back many years. Currently, we have

a President who thinks only of less regulation. A President and an EPA that fail to regulate responsibly and ignore key research studies put our health and our climate in danger.

Health providers know that facts may be scary when our health is threatened. But we also know that denying or ignoring facts blinds us to discovering and acting on the best ways to heal medical problems and protect our health. We can't let that happen. The EPA must live up to its charge and work to face facts and protect our environment and our health. With this proposed regulation, its leadership is pointing it in the opposite direction.

NESCAUM
www.nescaum.org

Northeast States for Coordinated Air Use Management
89 South Street, Suite 602 Boston, MA 02111
Phone: 617-259-2000 Fax 617-742-9162
Arthur N. Marin, Executive Director

Testimony of Northeast States for Coordinated Air Use Management
On Notice of Proposed Rule: Strengthening Transparency in Regulatory Science
[EPA–HQ–OA–2018–0259]
July 17, 2018
Washington, D.C.

My name is Paul Miller, and I am the Deputy Director of the Northeast States for Coordinated Air Use Management (NESCAUM). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

I offer today NESCAUM's comments on EPA's Proposed Rule "*Strengthening Transparency in Regulatory Science*." These comments reflect the majority view of NESCAUM members, and individual members may hold some views different from the NESCAUM states' majority consensus.

We present this testimony today out of our concern that should this proposal lead EPA to not fully consider the best available science in rulemakings, it will endanger public health and the environment.

The EPA invokes "strengthening transparency" as a primary driver for this proposal, but fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of where "EPA has not previously implemented these policies and guidance in a robust and consistent manner" nor what are the specific "agency culture and practices regarding data access" that require changing. The Agency also provides no cost analysis of the proposal.

Without additional clarity from EPA, we are having difficulty identifying the problem EPA seeks to address. Therefore, for the following reasons, we request that EPA withdraw this Proposed Rule.

First the proposal is too vague as written to provide the public with a meaningful opportunity to comment.

The Proposed Rule lacks credible specificity and is overly vague in its terms and scope. Under the Administrative Procedures Act (APA), EPA is required to articulate the specifics of its proposed rulemakings in a manner that provides a valid opportunity for public comment.

In this proposal, however, EPA solicits comment across a long list of topic areas, but fails to provide the Agency's own "sufficient detail and rationale" [APA § 553(b)(3)] on the solicited comment areas. We are left in the position of speculating on EPA's views and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment.

Second, EPA must describe how the proposed text in sections 30.5, 30.7, and 30.9 affect current practice.

Sections 30.5 and 30.7 of the Proposed Rule respectively say: "the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation," and "EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions[.]" EPA does not describe its approaches for "independent validation" and "independent review."

Furthermore, the Proposed Rule in section 30.5 also includes qualifying language that "The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible." EPA provides no examples of where and how, in the agency's view, past rulemakings specifically failed to make these efforts, and how EPA would change past practice in this context.

Adding to the vagueness of sections 30.5 and 30.7, section 30.9 would provide the Administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions "on a case-by case basis if he or she determines that compliance is impracticable." The Proposed Rule fails to provide specific criteria for determining when "compliance is impracticable." Lacking clear guidelines for transparent decision-making, the Administrator's discretion would appear to be unbounded in application and potentially based on haphazard non-transparent rationales.

Third, EPA has provided no meaningful cost estimate for the Proposed Rule.

The costs are likely quite significant, however, based on a Congressional Budget Office (CBO) cost estimate of a similar legislative proposal in Congress.[11] From that analysis, costs could range between a few million dollars to more than one hundred million dollars per year. In addition to lack of cost information, EPA offers no accounting of foregone benefits should a broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse health outcomes.

In conclusion, EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific Proposed Rule requirements, and its costs and benefits. These are well understood and basic elements that federal agencies must include to ensure informed public comment. Given that these elements are completely missing from this proposal, EPA should withdraw it.

Thank you.

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[11] Congressional Budget Office, "Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017" (March 29, 2017), at https://www.cbo.gov/publication/52545 (accessed May 14, 2018).

Testimony of Peter Lurie, MD, MPH

President

Center for Science in the Public Interest

U.S. Environmental Protection Agency Public Hearing on the Proposed Rule Titled

"Strengthening Transparency in Regulatory Science"

July 17, 2018

My name is Dr. Peter Lurie and I am the president of CSPI, the Center for Science in the Public Interest. CSPI is an independent science-based health advocacy organization with over 500,000 members. We accept no Industry or government donations and carry no advertising in our *Nutrition Action Healthletter*. Prior to joining CSPI, I served at the Food and Drug Administration as Associate Commissioner for Public Health Strategy and Analysis, where for several years I led the agency's Transparency Initiative. Over the course of my career, I have authored numerous academic articles on transparency.[1]

CSPI is a firm advocate of scientific transparency. Our Integrity in Science Project investigated, exposed, and sought to reduce corporate influence on science and science-based public policy for many years. More recently, CSPI led a call for the National Library of Medicine to be more transparent in publishing conflict of interest disclosures. But EPA's proposed rule is *not* about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep's clothing of transparency in science. The proposal should be withdrawn.

Transparency is not about restricting the use of sound science as this proposal would do; it is about communicating openly and clearly about the action taken, the strengths and limitations of the science used, and making that science and interpretation as available to the public as possible. Certainly,

[1] A partial list of my published articles relating to transparency is appended to this testimony.

the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be grounds for the summary exclusion of data that were rigorously gathered and reported.

The surest tests of any scientific transparency policy are: 1) whether it was itself developed transparently, and 2) whether it promotes transparent, rigorous, science-based decision-making in an even-handed manner. The proposal fails on both counts.

First, this proposal violates fundamental tenets of transparent rulemaking. EPA apparently failed to consult with relevant stakeholders such as scientific, research, or health professional associations, did not consult with other federal agencies, and did not even make the proposed rule available to its own Scientific Advisory Board for review.[2] In addition, the proposal lacks critical citations and documentation or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the agency has merely adopted a legislative initiative[3] that failed to pass despite support from the energy, chemical, manufacturing, and other key industries. That legislation was proposed by Rep. Lamar Smith (R-TX), Chair of the House of Representatives Committee

[2] EPA Science Advisory Board. Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14). May 12, 2018, https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[3] H.R.1430 - HONEST Act. https://www.congress.gov/bill/115th-congress/house-bill/1430.

on Science, Space, and Technology, who questions the science behind climate change[4] and the relationship between air pollution and mortality.[5]

Moreover, despite its professed fealty to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply asserts blithely that "EPA believes the benefits of this proposed rule justify the costs." But the rule would be costly indeed: analyses of an earlier version of Rep. Smith's legislation from the nonpartisan Congressional Budget Office predicted costs of $250 million per year over the next few years.[6]

But even more important, the proposal will not meet its purported scientific goals and will instead undermine the scientific basis for decision-making by the agency. Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA's greatest public health accomplishments, such as eliminating lead in gasoline and classifying secondhand smoke as a cause of cancer (which led to banning smoking from indoor public places), were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. It is particularly troubling that the proposal also opens the door to a reconsideration of past rules, which would be utterly inappropriate under prevailing principles of administrative law.

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[4] For example, see Tollefson J. Controversial chairman of US House science committee to retire. Nature, November 2, 2017. https://www.nature.com/news/controversial-chairman-of-us-house-science-committee-to-retire-1.22954; and Lavelle M, Hasemyer D. Instrument of power: How fossil fuel donors shaped the anti-climate agenda of a powerful congressional committee. Inside Climate News, December 5, 2017. https://insideclimatenews.org/news/05122017/lamar-smith-congress-climate-change-fossil-fuel-industry-house-science-committee.

[5] Servick K. House panel subpoenas EPA for all pollution data. Science, August 2, 2013. http://www.sciencemag.org/news/2013/08/house-panel-subpoenas-epa-air-pollution-data.

[6] Congressional Budget Office. Cost Estimate, H.R. 1030 Secret Science Reform Act of 2015, As ordered reported by the House Committee on Science, Space, and Technology on March 3, 2015, March 11, 2015. https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

In fact, the proposal would have an effect opposite to its claimed purpose; it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry. Most academic epidemiologic studies rely on aggregated data and other means to protect the privacy of their human subjects. In other cases, researchers conducting the studies may be prevented from making the underlying data publicly available for legal, practical, or ethical reasons.

The pro-industry orientation of the proposal is revealed once more in its assault on the linearity assumption in the dose/concentration-response function. (This approach assumes that there is no safe threshold at the population level for most chemical pollutants.) This assault runs counter to the advice provided to EPA by the National Research Council, which stated, "The committee recommends that cancer and noncancer responses be assumed to be linear as a default."[7] In another departure from its claimed commitment to transparency, EPA provides no scientific citations for its claim of "growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects." But what is most telling about the discussion of linearity is its inclusion in the proposed rule in the first place; there is simply no need to raise it in a proposed rule supposedly about transparency.

A legitimate approach to strengthening transparency in regulatory science would heed the advice provided by the National Academies to use the best and most current science to support and revise default assumptions, make implicit defaults explicit, and provide clear standards for the level of

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009, p. 180.

evidence needed to depart from default assumptions,[8] taking into account data-sharing guidelines already developed by NIH.[9]

Let me close with the question with which EPA should have started: What is the problem that this proposed rule seeks to fix? Where is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard? To the contrary, the record is replete with studies that formed the basis of health- and life-saving regulations that would now be precluded from use and that might even provide a basis for the revocation of rules enacted in the distant past.

[8] Institute of Medicine of the National Academies. Identifying and Reducing Environmental Health Risks of Chemicals in Our Society: Workshop Summary. Washington, D.C.: National Academies Press; 2014, p. 55.
[9] NIH. Data Sharing Policy and Implementation Guidance. March 5, 2003. https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#app.

Examples of articles by Peter Lurie relating to transparency

Lurie P. Suggestions for improving conflict of interest processes in US Food and Drug Administration Advisory Committees—past imperfect. JAMA Internal Medicine 2018. doi:10.1001/jamainternmed.2018.1324.

Cruz ML, Xu J, Kashoki M, Lurie P. Publication and reporting of the results of post-market studies required by the US Food and Drug Administration in 2009-2013. JAMA Internal Medicine 2017;177:1207-10.

Xu J, Emenanjo O, Ortwerth M, Lurie P. Association of appearance of conflicts of interest with voting behavior at FDA Advisory Committee meetings—a cross-sectional study. JAMA Internal Medicine 2017;177:1038-40.

Lurie P, Chahal HS, Sigelman DW, Stacy S, Sclar J, Ddamulira B. Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study. BMJ 2015;350:h2758. doi:10.1136/bmj.h2758.

Ross JS, Nazem AG, Lurie P, Lackner JE, Krumholz HM. Updated estimates of pharmaceutical company payments to physicians in Vermont. Journal of the American Medical Association 2008;300:1998-2000.

Ross JS, Lackner JE, Lurie P, Gross CP, Krumholtz HM. Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. Journal of the American Medical Association 2007;297:1216-23.

Lurie P, Zieve A. Sometimes the silence can be like the thunder: access to pharmaceutical data at the FDA. Law and Contemporary Problems 2006;69:85-97.

Lurie P, Almeida CM, Stine N, Stine AR, Wolfe SM. Financial conflict of interest disclosure and voting patterns at Food and Drug Administration drug advisory committee meetings. Journal of the American Medical Association 2006;295:1921-8.

Michaels D, Montforton C, Lurie P. Selected science: an industry campaign to undermine an OSHA hexavalent chromium standard. Environmental Health 2006;5:5.

July 17, 2018

I am Roy Gamse, formerly EPA Deputy Assistant Administrator, reading the comments of John Bachmann. He served EPA for 33 years and was the Associate Director for Science/Policy and New Programs for the Office of Air Quality Planning and Standards in Research Triangle Park, NC.

Comments of John Bachmann

I appreciate the opportunity to provide these comments on the proposed rulemaking "Strengthening Transparency in Regulatory Science" on behalf of the Environmental Protection Network (EPN). EPN will submit detailed written comments on the proposal later.

This proposal would *not* strengthen transparency of regulations. Instead it would preclude the assessment and use of the best scientific information available, as required by all major statutes administered by EPA. The process by which it was developed, the misuse of references that ultimately do not support its arguments, and the lack of specifics on what EPA actually intends to do are an embarrassment to the Agency. The new acting Administrator should withdraw it from consideration as soon as possible.

- EPA's Proposal is a Solution in Search of a Problem

  - The proposal asserts that it is dealing with a "replication crisis," but does not cite a single instance where a study used by EPA for any type of major rule was shown to be flawed due to a lack of access to the underlying data. In fact, EPA and industry funded an independent reanalysis of the two air pollution studies that were criticized for not releasing confidential health information to the public, and both were successfully *reproduced* with results published in 2000. Moreover, their key findings have been *replicated* dozens of times since then by other investigators using different health and air quality data.

  - The proposal to exclude important peer reviewed studies is wholly inconsistent with scientific practice and EPA's past use of science in

regulatory decisions. Where studies with novel results appear, EPA's assessments have noted limitations, and in some cases supported reanalyses. EPA's science/policy related assessments are themselves peer reviewed by SAB or CASAC to further ensure study evaluations consider all of the relevant scientific literature.

- As noted by an SAB workgroup, EPA's proposal downplays valid concerns about the risks of providing access to the confidential information of subjects in epidemiology studies. The SAB group noted:
  - Some of the largest and/or most useful health effects data sets cannot be made fully public, because certain personal information on age, sex, health and location could be used to identify the participants, or because of agreements made with study participants in advance.
  - EPA failed to mention various ways to assess the validity of prior epidemiology studies without access to data, nor that the rule might preclude continued use of studies published many years ago.

- The proposal includes a provision for the Administrator to waive this requirement. No clear decision criteria are provided to allow EPA scientists and stakeholders to understand when and how such waivers might be granted. It thus appears that this requirement could be applied in an arbitrary and capricious manner that does not reflect sound science judgment.

- Critical decisions like these must be made on the basis of science, not politics. Otherwise highly relevant studies for which data cannot be publicly shared, even if published in the best peer reviewed journals and replicated, may be judged to be inherently untrustworthy.

- The rushed and mostly secret process EPA followed in developing this proposal displays a complete disinterest in transparency in public policy, much less in science. In developing this proposal, EPA leadership:
  - Did not provide a role for its own career scientific and science/policy experts in crafting the proposal or in assessing its potential impacts,
  - Never included the rule in its regulatory agenda,
  - Did not notify or consult with the SAB, much less request a review of the draft proposal as required by law,

- Did not solicit the advice of the National Academy of Sciences on provisions that would change dose-response models used in risk assessment from those previously recommended by the NAS,
- Did not ask for a review to solicit the views of other Federal Agencies that conduct research and/or use health effects science in developing policies and regulations.
- Finally, the Agency originally allowed only a 30-day comment period on this remarkable, unvetted departure from decades of past practice in the assessment and use of science.

- In suggesting the potential costs of the rule would be minimal, EPA ignored the costs -
  - to researchers, who would have to pay to set up and maintain data sharing for their previously published studies to be considered,
  - to EPA for conducting the multiple reanalyses required in section 30.6 of the rule,
  - and to public health, for the disbenefits of undermining existing regulations.

  Having done no assessment, EPA has no basis for its claim that the benefits of the rule would exceed costs.

- Scientists and scientific publications that EPA cites as evidence of support for this rule have rejected the proposal's preemption of existing studies based on availability of raw data.

  - John Ioannidis reacted strongly to the proposal in an editorial, noting that "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim."
  - Editors of four major scientific journals, whose policies EPA cited as support, jointly stated that "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them...Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."

- EPA should immediately withdraw this flawed proposal from consideration. Given the fatal flaw of establishing an unnecessary regulation for science assessment that would elevate transparency over any other criterion, we are unable to offer any suggestions for improving it.

Testimony of the

American Petroleum Institute

Public Hearing on the

Proposed Rule: Strengthening Transparency in Regulatory Science

[April 30, 2018; 83 Fed. Reg. 18,768; Docket ID: EPA–HQ–OA–2018–0259]

July 17, 2018

Thank you for the opportunity to provide public comment today. My name is Ted Steichen a Senior Policy Advisor at the American Petroleum Institute (API).

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our 620 corporate members - from large integrated oil and gas companies to small independent companies - comprise all segments of the industry. API member companies are producers, refiners, suppliers, retailers, pipeline operators and marine transporters as well as service and supply companies providing much of the nation's energy. Science used when developing policy and regulations impacts all aspects of API member business.

The members of API are dedicated to continuous efforts to improve the compatibility of their operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. Our members recognize their responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

API supports the use of sound science as a critical component in public policy. To the extent possible, and consistent with the protection of other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing and evaluating environmental, health, welfare and economic impacts should be transparent and reproducible and available as early as possible in the rulemaking process. Transparency and reproducibility should also apply to underlying data and information, such as environmental and economic impact data and models that are utilized to predict costs, benefits, market impacts and/or environmental effects of specific regulatory interventions.

API members are aware there are some obstacles to full transparency and reproducibility and are committed to working with other stakeholders to develop practices that maximize science transparency while preserving existing confidentiality strictures.

As EPA goes about this rulemaking API suggests that regulatory decisions based on science should rely upon the following principles:

- Openness in science and related findings underpinning laws, regulations, standards and guidance documents.
  - This is especially true for government-funded research and science but should include all policy-relevant studies.

- Reproducibility of research and associated findings, including fully-annotated data, methodologies, model inputs, code and other critical information that support the conclusions of research. All of these should be available to the public.

- Inclusion of clear requirements to ensure that the data underlying decision-making are publicly available in a manner sufficient for independent validation, as much as practicable.
  - Privacy concerns are important, but advances in encryption technology and blinding of data make it possible to enhance transparency while ensuring privacy as necessary to comply with the law.

- Inclusion of clear requirements and a well-documented process are critical to ensure that the data underlying decision-making are publicly available in a manner sufficient for independent validation to the degree practicable.

- Protection for confidential business information (CBI) used in regulatory processes and support agency actions.
  - This protection for CBI may need to be maintained even for certain data that are submitted to EPA to inform rulemakings.
  - Protections for proprietary information or CBI should not be weakened, though results of agency analyses of this information could potentially be made available. Any such available results should be transparent regarding the agency's selection of key data, and the interpretation of that key data.

- Explicitly addressing and highlighting uncertainties in data, models and analyses when utilizing those studies in decision-making.
  - This is particularly important when models are used to quantify benefits of an action at levels at or below existing standards or background concentrations of a regulated substance.

- Broad application of these principles to information used to inform policy decisions, including scientific, economic and environmental impact data and models that are designed

to predict health and environment impacts, costs, benefits, and/or market impacts of specific regulatory interventions on complex economic or environmental systems.

- Engaging stakeholders, as early as possible, in the decision-making process to ensure application of data transparency principles for studies to be included and to address how studies that have not been reproduced or that are non-reproducible will be considered in the process.
  - For studies that are high quality and are regarded by the regulatory agency as the best available data for regulatory use though proprietary, identify the recourse for stakeholders regarding CBI, privacy concerns or other transparency issues, to ensure that regulatory decisions are indeed based on sound science.

- Application of these principles, as early as possible, in the pre-rule stage as technical support documents are prepared.

In closing, as described above, API supports the use of sound, transparent science in public policymaking and we plan to submit written comments to the docket.

Strengthening Transparency in Regulatory Science

Docket ID No. EPA-HQ-OA-2018-0259

From: Luke Michaelson, PhD RN

July 17, 2018

From the perspective of a nurse, the proposed rule titled **Strengthening Transparency in Regulatory Science** will harm the public and will implement unachievable transparency guidelines within population health research areas. For example, epidemiological studies correlating illness and air quality may require personal identifiable information and confidentiality agreements. The **Strengthening Transparency in Regulatory Science** regulation seeks to only use studies which allow public access to all data. Since those confidential raw data cannot be publicized, that research will not be used to develop future health guidelines.

In fact, if the **Strengthening Transparency in Regulatory Science** rule is implemented, the result will be less science influencing future health policy. Such a result will harm the American population, especially those more vulnerable to environmental hazards, such as children and the elderly. The scientific community already supports Transparency and Openness Standards which are able to accommodate research using strict confidentiality and private guidelines [1]. This proposed federal guideline is redundant and does impart a fiscal and labor burden on an agency President Trump has previously targeted for a 23 percent decrease in its budget. Furthermore, the EPA has lost hundreds of employees [2] and therefore, the agency will not be able to support the validation of even "approved research data" within a timely manner.

Prior to the proposed guideline, **Strengthening Transparency in Regulatory Science**, the scientific community has proactively contributed research directly helping the health of the American public. In 1955, the Air Pollution Control Act was the first federal legislation related to air pollution, and authorized funds for air quality research. In 1963, the Clean Air Act authorized the US Public Health Service to conduct research on how to control air pollution. Air quality legislation, culminating in amendments to the Clean Air Act in 1990, has produced an estimated $59-140 billion in health savings [3]. Furthermore, prior research associated the following pollutants with poor health outcomes; higher carbon monoxide and ozone levels correlated with lower birth weights and poor intrauterine growth; for every 10$\mu g/m^3$ increase in PM_{10} levels, respiratory related infant deaths increased by 16%, and children living in communities with the highest levels of $\leq PM_{2.5}$ particulate matter were approximately 5 times more likely to have abnormal lung function when compared to their peers with the lowest $\leq PM_{2.5}$ levels [3].

Good science and research help the American public. The **Strengthening Transparency in Regulatory Science** guideline ignores the documented public health successes from prior research. This guideline will immediately harm the American communities and reverse health gains we have made. I suggest this guideline not be implemented.

References

1. Berg, J., et al., *Joint statement on EPA proposed rule and public availability of data.* Proc Natl Acad Sci U S A, 2018. **115**(24): p. 6098.
2. Dennis, B., *Trump budget seeks 23 percent cut at EPA, eliminating dozens of programs,* in *The Washington Post*. 2018: Washington DC.
3. Ross, K., J.F. Chmiel, and T. Ferkol, *The impact of the Clean Air Act.* J Pediatr, 2012. **161**(5): p. 781-6.

Thank you for your input.

Please use this form to submit written comments on the proposed rule "Strengthening Transparency in Regulatory Science." Once completed, please return to the registration desk.

Public Comment Form
(Please Print)

Name Meredith Haines

Address Personal Matters / Ex. 6

Affiliation * member of public * concerned!

Telephone Personal Matters / Ex. 6

E-mail

Public Hearing on the proposed rule "Strengthening Transparency in Regulatory Science" **Docket Number: EPA-HQ-OA-2018-0259**

Comments:

The only transparency in this rule is the clear political wrench being proposed.

This wrench is designed, in industry's favor, to dismantle the EPA's ability to function in its mission.
Retroactively, no less.

The proposed rule would hand the EPA administrator this wrench to wield at whim.

Wow.

Wrong.
Withdraw it!

Over →

Submitted by a member of the public who trusts the established scientific practices.

Let the polluters try to hide behind 'transparency'.

Testimony of
Victoria Rachmaninoff, Moms Clean Air Force Intern
on
July 17, 2018
for
Censored Science Hearing
Docket Identification No. [EPA-HQ-EPA-HQ-OA-2018-0259]
at
EPA Headquarters
William Jefferson Clinton East Building, Main Floor
Room 1153
1201 Constitution Avenue NW., Washington, DC 20460
Public Hearing Testimony

Hello, my name is Victoria Rachmaninoff and I am from Winnetka, Illinois. I want to start by saying thank you for this opportunity to offer comment. I am deeply concerned about Acting Administrator Andrew Wheeler's attempts to censor science in the name of transparency and am here today to speak out against this proposed rule.

My mother grew up in a house of smokers. From infancy, her lungs were filled with the second-hand smoke of my grandmother, and later her older sister. While driving, the windows were kept shut no matter how many cigarettes were lit. Their home was no different. All throughout her life, until she herself started smoking, my mother breathed in the cigarette smoke of others, as studies showing the links between cigarettes and cancer were suppressed by the tobacco industry.

We now know that cigarettes can lead to more than just cancer; they also severely increase your risk of heart disease and stroke. My mother is 58 and I am thankful that she is still healthy. Her mother quit smoking at 68. This was not by choice. Just ten years older than my mother is now, she suffered from a massive brain hemorrhage. Her stroke left her paralyzed and nearly took her life.

In the early 1990s, when I was born, the tobacco industry tried to do something similar to what is being proposed now. In reaction to well respected, sound science, they created their own guidelines for "transparency" to discredit research showing the damaging impacts of second hand smoke. If they had gotten their way, my generation, a whole other generation, may have grown up inhaling second-hand smoke, just like my mother.

As early as the 1940s, the tobacco industry knew that cigarette smoking could cause cancer. While actively hiding this research, and producing cigarettes veiled as "safe," millions of Americans endowed this industry with misplaced trust. It took over 50 years to undo the detrimental effects of the tobacco industry's scientific cover-up. Countless people have died, and more will continue to die as a result. Now is not the time to let this injustice repeat itself.

Like cigarettes, pollution from smokestacks and tailpipes cause serious health problems and can even lead to death. Just as we have finally accepted the health impacts of cigarettes, it is time to accept that there are real, and consequential health impacts from pollution— and start dealing with them. Those industries want to avoid accountability for the harm they cause by throwing out the scientific evidence.

But while this ruling is being done under the guise of "transparency," there is nothing secret about the science EPA uses to protect us. The EPA already makes available the scientific studies it relies on to make decisions. But many of those studies depend on the use private medical data that cannot and should not be made public. This rule is an excuse to discount these studies so they can weaken public health protections.

Today, I work for Moms Clean Air Force. I fight each day with over 1,000,000 parents and people dedicated to protecting children's health. Before, I spent four years working with elementary and preschool children, in the field of education. The students I worked with all came from low-income families. And when I think about who will suffer most from this ruling, it is children like them. At the age of four, six, and ten their vulnerable lungs and bodies are highly susceptible to the effects of air pollution. And because of their income, they are more likely to live near dangerous sources of pollution.

This proposal means that many studies on young people, people of color, and low-income communities - groups who suffer disproportionately from pollution - would be excluded from EPA consideration. Making the data public could identify the participating individuals. And simply redacting information is not enough. The information required to be made public still would allow with simple decoding for the identification of participants. Perhaps even worse, excluding this important data from consideration could further exacerbate negative environmental impacts on these and other vulnerable communities.

The EPA has used transparent and sound science for decades. My family, the families I work with at Moms Clean Air Force, and millions of Americans are counting on the EPA to continue using this science, without putting our privacy at risk. I strongly urge the EPA to stop this radical proposal - for the health and safety of all Americans. Thank you very much.

Public Hearing - Strengthening Transparency in Regulatory Science
Afternoon Session - Final List of Speakers | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Assigned Speaker No.	First Name	Last Name	Organization
1	Pamela	Miller	Alaska Community Action on Toxics
2	Elizabeth Ann Glass	Geltman	CUNY School of Public Health
3	Patricia	Koman	University of Michigan
4	Alexis	Andiman	Earthjustice
5	Alexis	Andiman	on the behalf of Devon Hall, Rural Empowerment Association for Community
6	Sarah	Kogel-Smucker	Office of the Attorney General for the District of Columbia
7	John	Doherty	Independent Toxicologist
8	Trisha	Sheehan	Moms Clean Air Force
9	James	Duffy	Clean Air Task Force
10	Erika	Rosen	George Washington University
11	Gretchen	Goldman	Union of Concerned Scientists
12	Maggie	Flaherty	League of Conservation Voters
13	Adam M.	Finkel	University of Michigan School of Public Health
14	Augusta	Wilson	Climate Science Legal Defense Fund
15	David	Coursen	Environmental Protection Network
16	Abigail	Omojola	Breast Cancer Prevention Partners
17	Alan	Lockwood	Physicians for Social Responsibility
18	Elizabeth	Woolford	National Parks Conservation Association
19	Paul	Allwood	Minnesota Department of Health
20	John	Stine	Minnesota Pollution Control Agency
21	Virginia	Ruiz	Farmworker Justice
22	Karen	Mongoven	National Association of Clean Air Agencies
23	Steve	Milloy	JunkScience.com
24	Steve	Milloy	On the behalf of John Dunn, No Affiliation
25	Meredith	McCormack	American Thoracic Society
26	Olivia	Bartlett	Do The Most Good
27	Dan	Byers	U.S. Chamber of Commerce Global Energy Institute
28	Antonia	Herzog	Physicians for Social Responsibility
29	Tess	Dernbach	EarthJustice
30	Mary	Angly	Physicians for Social Responsibility
31	Brenda	Munive	Physicians for Social Responsibility
32	George	Thurston	International Society of Environmental Epidemiology

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33	Brittany	Meyer	Michael J. Fox Foundation for Parkinson's Research
34	Adam M.	Spanier	American Academy of Pediatrics
35	Sean	Moulton	Project on Government Oversight
36	Andrew	Bergman	Project on Government Oversight
37A	Emma	Gildesgame	National Parks Conservation Association
38A	Jyotsna	Pandey	American Institute of Biological Sciences
39A	Patricia	Koman	on the behalf of Tracey Woodruff, UCSF
40A	Peter	Ferrara	Heartland Institute
41A	Elizabeth	Hitchcock	Safer Chemicals Healthy Families
42A	Benjamin	Kirby	on the behalf of John Hall, Center for Regulatory Reasonableness
43A	Mahealani	Daniels	The League of Conservation Voters

Assigned Speaker Letter	First Name	Last Name	Organization
C	Dan	Lipinski	U.S. Representative for Illinois's 3rd congressional district

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11	Gretchen	Goldman	Union of Concerned Scientists
12	Maggie	Flaherty	League of Conservation Voters
13	Adam M.	Finkel	University of Michigan School of Public Health
14	Augusta	Wilson	Climate Science Legal Defense Fund
15	David	Coursen	Environmental Protection Network
16	Abigail	Omojola	Breast Cancer Prevention Partners
17	Alan	Lockwood	Physicians for Social Responsibility
18	Elizabeth	Woolford	National Parks Conservation Association
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Public Hearing - Strengthening Transparency in Regulatory Science
Evening Session - Final List of Speakers | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Assigned Speaker No.	First Name	Last Name	Organization
1	Karl	Shipps	Representing Self
2	Kimberly	White	American Chemistry Council
3	Walter	Tsou	Philadelphia Physicians for Social Responsibility
4	Mark	Mitchell	National Medical Association

Public Hearing - Strengthening Transparency in Regulatory Science
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Public Hearing - Strengthening Transparency in Regulatory Science
Final List of Attendees | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Count	First Name	Last Name	Organization
1*	Carrie	Apfel	Earthjustice
2	John	Bobka	William & Mary Law School
3	Tom	Brennan	US EPA
4	*[Name Illegible]*	Broder	*[Organization illegible]*
5	Vincent	Cogliano	US EPA
6*	Joanne	Collins	HRI Science and Environment Group
7*	Timia	Crisp	American Geophysical Union
8	Bridgid	Curry	US EPA, OP
9	Ian	DeValliere	USCE
10	Mark	Drajem	NRDC
11*	Ligia	Duarte Botelho	B&C Consortia Management, LLC
12*	David	Dunlap	KII
13	Grayson	Feist	EVA
14*	Rebecca	Fowler	Climate Science Legal Defense Fund
15	Eve	Garthner	Earthjustice
16	Kelly	Good	Carnegie Mellon University
17*	Ruth	Greenspan Bell	Environmental Protection Network
18*	Meredith	Haines	HRI Science and Environment
19	Fred	Hauchman	US EPA
20	Bob	Hotes	US EPA
21*	Sebastian	Irby	Environmental Protection Network
22	Kysia	Jones	US EPA
23	Miles	Keogh	NACAA
24*	Yogin	Kothari	Union of Concerned Scientists
25*	Kevin	Letterly	Assoc. of State Drinking Water Admin.
26*	Angela	Logomasini	Competitive Enterprise Institute
27	Kamala	Lyon	University of California
28	Kelli	McPhail	Embassy of Canada
29	Sam	Miller	MTR
30	Christina	Motilall	US EPA
31*	Ryan	Mowrey	The Fertilizer Institute
32	Caryn	Muellerleile	US EPA, OP
33	Zoe	Need	US EPA
34*	Anna	Normand	American Geosciences Institute
35	Alison	Parker	US EPA
36	Dhara	Patel	UCLA Fielding, School of Public Health
37*	Mel	Peffers	US EPA

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39	Jack	Rayburn	trust for America's Health
40*	Kathleen	Roberts	B&C Consortia Management, LLC
41*	Eric	Rosenfield	OMB
42	Julia	Rowe	University of California
43	Keith	Rushing	Earthjustice
44*	Eunice	Salcedo	AFSCME
45*	Seema	Schappelle	US EPA
46*	Racquel	Segall	IAFF
47	Nicole	Shao	US EPA
48	Frank	Shipps	Dominican Friars
49*	Diana	Smith	Herndon-Reston Indivisible Science and Environment Group
50	Latosha	Thomas	US EPA
51*	Jeanne	VanBriesen	Carnegie Mellon University
52	Brianna	VanNoy	George Washington University
53*	Margaret	Wang	National Parks Conservation Association
54	Kara	Watkins	BCPP
55	Emma	Wheeler	Constituent
56*	Eleanor	Wintersteen	MIT
57*	Chris	Zarba	None

* Indicates onsite registrant

Public Hearing - Strengthening Transparency in Regulatory Science
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57*	Chris	Zarba	None

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Public Hearing - Strengthening Transparency in Regulatory Science
Morning Session - Final List of Speakers | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Assigned Speaker No.	First Name	Last Name	Organization
1	Ted	Steichen	American Petroleum Institute
2	Jodi	Feld	New York State Office of the Attorney General
3	Robert	Sussman	Safer Chemicals Healthy Families
4	Andrew	Rosenberg	Union of Concerned Scientists' Center for Science and Democracy
5	Daniel	Greenbaum	Health Effects Institute
6	Jennifer	McPartland	Environmental Defense Fund
7	David	Michaels	George Washington University School of Public Health
8	Paul	Billings	American Lung Association
9	Gary	Timm	Environmental Protection Network
10	Tyler	Smith	Earthjustice
11	Eugenia (Jeannie)	Economos	Farmworker Association of Florida
12	Anne	LeHuray	Pavement Coatings Technology Council
13	Diana	Van Vleet	American Lung Association
14	John	Auerbach	Trust for America's Health
16	Joseph	Stanko	Hunton Andrews Kurth
17	Peter	Lurie	Center for Science in the Public Interest
18	Jamie	Wells	American Council on Science and Health
19	Ami	Zota	The George Washington University
20	Surbhi	Sarang	Environmental Defense Fund
21	Laura	Bloomer	Harvard Law School
22	Nsedu	Obot Witherspoon	Children's Environmental Health Network
23	Joanne	Zurcher	National Environmental Health Association
24	Michelle	Endo	Environmental Defense Fund
25	Jia Ning (Jenny)	Xie	Environmental Defense Fund
26	Ann	Mesnikoff	Environmental Law & Policy Center
27	Roy	Gamse	EPN
28	Jennifer	Sass	Natural Resources Defense Council
29	Paul	Miller	NESCAUM
30	Matthew	McKinzie	Natural Resources Defense Council
31	Anne	Mellinger-Birdsong	Consultant
32	Erica	Bardwell	The reality-based community
33	Jennifer	Reaves	Moms Clean Air Force
34	Molly	Rauch	Moms Clean Air Force

Public Hearing - Strengthening Transparency in Regulatory Science
Morning Session - Final List of Speakers | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Assigned Speaker No.	First Name	Last Name	Organization
35	Barbara	Gottlieb	Physicians for Social Responsibility
36	Lyndsay	Alexander	American Lung Association
37	Laura	Bender	American Lung Association
38	Liz	Borkowski	Jacobs Institute of Women's Health (at Milken Institute School of Public Health, George Washington University)
39	Janice	Nolen	American Lung Association
40	Albert	Donnay	Donnay Detoxicology LLC
41	Mona	Sarfaty	Program on Climate and Health
No Show	Harvey	Fernbach MD MPH	Physicians for Social Responsibility

Assigned Speaker Letter	First Name	Last Name	Organization
A	Paul	Tonko	U.S. Representative from New York's 20th congressional district
B	Suzanne	Bonamici	U.S. House of Representatives, Oregon First Congressional District

Public Hearing - Strengthening Transparency in Regulatory Science
Morning Session - Final List of Speakers | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Assigned Speaker No.	First Name	Last Name	Organization
1	Ted	Steichen	American Petroleum Institute
2	Jodi	Feld	New York State Office of the Attorney General
3	Robert	Sussman	Safer Chemicals Healthy Families
4	Andrew	Rosenberg	Union of Concerned Scientists' Center for Science and Democracy
5	Daniel	Greenbaum	Health Effects Institute
6	Jennifer	McPartland	Environmental Defense Fund
7	David	Michaels	George Washington University School of Public Health
8	Paul	Billings	American Lung Association
9	Gary	Timm	Environmental Protection Network
10	Tyler	Smith	Earthjustice
11	Eugenia (Jeannie)	Economos	Farmworker Association of Florida
12	Anne	LeHuray	Pavement Coatings Technology Council
13	Diana	Van Vleet	American Lung Association
14	John	Auerbach	Trust for America's Health
16	Joseph	Stanko	Hunton Andrews Kurth
17	Peter	Lurie	Center for Science in the Public Interest
18	Jamie	Wells	American Council on Science and Health
19	Ami	Zota	The George Washington University
20	Surbhi	Sarang	Environmental Defense Fund
21	Laura	Bloomer	Harvard Law School
22	Nsedu	Obot Witherspoon	Children's Environmental Health Network
23	Joanne	Zurcher	National Environmental Health Association
24	Michelle	Endo	Environmental Defense Fund
25	Jia Ning (Jenny)	Xie	Environmental Defense Fund
26	Ann	Mesnikoff	Environmental Law & Policy Center
27	Roy	Gamse	EPN
28	Jennifer	Sass	Natural Resources Defense Council
29	Paul	Miller	NESCAUM
30	Matthew	McKinzie	Natural Resources Defense Council
31	Anne	Mellinger-Birdsong	Consultant
32	Erica	Bardwell	The reality-based community
33	Jennifer	Reaves	Moms Clean Air Force
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Assigned Speaker No.	First Name	Last Name	Organization
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40	Albert	Donnay	Donnay Detoxicology LLC
41	Mona	Sarfaty	Program on Climate and Health
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Assigned Speaker Letter	First Name	Last Name	Organization
A	Paul	Tonko	U.S. Representative from New York's 20th congressional district
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Public Hearing - Strengthening Transparency in Regulatory Science
Press/Media List | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Count	First Name	Last Name	Organization
1	Sam	Brock	Argus Media
2	Sylvia	Carignan	Bloomberg Environment
3	Francie	Diep	Pacific Standard
4	Maria	Hegstad	Inside EPA
5	Emily	Holden	Politico
6	Ellen	Knickmeyer	AP
7	Jeffrey	Mervis	Science
8	Sean	Reilly	E&E News
9	Esther	Whieldon	S&P Global

Public Hearing - Strengthening Transparency in Regulatory Science
Press/Media List | July 17, 2018
1201 Constitution Ave. NW | WJC East Building, Room 1153

Count	First Name	Last Name	Organization
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2	Sylvia	Carignan	Bloomberg Environment
3	Francie	Diep	Pacific Standard
4	Maria	Hegstad	Inside EPA
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6	Ellen	Knickmeyer	AP
7	Jeffrey	Mervis	Science
8	Sean	Reilly	E&E News
9	Esther	Whieldon	S&P Global

Master

Public Hearing - Strengthening Transparency in Regulatory Science

List of Attendees (as of July 16 2018)

No	Checked-in	First Name	Last Name	Organization	Registered to speak?
1	✓	Carrie	Apfel	Earthjustice	No
2		Lindsey	Beare	None	No
3		Emily	Berman	Union of Concerned Scientists	No
4		Renate	Caskey	Mrs.	No
5		Emily	Clark	Eastman Chemical Company	No
6	✓	Joanne	Collins	HRI Science and Environment Group	No
7	✓	Timia	Crisp	American Geophysical Union	No
8		Samantha	Day	GW Center for Regulatory Studies	No
9	✓	Ligia	Duarte Botelho	B&C Consortia Management, LLC	No
10	✓	David	Dunlap	KII	No
11		Alison	Elliott	Research!America	No
12		Neeraja	Erraguntla	American Chemistry Council	No
13		P A	Fenner-Crisp	N/A	No
14	✓	Rebecca	Fowler	Climate Science Legal Defense Fund	No
15		Kelly	Franklin	Chemical Watch	No
16		Julie	Froelicher	The Procter & Gamble Company	No
17		Whitney	Glaccum	Noblis	No
18	✓	Kelly	Good	Carnegie Mellon University	No
19		Anna Mae	Green	do not wish to answer	No
20	✓	Ruth	Greenspan Bell	Environmental Protection Network	No
21	✓	Meredith	Haines	HRI Science and Environment	No
22		Suzanne	Hartigan	ACC	No
23		Susan	Hazen	Hazen Consulting Support and S	No
24		Maria	Hegstad	Inside EPA	No
25	✓	Sebastian	Irby	Environmental Protection Network	No
26		Thomas	Johnson	Healthy Legacy Coalition	No
27		Ourania	Kosti	National Academies	No
28	✓	Yogin	Kothari	Union of Concerned Scientists	No
29		Bill	LaMarr	California Small Business Alliance	No
30	✓	Kevin	Letterly	Assoc. of State Drinking Water Admin.	No
31		Eric	Lipton	New York Times	No
32	✓	Angela	Logomasini	Competitive Enterprise Insitute	No
33		Delina	Lyon	Shell Oil Company	No
34		Chloe	McPherson	AAAS	No
35	✓	Jeffrey	MERVIS	Science	No
36		Katie	Morgan	Ocean Conservancy	No
37	✓	Ryan	Mowrey	The Fertilizer Insitute	No
38		Amandine	Muskus	Global Automakers	No
canceled		~~Marcie~~	~~Natale~~	~~Eastman Chemical Company~~	
39	✓	Anna	Normand	American Geosciences Institute	No
40		Bridget	O'Grady	Assoc. of State Drinking Water Admin.	No
41		Darrell	Osterhoudt	Assoc. of State Drinking Water Admin.	No
42		Jyotsna	Pandey	American Institute of Biological Sciences	No
43		Devon	Payne-Sturges	UMD	No
44	✓	Mel	Peffers	EPA	No

45	✓	Mikayla	Pellerin	Environmental Protection Network	No
46		George	Penny	1946	No
47		Rachel	Plett	RSM	No
48		Sunny	Qiao	National Parks Conservation Association	No
49		**Randy**	**Rabinowitz**	**OSH Law Project**	**No**
50		Jennifer	Reaves	Mom's Clean Airforce Maryland	No
51	✓	**Sean**	**Reilly**	**E&E News**	**No**
52		**Alan**	**Roberson**	**Assoc. of State Drinking Water Admin.**	**No**
53	✓	Kathleen	Roberts	B&C Consortia Management, LLC	No
54		Michelle	Roos	Environmental Protection Network	No
55	✓	Eric	Rosenfield	OMB	No
56	✓	Eunice	Salcedo	AFSCME	No
57	✓	Lauren	Schapker	National Ground Water Association	No
58	✓	**Seema**	**Schappelle**	**US EPA**	No
59		Stephanie	Schlea	Association of Metropolitan Water Agencies	No
60	✓	Racquel	Segall	IAFF	No
61		Joanna	Slaney	Environmental Defense Fund	No
62	✓	Diana	Smith	Herndon-Reston Indivisible Science and Environment Gr	No
63		Kristine	Smith	Bureau of Reclamation	No
64		Lucky	Tran	March for Science	No
65	✓	Jeanne	VanBriesen	Carnegie Mellon University	No
66		**Scott**	**Waldman**	**E&E News**	No
67	✓	Margaret	Wang	National Parks Conservation Association	No
68	✓	Eleanor	Wintersteen	MIT	No
69		Mark	Wright	self	No
70		George	Wyeth	Environmental Protection Network	No
71		Christopher	Yarosh	American Chemical Society	No
72		RP	Yeager	FDA	No
73	✓	Chris	Zarba	None	No

Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				*Note: To be filled out by Registration Desk Staff Members* - **Decided to Speak**	
Name	**Affiliation**	**Phone No.**	**Email**	**Session Assigned (M,A,E)**	**No. Assigned**
MILES KEOGH	NACAA	202 6247864	MKeogh@4cleanair.org		
Ian DeValliere	USCC	775-846-9788	idevalliere@uschamber.com		
Michael Baker, ECTA					
Kara Watkins	BCPP	2042466858	kwatkins@rcabengwv.com		
Dhara Patel	MPH Student, Health Policy and Management, Class of 2019	(312) 914-7329	dpatel@g.ucla.edu		

UCLA FIELDING SCHOOL OF PUBLIC HEALTH

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Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				Note: To be filled out by Registration Desk Staff Members - Decided to Speak	
Name	Affiliation	Phone No.	Email	Session Assigned (M,A,E)	No. Assigned
Caryn Muellerleile	EPA / OP	564-2855			
Bridget Curry	EPA/OP	565-2567			
Kamala Lyon	University of California	Personal Matters / Ex. 6			
Frank Shipps	Dominican Friars	Personal Matters / Ex. 6			

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Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				Note: To be filled out by Registration Desk Staff Members - Decided to Speak	
Name	Affiliation	Phone No.	Email	Session Assigned (M,A,E)	No. Assigned
JACK RAYBURN	TRUST FOR AMERICA'S HEALTH	202-223-9870 x28	JRAYBURN@TFAH.ORG		
Tess Dernbach	Earthjustice	717-439-4925	tdernbach@earthjustice.org		
Fred Hauchman	EPA	202-564-3151	hauchman.fred@epa.gov		
Eve Gartner	Earthjustice		egartner@earthjustice.org		
Tom Brennan	EPA	202 564 6953	brennan.thomas@epa.gov		
John Bobka	William + Mary Law School		Personal Matters / Ex. 6		

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Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				Note: To be filled out by Registration Desk Staff Members - Decided to Speak	
Name	**Affiliation**	**Phone No.**	**Email**	**Session Assigned (M,A,E)**	**No. Assigned**
Brianna VanNoy	George Washington Univ	937 902 8359	bnvannoy@gwu.edu		
Nicole Shao	US EPA	202-564-6779	shao.nicole@epa.gov		
Kell McPhail	Embassy of Canada				
Bob Hoten	USEPA				
Julia Rowe	University of California				
Grayson Feist	EPA				

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Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				Note: To be filled out by Registration Desk Staff Members - Decided to Speak	
Name	**Affiliation**	**Phone No.**	**Email**	**Session Assigned (M,A,E)**	**No. Assigned**
Kysia Jones	EPA				
Zoe Need	EPA				
Mark Dsajem	NRDC				
Keith Rucking	Earthjustice				
Sam Miller	NRL				
~~Jeff Fort~~	~~Dentons~~				

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Strengthening Transparency in Regulatory Science – Public Hearing

WJC East- Building Washington DC, Room 1153

Non-Registered Attendees (Attending Only) Sign-In Sheet

July 17, 2018

Contact Information				Note: To be filled out by Registration Desk Staff Members - Decided to Speak	
Name	**Affiliation**	**Phone No.**	**Email**	**Session Assigned (M,A,E)**	**No. Assigned**
Alison Parker	Fellow hosted by EPA	202 564 6058	Parker.Alison@epa.gov		
Latrisha Thomas	EPA	202 564 2621	thomas.latrisha@epa.gov		
Emma Wheeler	Constituent	**Personal Matters / Ex. 6**			
Vincent Cogliano	U.S. EPA	202-564-4313	cogliano.vincent@epa.gov		
Christina Motilal	US EPA	202-564-1257	motilall.christina@epa.gov		

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American Institute of Biological Sciences

38A

Jyotsna Pandey
Public Policy Manager
jpandey@aibs.org
202.628.1500 ext. 225
1401 New York Avenue, NW
Suite 430
Washington, DC 20005

Non-Registered Speakers Sign-In Sheet

17-Jul-18

		Phone No.	Email	Session Assigned (M,A,E)	No. Assigned
→				A	38A
PETER FERRARA	HERITAGE INSTITUTE	703-546-6814	peterjferrara@yahoo.com	A	40A
MARC MITCHELL	NATIONAL MEDICAL ASSOCIATION	860-794-9497	MMITCHELL@ENVIRO-MD.COM	E	4
KATE HARRIS					

U.S. EPA PUBLIC HEARING ON THE PROPOSED RULE "STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE"

Tuesday 07/17/2018 8:00AM to 8:00PM EDT William J. Clinton East Building Room 1153 (Map Room) 1201 Constitution Ave. NW Washington, DC 20460

NO.	NAME	AFFILIATION	CONTACT INFORMATION
1	Sylvia Carignan	Bloomberg Environment	scarignan@bloombergenvironment.com
2	Jeff Mervis	Science	jmervis@aaas.org
3	ellenknickmeyer	AP	eknickmeyer@ellen.gg apnews
4	Francie Diep	Pacific Standard	fdiep@psmag.com
5	Sean Reilly	E&E News	sreilly@eenews.net
6	Esther Whieldon	S&P Global	esther.whieldon@spglobal.com
7	Sam Brock	Argus Media	sam.brock@argusmedia.com
8	Emily Holden	Politico	eholden@politico.com
9	MALIA HEGSTAD	INSIDE EPA	mhegstad@iwpnews.com
10			
11			
12			

Public Hearing - Strengthening Transparency in Regulatory Science MASTER

Morning Session - List of Speakers (as of July 12, 2018)

No	Speaker No. Assigned	First Name	Last Name	Organization	Do you wish to speak?	Time slot	Est. Start Time
1	36	Lyndsay	Alexander	American Lung Association	Yes	8am-12pm	8:10 AM
2	32	Erica	Bardwell	The reality-based community	Yes	8am-12pm	:15
3	37	Laura	Bender	American Lung Association	Yes	8am-12pm	:20
4	8	Paul	Billings	American Lung Association	Yes	8am-12pm	:25
5	21	Laura	Bloomer	Harvard Law School	Yes	8am-12pm	:30
6	EO B	Suzanne	Bonamici	U.S. House of Representatives, Oregon First	8:35 AM	8am-12pm	:35
7	38	Liz	Borkowski	Jacobs Institute of Women's Health (at		8am-12pm	:40
8		Adam	Carpenter	American Water Works Association	Yes	8am-12pm	:45
9		Kara	Cook	US PIRG	Yes	8am-12pm	:50
10	40	Albert	Donnay	Donnay Detoxicology LLC	Yes	8am-12pm	:55
11	1	Eugenia	Economos	Farmworker Association of Florida	Yes	8am-12pm	9:00 AM
12	24	Michelle	Endo	EDF	Yes	8am-12pm	:05
13	2	Jodi	Feld	New York State Office of the Attorney General	Yes	8am-12pm	:10
14	15	Harvey	Fernbach MD MPH	Physicians for Social Responsibility	Yes	8am-12pm	:15
15	27	Roy	Gamse	(cancelled 7-16-18, taking John Bachmann's place in 8am-noon session)	Yes	8am-12pm	:20
	canceled	~~Irena~~	~~Gorski~~	~~Johns Hopkins Bloomberg School of Public~~	~~Yes~~		
16	35	Barbara	Gottlieb	Physicians for Social Responsibility	Yes	8am-12pm	:25
17	5	Daniel	Greenbaum	Health Effects Institute	Yes	8am-12pm	:30
18	12	Anne	LeHuray	Pavement Coatings Technology Council	Yes	8am-12pm	:35
19	NS	Vijay	Limaye	Natural Resources Defense Council	Yes	8am-12pm	:40
20	EO [redacted]	Dan	Lipinski	U.S. Representative for Illinois's 3rd	9:15 AM	8am-12pm	:45
21	17	Peter	Lurie	Center for Science in the Public Interest	Yes	8am-12pm	:50
22	30	Matthew	McKinzie	Natural Resources Defense Council (NRDC)	Yes	8am-12pm	:55
23	6	Jennifer	McPartland	Environmental Defense Fund	Yes	8am-12pm	10:00 AM
24	31	Anne	Mellinger-Birdsong	Consultant	Yes	8am-12pm	:05
25	26	Ann	Mesnikoff	Environmental Law & Policy Center	Yes	8am-12pm	:10
26	7	David	Michaels	George Washington University School of	Yes	8am-12pm	:15
27		Luke	Michaelson	Self	Yes	8am-12pm	:20
28	29	Paul ~~Kathy~~	Miller ~~Kinsey~~	NESCAUM	Yes	8am-12pm	:25
29	39	Janice	Nolen	American Lung Association	Yes	8am-12pm	:30
30	22	Nsedu	Obot Witherspoon	Children's Environmental Health Network	Yes	8am-12pm	:35
31	34	Molly	Rauch	Moms Clean Air Force	Yes	8am-12pm	:40
32	14	~~Jack~~ John	~~Raybum~~ Auerbach	~~Tryst~~ for America's Health	Yes	8am-12pm	:45
33	4	Andrew	Rosenberg	Union of Concerned Scientists' Center for	Yes	8am-12pm	:50
34	20	Surbhi	Sarang	Environmental Defense Fund	Yes	8am-12pm	:55
35	41	Mona	Sarfaty	Program on Climate and Health	Yes	8am-12pm	11:00 AM
36	28	Jennifer	Sass	NRDC	Yes	8am-12pm	:05

37	33	~~Trisha~~ Jennifer	~~Sheehan~~ Reaves	Moms Clean Air Force	Yes	8am-12pm	:10	
38	10	Tyler	Smith	Earthjustice	Yes	8am-12pm	:15	
39	16	Joseph	Stanko	Hunton Andrews Kurth	Yes	8am-12pm	:20	
40	1	Ted	Steichen	American Petroleum Institute (request time	Yes	8am-12pm	:25	
41	3	Robert	Sussman	Safer Chemicals Healthy Families	Yes	8am-12pm	:30	
42	9	Gary	Timm	Environmental Protection Network	Yes	8am-12pm	:35	
43	EO A	Paul	Tonko	U.S. Representative from New York's 20th	8:30 AM	8am-12pm	:40	
44	13	Diana	Van Vleet	American Lung Association	Yes	8am-12pm	:45	
45	KB	Jamie	Wells (for Hank Campbe	American Council on Science and Health	Yes	8am-12pm	:50	
46	25	Jia Ning (Jenn	Xie	Environmental Defense Fund	Yes	8am-12pm	:55	
47	19	Ami	Zota	The George Washington University	Yes	8am-12pm	12:00 PM	
48	23	Joanne ~~David~~	Zurcher ~~Dyjack~~	National Environmental Health Association	Yes	8am-12pm	:05	

Public Hearing - Strengthening Transparency in Regulatory Science — Master

Afternoon Session - List of Speakers (as of July 16 2018)

37

No	Speaker No. Assigned	First Name	Last Name	Organization	Do you v	Time slot	Est. Start Time (Note:10 Min Opening Statement; 15 minutes court reporter setup)
1	19	Paul	Allwood	Minnesota Department of Health	Yes	12pm-4pm	
2	4	Alexis	Andiman	Earthjustice	Yes	12pm-4pm	:30
3	17	~~Mary~~ Alan	~~Angly~~ Lockwood	Physicians for Social Responsibility	Yes	12pm-4pm	:35
	no longer speaking	~~Carrie~~	~~Apfel~~	~~Earthjustice~~	~~Yes~~	~~12pm-4pm~~	
4	26	Olivia	Bartlett	Do The Most Good	Yes	12pm-4pm	:40
5	36	Andrew	Bergman	Project on Government Oversight	Yes	12pm-4pm	:45
6	8	~~Elizabeth~~ Kiera	~~Brandt~~ Sheehan	Moms Clean Air Force	Yes	12pm-4pm	:55
7	27	Dan	Byers	U.S. Chamber of Commerce Global Energy Instit	Yes	12pm-4pm	1:00 PM
8	7	John	Doherty	iNdependent Toxicologist	Yes	12pm-4pm	:05
9	9	James	Duffy	Clean Air Task Force	Yes	12pm-4pm	:10
10	24	~~John~~ Steve	~~Dunn~~ Milloy	None	Yes	12pm-4pm	:15
11	13	Adam M.	Finkel	University of Michigan School of Public Health	Yes	12pm-4pm	:20
12	12	Maggie	Flaherty	League of Conservation Voters	Yes	12pm-4pm	:25
13		Christina	Franz	American Chemistry Council	Yes	12pm-4pm	:30
14	34	~~Ann~~ Adam	~~Gadilla~~ Spanier	American Academy of Pediatrics	Yes	12pm-4pm	:35
15	2	Elizabeth Ann Glas	Geltman	CUNY School of Public Health	Yes	12pm-4pm	:40
16	11	Gretchen	Goldman (for Vivian Chang)	Union of Concerned Scientists	Yes	12pm-4pm	:45
17	N/S	Bernard	Goldstein	University of Pittsburgh Graduate School of Publi	Yes	12pm-4pm	:50
18	5	~~Devon~~ Alexis	~~Hall~~ Andiman	Rural Empowerment Association for Community	Yes	12pm-4pm	2:00 PM
19	15	~~Michael~~ David	~~Halpern~~ Coursen	Union of Concerned Scientists EPN	Yes	12pm-4pm	:05
20	29	~~Chris~~ Tess	~~Heaney~~ Dernbach	Johns Hopkins Bloomberg School of Public Health	Yes	12pm-4pm	:10
21	28	Antonia	Herzog	Physicians for Social Responsibility	Yes	12pm-4pm	:15
22	6	Sarah	Kogel-Smucker	Office of the Attorney General for the District of	Yes	12pm-4pm	:20
23	3	Patricia	Koman	University of Michigan	Yes	12pm-4pm	:25
24	30	~~Alan~~ Mary	~~Lockwood~~ Angly	Physicians for Social Responsibility	Yes	12pm-4pm	:30
25	25	Meredith	McCormack	American Thoracic Society	Yes	12pm-4pm	:35
26	33	Brittany	Meyer	Michael J. Fox Foundation for Parkinson's Resear	Yes	12pm-4pm	:40
27	1	Pamela	Miller	Alaska Community Action on Toxics	Yes	12pm-4pm	:45
28	23	Steve	Milloy	JunkScience.com	Yes	12pm-4pm	:50
29	32	Karen	Mongoven	National Association of Clean Air Agencies	Yes	12pm-4pm	:55
30	35	Sean	Moulton	Project On Government Oversight	Yes	12pm-4pm	3:00 PM
31	31	Brenda	Munive	Physicians for Social Responsibility	Yes	12pm-4pm	:05
32		Tammy	Murphy	Physicians for Social Responsibility Philadelphia	Yes	12pm-4pm	:10
33	16	Abigail	Omojola	Breast Cancer Prevention Partners	Yes	12pm-4pm	:15
34	10	Erika ~~Lynn~~	Rosen ~~Goldman~~	George Washington University	Yes	12pm-4pm	:20
35	21	Virginia	Ruiz	Farmworker Justice	Yes	12pm-4pm	:55
36	Attendee	~~Joanna~~	~~Slaney~~	EDF	~~Yes~~	~~12pm-4pm~~	:25
37		Sarah	Spengeman	Health Care Without Harm	Yes	12pm-4pm	:30

38	20	John	Stine	Minnesota Pollution Control Agency	Yes	12pm-4pm	:35
39		~~Craig~~	~~Thompson~~	~~#WTMAPVigil~~	Yes	~~12pm-4pm~~	~~:40~~
40	32	George	Thurston	International Society of Environmental Epidemio	Yes	12pm-4pm	:45
41	15	Augusta	Wilson	Climate Science Legal Defense Fund	Yes	12pm-4pm	:50
42	18	Elizabeth	Woolford	NPCA	Yes	12pm-4pm	:55
43							4:00 PM
	C	Dan	Lipinski	Rep		2:45-3pm	

Public Hearing - Strengthening Transparency in Regulatory Science Master

Evening Session - List of Speakers (as of July 16, 2018)

No	Speaker No. Assigned	First Name	Last Name	Organization	wish to speak?	Time slot	Est. Start Time
1	43A	Mahealani	Daniels	The League of Conservation Voters	Yes	4pm-8pm	4:10 PM (Note:10 Min Opening Statement)
2	37A	Emma	Gildesgame	National Parks Conservation Association	Yes	4pm-8pm	:15
3	42A	Benjamin John	Kirby Hall	Center for Regulatory Reasonableness	Yes	4pm-8pm	:20
4		Patrick	Hedger	~~FreedomWorks Foundation~~	Yes	4pm-8pm	:25
5	~~41A~~	Liz	Hitchcock	Safer Chemicals Healthy Families	Yes	4pm-8pm	:30
6		Geoffrey	Kidd	United States citizenry	Yes	4pm-8pm	:35
	canceled	~~Peter~~	~~Lehner~~	~~Earthjustice~~	~~Yes~~	~~4pm-8pm~~	
7		Patrick	MacRoy	Environmental Health Strategy Center	Yes	4pm-8pm	:40
8		Joseph	Manuppello	Physicians Committee for Responsible Medicir	Yes	4pm-8pm	:45
9		Mara	Ponce	private citizen	Yes	4pm-8pm	:50
10	1	Karl	Shipps	Representing Self	Yes	4pm-8pm	:55
	canceled	Steve	Spacek	American State Litter Scorecard	Yes	4pm-8pm	5:00 PM
~~11~~		~~Theodore~~	~~Steichen~~	~~American Petroleum Institute~~	~~Yes~~	~~4pm-8pm~~	~~:05~~
12	3	Walter	Tsou	Philadelphia Physicians for Social Respo	Yes	4pm-8pm	:15
13		~~Johanna~~	~~Wermers~~	~~Environmental Defense Fund~~	~~Yes~~	4pm-8pm	:20
14	2	Kimberly	White	American Chemistry Council	Yes	4pm-8pm	:25
15	Women for her	Tracey	Woodruff	UCSF	Yes	4pm-8pm	:30
16		Terry	Yosie	Self	Yes	4pm-8pm	:35
17	38A move up	JYOTSNA	PANDEY	AMERICAN INST. OF BIOL. SCIENCES	YES		:40
18	40A	Peter	Ferrara	Heartlan Inst.			:45
19	4	Mark	Mitchell	National Medical Ass.			:50
20	9A						:55
21							6:00 PM
22							:05
23							:10
24							:15
25							:20
26	9						:25
27							:30
28							:35
29							:40

Message

From: Nanishka Albaladejo [nalbaladejo@scainc.com]
Sent: 7/20/2018 3:26:16 PM
To: Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere1144e76]; Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
Subject: RE: Public Comment - July 17 Hearing (1 file)
Attachments: July 17 PH Final Registration List.xlsx; Testimony of Lynn Goldman.pdf

Morning All,

You already have a copy of Ms. Goldman's testimony; she submitted it prior to the hearing. But I forgot to include in the packets sent yesterday.

Please let me know if you have any questions.

Thank you.

Nanishka (Nan) Albaladejo
LEED Green Associate/Environmental Scientist
1414 Raleigh Rd., Ste. 450
Chapel Hill, NC 27517
Office: (919) 484-0222, ext 959
Direct: (984) 243-3959
nalbaladejo@scainc.com
www.scainc.com


From: Nanishka Albaladejo
Sent: Thursday, July 19, 2018 4:54 PM
To: 'Perry, Dale' <Perry.Dale@epa.gov>; 'Clarke, Robin' <Clarke.Robin@epa.gov>
Cc: 'Sinks, Tom' <Sinks.Tom@epa.gov>; Joanne O'Loughlin <joloughlin@scainc.com>; Phil Norwood <pnorwood@scainc.com>; 'Hawkins, CherylA' <Hawkins.CherylA@epa.gov>
Subject: Public Comment - July 17 Hearing (1 file)

Good afternoon,

Attached is a condensed (zipped) public comments folder that includes scanned copies of oral testimonies submitted, scanned copies of written comments submitted to the docket box, final speaker, attendee and press lists, scanned copies of the original check-in/sign-in sheets.

Please note that I plan to follow up with the court reporters to see if they received any copies (while at the hearing) that were not provided to us (or that we are missing).

Please let me know if you have any questions or concerns.

Thank you and have a great day.

Nanishka (Nan) Albaladejo
LEED Green Associate/Environmental Scientist
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Message

From: Staff_OSA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BE69B6688A614CA39759D52CA5716EF3-OSA]
Sent: 7/16/2018 4:35:41 PM
To: Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]
CC: Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]
Subject: FW: U.S. Environmental Protection Agency (US EPA) public hearing on the proposed rule, "Strengthening Transparency in Regulatory Science,"
Attachments: EPA transparency comment.doc; EPA transparency in regulatory science ATTACHMENT to COMMENTS.pdf; DUNN EPA Science Transparency submission(1).pdf

Hi Dale,

Tom wanted me to get your opinion on the case below. We've been allowing substitutions for registrants but everyone we've allowed wasn't already speaking themselves.

In the case below, John Dunn wants Steve Milloy from Junk Science, who is already registered to speak at the 12-4 session, to replace him at the 12-4pm session.

In my opinion, John Dunn's registration should be cancelled and Steve Milloy not given another 5 minutes to speak. Tom suggests we allow Steve to represent John, but make it clear that he needs to be presenting John's comments.

What would you prefer we do?

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: Jill Breeden [mailto:jbreeden@scainc.com]
Sent: Monday, July 16, 2018 12:06 PM
To: Staff_OSA <Staff_OSA@epa.gov>
Cc: Nanishka Albaladejo <nalbaladejo@scainc.com>
Subject: FW: U.S. Environmental Protection Agency (US EPA) public hearing on the proposed rule, "Strengthening Transparency in Regulatory Science,"

Please see the below information from Dr. John Dunn.

Thank you,
Jill

From: John Dunn <jddmdjd@web-access.net>
Sent: Monday, July 16, 2018 11:56 AM
To: Jill Breeden <jbreeden@scainc.com>
Cc: steve milloy <milloy@me.com>
Subject: Re: U.S. Environmental Protection Agency (US EPA) public hearing on the proposed rule, "Strengthening Transparency in Regulatory Science,"

Ms. Breeden,

I talked to Tom in the Science Advisor's office a few weeks ago after the hearing was announced and I was assured that since I could not make the trip from Texas for in person testimony, I could have a substitute, who is Steve Milloy. Mr. Milloy is familiar with my work and has the submission and will make the in person verbal 5 minute presentation during the afternoon session that I signed up for.

I have submitted my comments and attachments for materials on my submission to the docket previously and Mr. Milloy has agreed to take my 5 minutes. I signed up for the afternoon segment.

My comments and submissions for the docket are attached above FYI, please inform me if there is a problem.

Thanks for your courtesy and consideration.

John Dale Dunn MD JD
Lecturer Civilian Faculty Emergency Medicine
Carl R Darnall Army Medical Center

Personal Matters / Ex. 6

From: Jill Breeden
Sent: Monday, July 16, 2018 8:56 AM
To: Nanishka Albaladejo
Subject: U.S. Environmental Protection Agency (US EPA) public hearing on the proposed rule, "Strengthening Transparency in Regulatory Science,"

Good morning,

You are registered to speak at the U.S. Environmental Protection Agency (US EPA) public hearing on the proposed rule, **"Strengthening Transparency in Regulatory Science," on July 17, 2018, at the EPA, William Jefferson Clinton (WJC) East Building, 1201 Constitution Avenue NW, in Washington, DC 20460, Room 1153.**

The hearing will begin at 8:00 a.m. (EST) and continue until 8:00 p.m. (EST) or one hour after the last registered speaker has spoken, whichever is earlier. Oral testimonies will be heard in 3 session increments: 8am to 12pm, 12pm to 4pm and 4pm to 8pm.

When you arrive please enter the William Jefferson Clinton (WJC) East Building on Constitution Avenue NW. Please be prepared to show a valid picture identification to enter. Room 1153 is located near the 1201 Constitution Avenue NW entrance.

A registration table will be located outside of room 1153. You will be assigned a speaker number based on when you check-in (i.e., on a first-come, first-served basis). Check-in for each session will begin one hour before the start of that session.

Each session will begin with opening remarks from an EPA official. The speakers for the session will be placed in order and testimonies will be given until everyone registered for that session has spoken. Oral testimony will be limited to 5

minutes for each commenter. A timer will be used to indicate when the 5 minutes are completed. Due to time constraints, slides and videos will not be permitted during testimony. Lunch, dinner and session breaks have not been scheduled. If you need to enter or leave the room during the hearing, we ask that you do so quietly.

The EPA encourages commenters to provide a copy of your oral testimony and any other materials electronically to Docket ID No. EPA-HQ-OA-2018-0259 at https://www.regulations.gov, or in hard copy form at the hearing.

Please forward any additional questions, comments, or concerns to staff_osa@epa.gov.

Jill Breeden
SC&A, Inc.
1414 Raleigh Road, Suite 450
Chapel Hill, NC 27517
P: 984-234-3962

This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

https://www.regulations.gov.

Docket ID No. EPA-HQ-OA-2018-0259

Comments submitted on the Docket Subject titled

Strengthening Transparency in Regulatory Science
Comment on Strengthening Transparency in Regulatory Science, Environmental Protection Agency, 40 CFR Part 30, RIN 2080—AA14 [EPA-HQ-OA-2018-0259; FRL-9977-40-ORD].

Comments submitted by John Dale Dunn MD JD
Emergency Physician, inactive attorney
Lecturer, retired Clinical Instructor,
Emergency Medicine Residency
Carl R. Darnall Army Medical Center, Fort Hood, Texas.

Table of contents of elements of the submission

The Submitter's opinions are personal and not attributable to the US Army or Department of Defense.

This submitter has witnessed US EPA misconduct for a period of 3 decades on a scale that is stunning, or alarming, going back to the EPA decision to ban DDT in the early 1970s, resulting in the deaths of millions in the 3rd world, and a particularly horrific impact on children.

More recently in addition to serial misconduct with regards to toxicology and epidemiology research the EPA has compounded its scientific methodology misconduct with a systematic violation of domestic and international ethical and moral/legal norms in regards to human experimentation—promoting and funding, approving human experiments that resulted in uninformed subjects being involved in experiments at 10 domestic and 6 foreign medical research institutions where they were intentionally observed while inhaling small particle contaminated air while being observed for adverse effects. These experiments carried out by prominent Medical Schools, is in spite of US EPA public pronouncements and testimony before congress that small particles are toxic, lethal (Hundreds of thousands of deaths annually) and carcinogenic.

US domestic law prohibits human experiments that might harm and international medical ethical standards for human experiments prohibit human experiments with no exceptions except exigencies of great need if the researchers act as subjects. Any other human experiments with a risk of harm are prohibited, and no consent will remove that proscription.

In the past 3 decades US EPA air quality research has been an abomination, relying on junk toxicology/epidemiology and the precautionary principle. The submitter has actively tried to expose the misconduct.

The proposal by the US EPA, discussed here to force EPA scientific transparency and scientific integrity is salutary and significant in all its elements, and the submitter is grateful for the change from the formerly fraudulent toxicology and epidemiology of the EPA to impose a new form of integrity.

I will detail in this submission the nature of the EPA sponsored research fraud, the methods and data manipulation and management that have resulted in EPA fraud on the public about air quality health effects, toxicological claims in other areas of EPA responsibility and the EPA full blown commitment to the hoax of CO2 levels as a cause of catastrophic warming. In these three areas of EPA research and policy making it is easy to identify the frauds on the public that are supported by a well-paid band of hired researchers and an in house gang of committed environmental true believers. The result is a fraud and research and policy conduct that is so badly informed and poorly researched and developed that it includes systematic commission of civil and even criminal acts to further an EPA agenda of aggressive environmental regulations that have created tremendous economic burdens for no good reason other than a fanatic environmental ideological agenda.

I will elaborate with specific references and documents in the submission below—elaborate on the irresponsible and flagrantly unscientific research funded and promoted by the USEPA on all matters of toxicology and epidemiology and my admonition to any reader is that if we do not stop this junk science for politics and ideology, we will follow the path of fools for a cause—the path of true believers that is paved with confirmation biases and fallacious science and policy making that violates the law and cheats the taxpayer in two ways, scaremongering, and regulatory burdens that steal resources and assets for regulatory compliance that diminishes better use of those resources in the public and private sectors. My promise to the reader is I will show you how and how much the EPA disrespects and abuses the rules and methods of science.

1. Other commentaries I agree with highlighted

The Washington Post
By Robert Hahn
May 10, 2018

https://www.washingtonpost.com/opinions/many-mocked-this-scott-pruitt-proposal-they-should-have-read-it-first/2018/05/10/31baba9a-53c2-11e8-abd8-265bd07a9859_story.html?noredirect=on&utm_term=.f7bcbc0a1887

Robert Hahn is a visiting professor at Oxford University's Smith School of Enterprise and the Environment and a non-resident senior fellow at the Brookings Institution. He recently served as a commissioner on the U.S. Commission on Evidence-Based Policymaking.

When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science."

But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

Critics typically argue that the proposed regulation would suppress research that contains confidential medical records and therefore scientists could not share underlying data publicly for privacy reasons. Such restrictions, these critics say, would have excluded landmark research, such as Harvard University's "Six Cities" study, which suggested that reducing fine particles in the air would dramatically improve human health and helped lead to more stringent regulation of fine particles in the United States.

...

But it appears that few defenders or opponents of the proposal have actually read the proposed EPA regulation, which is only seven pages long. Both sides distort the regulatory text.

Here's what the rule would actually do about the question of confidentiality of Personal Health Information under HIPAA or any other rule.

First, it would require the EPA to identify studies that are used in making regulatory decisions.

Second, it would encourage studies to be made publicly available "to the extent practicable."

Third, it would define "publicly available" by listing examples of information that could be used for validation, such as underlying data, models, computer code and protocols.

Fourth, the proposal recognizes not all data can be openly accessible in the public domain and that restricted access to some data may be necessary.

Fifth, it would direct the EPA to work with third parties, including universities and private firms, to make information available to the extent reasonable.

Sixth, it would encourage the use of efforts to de-identify data sets to create public-use data files that would simultaneously help protect privacy and promote transparency.

Seventh, the proposal outlines an exemption process when compliance is "impracticable." Finally, it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

(It is this submitter's position that the privacy/confidentiality issues raised by EPA sponsored researchers are intended to be a distraction—there is nothing that prevents a release of the data used in the EPA studies of the 90s, and since, because data can be collected without identifiers that penetrate to reveal Personal Health Information or the identity of individuals. Most of the EPA Sponsored studies on small particle effects are death studies—there is nothing that is sacred and confidential about a death certificate. The Studies the on ozone effects can easily be done to redact personal health information.) Here's what the EPA's new proposed rule wouldn't do: nullify existing environmental regulations, disregard existing research, violate confidentiality protections, jeopardize privacy or undermine the peer-review process.

Taking steps to increase access to data, with strong privacy protections, is how society will continue to make scientific and economic progress and ensure that evidence in rule-making is sound. The EPA's proposed rule follows principles laid out in 2017 by the bipartisan Commission on Evidence-Based Policymaking — humility, transparency, privacy, capacity and rigor — and moves us toward providing greater access to scientific data while protecting individual privacy.

Instead of throwing stones, the scientific community should come together to offer practical suggestions to make the rule better. For example, the rule should recognize the incentives for scientists to produce new research. . . .

Done right, this could improve government policy not only in the United States but also around the world.
It's still hard to tell how this rule will affect EPA decisions, but one thing is clear: The rule will make the evidence by which we make policy decisions more transparent. The policy might not be perfect, but its benefits will likely far outweigh its costs.

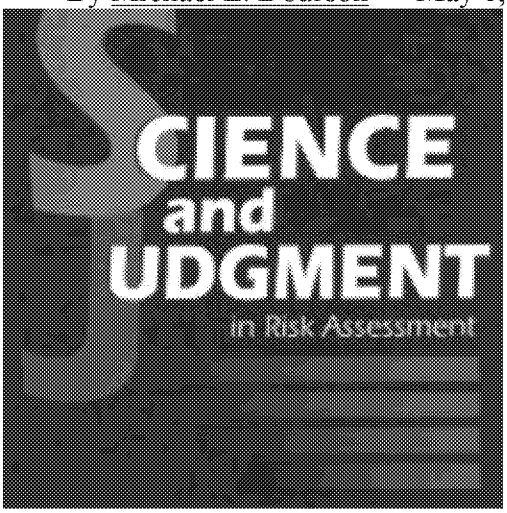
Comment by the submitter—this is blowing smoke and making excuses for the "secret science" that has dominated EPA activities for decades—there is no privacy or confidentiality problem with gathering data on deaths in studies that do not depend on personal data or release that personal data. Death Certificates with accompanying information do not violate confidentiality or privacy rules and can be used to assess the validity of the studies submitted—period.

Michael Dourson is a prominent toxicologist in the private sector. Here, again below I provide bold highlighting for his essay on the matter of the transparency proposal:

From A Risk-Assessment Perspective, EPA Getting Rid Of 'Secret Science' Makes Sense

•

By Michael L. Dourson — May 8, 2018 Washington Examiner



Science and Judgment in Risk Assessment - the "Blue Book"

Environmental Protection Agency Administrator Scott Pruitt's recent announcement that EPA will not use "secret science" — that is science for which the underlying data is not available — is challenging. Whereas EPA is routinely in receipt of unpublished toxicity studies for chemicals designed for commerce, not all important scientific findings are publishable. Nor do scientific journals generally have sufficient space to include all data.

Much has been made in recent weeks of this new EPA policy, including an op-ed opposing it by former EPA Administrator Gina McCarthy and former acting Assistant Administrator Janet McCabe.

The media coverage has focused attention on how science is considered acceptable and useful in EPA's rulemaking. But missing from this is the perspective of risk scientists charged with protecting public health. In the case of EPA, it is often not enough for any one positive study to be published in a peer-reviewed journal. Such work often needs replication because a positive finding occurs, on average, in one out of every 20 studies due to chance.

If a study cannot be replicated, then it at least needs to make sense within the pattern of available data. For pesticides regulated by EPA, these data are often from hundreds of studies done according to federal guidelines.

Studies that are not replicated or that do not make sense in an overall pattern are still considered, however. Risk scientists will often contact the authors to obtain additional information in order to conduct their own analysis, a common practice within EPA.

When such data are forthcoming, without the need to break confidentiality or disclose confidential business information, independent analyses can be conducted and the public health is better served. But when such information is withheld by the authors, government risk scientists are often left with a dilemma.

For example, imagine that a series of studies come out on a single human group that is exposed to a commonly used insecticide, and they show an unexpected effect at extremely low exposures. This finding

has not been replicated and clashes with multiple animal and human studies that point to danger only at much higher exposures.

In this case, EPA scientists would ask the authors for the underlying data to confirm this unexpected low-dose effect. But let's say they can't get it. EPA is then left with neither confirmatory studies, nor information that makes sense in light of other studies, nor the ability to conduct its own analysis. Understandably, Pruitt has chosen a policy of not using such studies.

There is one sense in which McCarthy and McCabe are spot on. The judgment over which epidemiology and/or toxicology data to use for risk or safety assessment purposes should be left to risk scientists. But from my perspective as a risk scientist, Pruitt's decision is still correct. The public's interest is best served when science is replicable and consistent with other information. When studies cannot be replicated or are inconsistent with other information, access to their underlying data is vital to independent analysis. When the underlying data are not provided to a risk scientist, it is difficult to use this study to make a credible risk judgment, much less national rulemaking.

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a safety level. But the public's interest is best served by trusting in experts dedicated to public health protection, not by withholding scientific data from independent analysis.

This article is republished from the *Washington Examiner*. Read the original here.

By Michael L. Dourson

Michael L. Dourson, PhD, DABT, FATS, FSRA, is prominent and accomplished toxicologist.

2. Choices in Risk Assessment--Report for the DOE 1994 by Steve Milloy

Steve Milloy, the founder and main writer for JunkScience.com for 20 plus years wrote a major research Monograph on Toxicological Policy issues as a contractor for the US Department of Energy in the early 90s. He exposed the federal agency science and policy misconduct in a major report "Choices in Risk Assessment" completed in 1994 on EPA 'science policy' and 'default assumptions.'

What is science policy? From "Choices in Risk Assessment", below are 10 common science policy issues and default assumptions used in EPA risk assessment.

Click here for a PDF of "Choices in Risk Assessment." It is more than 200 pages that explain why the EPA has lost its way, had lost its way in the early 90s because of ideologically energized environmental nonsense science.

Following the end of the Cold War, the Department of Energy (DOE) faced clean-up costs for its nuclear weapons sites amounting to hundreds of billions of dollars. The high costs would largely have been incurred because of EPA standards that essentially would have required the former weapons sites be returned to "Garden of Eden" status.

At the time, the DOE took the EPA standards so seriously that it was actually developing essentially a giant vacuum cleaner to suck-up the top layer of sand at the Nevada Test Site (approximately 5,400 square miles in size), decontaminate it and replace the sand.

Overwhelmed by the magnitude of the clean-ups, the Bush administration DOE commissioned Milloy in 1992 to lead an investigation into whether EPA clean-up standards were based on science or politics. Milloy's team of science and policy experts (called the Regulatory Information Analysis Project) compiled a report titled, "Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process."

Completed in the fall of 1994, the report concluded that environmental policy was largely based on politics, not science. But when the report was completed and circulated for review within the Clinton administration-run DOE, the report was flagged as politically incorrect and Milloy was ordered by Clinton appointee Carol Henry (a former EPA staffer) to keep the report secret.

Sacrificing his business relationship with the Clinton DOE, Milloy disobeyed the order and released the report, which was subsequently featured in a Wall Street Journal editorial.

The attention that "Choices in Risk Assessment" garnered coincided with the Republican takeover of 104th Congress and congressional focus on regulatory reform, vaulting Milloy into the regulatory reform debate about to take place on Capitol Hill. Milloy testified before the U.S. Senate about risk assessment in the context of DOE clean-up on March 6, 1995. The DOE never wound up spending hundreds of billions of dollars to clean up its weapons sites. No word on what ever happened to the giant NTS vacuum cleaner.

Dunn comment:

The DOE report by Milloy

CHOICES IN RISK ASSESSMENT: THE ROLE OF SCIENCE POLICY IN THE

ENVIRONMENTAL RISK MANAGEMENT PROCESS

Prepared for Sandia National Laboratories

Sponsored by the U.S. Department of Energy

Office of Environmental Management and Office of Environment, Safety and Health (1994)

There are more than 200 pages, so I provide some pertinent sections emphasized by Milloy that pertain to scientific issues that hit on the big issues.

This is the link to the document:

https://junkscience.com/wp-content/uploads/2018/05/Choices-In-Risk-Asscssment-v-01-01Interior-With-Cover.pdf

Below is the table of contents, that will give one a sense of the magnitude of the report.

Hereunder I also feature sections of the summary and conclusions of the report—that are stunning. Consider—this is a report written by one man, essentially, a biostatistician and lawyer, and it exposes the problem of risk management in a politically charged atmosphere—the scaremonger environment of the US federal agencies committed to the environmental cause. Misconduct of the federal agencies and their paid researchers in matters of toxicology/epidemiology/risk management.

My question would be—why didn't this author get a National Award for exposing scientific malfeasance and scaremongering in Federal Agencies in the early 1990s? Well the answer is found in an analysis of what has gone on since—Deep State, totalitarian, junk science fraud that promotes the precautionary principle approach in all matters of public health research and science, the agenda of leftist environmentalist fanatics.

The proposal for scientific integrity and transparency is long overdue and the damage done by ideologues in the federal agencies will require a major overhaul in methods and internal review processes.

Much of the damage could have been avoided, had Milloy's report been respectfully considered and used as a guide for federal agency risk management. Instead it was suppressed and ignored by the Clinton Administration environmental fanatics.

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Many risks to human health and the environment are "unprovable."

Some risks to human health and the environment are provable. Provable risks can be measured or observed directly and include actuarial risks such as those associated with highway or air travel accidents. In contrast, other risks—such as those associated with low-doses of radiation or exposure

to chemicals in the environment—are often too small to be measured or observed directly with existing scientific methods and available resources. Additionally, specific health and environmental effects are often difficult to attribute to specific causes because other competing causes cannot be excluded with reasonable certainty. Such risks are unprovable. However, the fact that a risk is unprovable does not mean that it does not exist. Provable risks can be calculated, whereas unprovable risks can only be estimated through the risk assessment process. Although unprovable risks may be estimated and expressed in probabilistic terms, they are at best educated guesses and do not constitute knowledge or uncontroverted fact. In other words, the ability to produce a numerical estimate of an unprovable risk does not mean that the risk is proven.

Science policy issues are unavoidable in, and science policy decisions are essential to, the regulatory risk assessment process.

Risks are unprovable because of significant gaps and uncertainties in scientific knowledge, data, and method. When risk assessment is used to estimate unprovable risks, these gaps and uncertainties become science policy issues. Both risk assessors and risk managers make science policy decisions in order to bridge the gaps and uncertainties. Thus, science policy decisions enable the estimation of unprovable risks.

. . .

CHOICES IN RISK ASSESSMENT

The existence and extent of science policy in risk assessment are rarely fully and fairly disclosed.

. . .

The lack of disclosure causes risk assessment results to be communicated essentially as fact. Such communication is misleading. Lack of full and fair disclosure of the role of science policy in risk assessment is not the fault of regulators alone. Media communication of risk information tends to omit discussions of science policy because such discussions: (1) do not fit into sound bites; (2) tend to detract from the sensationalism of the risk information; or (3) are not simple to communicate, and subtleties are lost.

Science policy decisions are responsible for regulatory programs and regulatory impacts that are justified on the basis of risk assessment

. . .

CONCLUSIONS AND RECOMMENDATIONS

As in the risk assessment process, science policy and other assumptions play a significant role in the estimation of benefits and costs associated with regulatory programs.

When risks can only be estimated, the benefits of regulatory programs to reduce those risks also can only be estimated, are not verifiable, and depend on science policy-based assumptions. Similarly, cost assessments often depend on assumptions, are uncertain, and cannot constitute uncontroverted fact. An important distinction between estimates of costs and benefits is in the certainty of their existence. Because it is not possible to prove with certainty the existence of unprovable risks, the existence of benefits from regulatory

programs also cannot be proven. In contrast, while there is uncertainty involved in cost assessments, such uncertainty is associated with the magnitude of the estimated costs, not their existence.

Science policy decisions can be made so as to result in desired regulatory outcomes.

The case studies of fluoride in drinking water, asbestos in consumer products, unleaded gasoline, and used oil are examples of decisions where science policy-based assumptions help to justify desired regulatory outcomes.

- In the case of fluoride in drinking water, the weight-of-evidence science policy decision that fluoride was not carcinogenic in humans supported the continued fluoridation of water, a highly valued and desirable public health measure. This science policy decision also helped maintain the credibility of the Public Health Service, which has been promoting the use of fluoride since the 1940s.

- In the case of asbestos in consumer products, the science policy decision to consider only the estimated cancer risk from asbestos brake products and not to consider the potentially offsetting safety risk from the use of non-asbestos brake product substitutes helped justify EPA's decision to promulgate a ban on commercial uses of asbestos.

- In the case of unleaded gasoline, the science policy decision that mechanisms of carcinogenicity varied between rodents and humans provided the basis for concluding that unleaded gasoline is not carcinogenic to humans. This science policy decision helped maintain the credibility of EPA's program to remove lead from gasoline.

- In the case of used oil, the science policy decision that used oil is not a hazardous waste facilitates used oil recycling. Labeling of used oil as a hazardous waste would have resulted in a burdensome cradle-to-grave regulatory scheme for used oil that might have undermined recycling efforts and increased pollution from illegal or improper disposal of used oil.

CHOICES IN RISK ASSESSMENT

For the foreseeable future, science policy will remain the key to all regulatory programs that rely on quantitative risk assessment.

. . .

Recommendations

Policy makers, risk managers, the media, and the public should be made aware of the role of science policy in risk assessment and subsequent risk management decisions.

Although risk assessors are likely to be aware of science policy issues and decisions, the same cannot be said for policy makers, risk managers, the media, and the public. Risk assessors often fail to emphasize the existence and extent of science policy in risk assessment. Where the role of science policy is not explicitly explained, risk estimates may be erroneously communicated to policy makers, risk managers, the media, and the public as uncontroverted fact. Because these groups are unaware of the role of science policy, they often fail to inquire about its impact on risk assessment. Either failure may result in regulatory decisions that are made on an uninformed basis to an uninformed, misled, or unnecessarily alarmed public. Risk assessors

should ensure that such miscommunication does not occur. Policy makers, risk managers, and the media should inquire about the existence and extent of science policy.

The federal government should institute a mandatory training and continuing education program on regulatory risk assessment and risk management for policy makers, risk managers, risk assessors, and their staffs.

Communication of risk assessment results should emphasize the role of science policy.

Because risk assessments for unprovable risks are educated guesses, risk assessment results should never intentionally or inadvertently be presented as fact. Full disclosure of the role of science policy should accompany risk estimates wherever presented, including Federal Register notices, executive summaries of regulatory documents, press releases, and other public and media communications. Disclosure is ineffective if it is inaccessible, comprehensive, explicit, and understandable. Disclosure should attempt to address the following questions:

- **Is the risk of concern provable, and can it be calculated? If the risk is unprovable, is it because the risk is too small to be detected with current scientific methods or because competing risk factors cannot be sufficiently distinguished?**

- **If the risk is unprovable, or provable but incalculable, what are the gaps and uncertainties in scientific knowledge and data that preclude the calculation of risk?**

- **What science policy decisions have been made to bridge these gaps and uncertainties? For unprovable risks, what science policy decisions have been made that concern the existence of the risk?**

- **Could alternative science policy decisions have been considered? What would the impacts have been on the risk assessment of these alternative decisions?**

- **What are the implications for regulation of the science policy decisions made as well as the alternatives? Do alternative science policy decisions reduce or eliminate the basis for regulation? Does consideration of substitution risks or lifecycle risks affect the basis for regulation?**

Answers to these questions will facilitate understanding of the likelihood that a risk exists and its potential magnitude. Improved understanding will enable: (1) policy makers and risk managers to decide on a more fully informed basis whether and what resources should be expended to address the risk; and (2) the public and media to debate the issue on a more fully informed basis.

Risk assessment guidelines may help provide a framework for the use of science policy in risk assessment, but only if such guidelines are flexible and complied with in good faith.

Risk assessment guidelines can provide a framework within which regulators can make science policy decisions. Such a framework would provide the regulated community and the public with the "rules" for science policy decisions in regulatory risk assessment. . . . With respect to potential judicial review, although it will be difficult for a court to rule on the scientific merits of an agency science policy judgment, a court can rule whether that judgment has been explained adequately. Ultimately, the merits of the judgment will be evaluated, and the agency's credibility will be weighed in the court of public opinion as well as by the scientific community.

Precedent has been established, and agencies should be encouraged to give meaningful consideration to alternatives to the default assumptions used in risk assessment

Only when policy makers, risk managers, the public, and the media fully understand the role of science policy decisions in risk assessment can the "real" issue in environmental and public health protection be debated. We must determine what society is willing to pay to reduce or avoid risks to human health and the environment which have been identified and estimated using science policy rather than science alone. These risks may or may not actually exist. If they do exist, they are likely to be relatively small or indistinguishable from other risks. If risks are too small or indistinguishable, it likely will not be possible to know whether regulation produced any benefit. The open debate of the value and priority of regulating these types of risks will enable, but not guarantee, policy and regulatory decisions to be made on a fully informed basis.

3. Commentary on proposed new, more stringent EPA ambient air standards for 2006.

Submitted for consideration in the comment period to end April 17, 2006.

April 13, 2006

John Dale Dunn MD JD

Brownwood, Texas violations of epidemiological and toxicology scientific rules are a scandal that cannot be ignored. The Dockery 1993, Pope 1995, and Samet 2000 studies (see endnotes) and other studies of health effects of air pollution relied on by the EPA, all showed that large studies with adequate power could not demonstrate relative risk of any significance. The studies all showed effects less than ten percent, rather than the statistically and scientifically required 200 to 300 percent effect. It is astounding the EPA has the gall to announce an air pollution crisis and propose more stringent air quality standards when none of the studies the EPA relies on show and proof of health effects.

The EPA is obligated to educate the public on the clear evidence that air pollution may have aesthetic and cultural import, but that there is no air pollution health "crisis." The EPA and its sponsored and supported health effects researchers are now just raising their voice in this debate instead of trying to use science. The EPA air pollution health effects science is an emperor with no clothes, as discussed below.

This commentary challenges the EPA to show one study that proves that one person has died due to air pollution in America in this past 20 years. People die for various reasons, suddenly and not so suddenly, as will be discussed below. That reality eludes the work of numbers crunchers who slave at desks over death certificate information like Pope and Dockery. One doesn't die from an exposure to air pollution, one dies from failed medical therapy, arrhythmias caused by long term coronary disease, stroke, pulmonary embolism, which are not caused by air pollution. The Asthma problem is an increasing problem not related to air pollution, since the rate of asthma is increasing with decreasing air pollution. The deaths from asthma will be discussed below and have nothing to do with air pollution, it is a socioeconomic phenomenon. It is time to retire the air pollution health effects studies of crude death tallies and it's time for the EPA to stand down from this repeated use of crisis talk and aggressive pursuit of pure air—a religious campaign disguised as science in the public interest.

As a last and compelling consideration, this author is familiar with death in America. As an emergency physician, much more familiar with what kills people than economists and public health officials who don't know which is the business end of a ventilator and live in the world of death certificates and mortality data. People die for many reasons and under many circumstances in America, but air pollution doesn't kill them, even the worst levels of outdoor air pollution one might imagine in America don't create a toxic level, which reveals the other major flaw in the EPA crisis rhetoric, junk science toxicology that completely disregards any effort to define toxin or toxicity. That subject will also be dealt with herein below.

The scientific epidemiological and toxicological criticisms of the EPA health effects studies and policy making are:

1. The Dockery 1993 and Pope 1995 studies did not show valid evidence of death effects, since they showed a death effects relative risk below 1.1, a negligible relative risk that is 10 percent of the minimal relative risk all epidemiologists consider necessary for proof of causation. A 200% or 300% change in death effect is the lower limit. Some epidemiologists require relative risk of 4 or a 400% effect when evaluating poorly controlled cohort studies.

2. This relative risk problem cannot be overcome by EPA and health effects researchers emphasizing the misleading use of the term statistical significance, which is not a proof test, but a statistical reliability test. One can be statistically confident and reliable but absolutely wrong.

3. The EPA and its health effects researchers have consistently and persistently ignored the lack of proof of health effects in these studies, and have made public announcements and allowed media reports to proclaim that thousands are dying in America due to air pollution when the studies do not show any proof of death effect at all. Lying for justice or an environmental ideal does not make the lie any less dishonest.

4. The health effects research used by the EPA has consistently ignored the basic rules for toxicology and the well-known phenomenon of threshold for toxicity. Only at the EPA does straight line toxicology have any status, mostly because it avoids serious science. Main stream toxicology science is still committed to the idea of threshold of effect and the old saying—the dose makes the toxin. The EPA scientists in house know the truth, but again politics and a commitment to a policy/environmental ideal results in lies.

5. Under no valid scientific analysis retro or prospectively, can the EPA use the methodologies or the results of the Pope, Dockery, McDonnell, or Lipfert (see endnotes) studies to justify one more burdensome air pollution regulation, but there is strong evidence for rescinding the last round of Air Quality Standards.

6. The EPA has a mandate to act only on the basis of acceptable scientific evidence of health effects, and is obligated to abandon the precautionary principle approach to regulatory policy, a pathetic substitute for legitimate science and clearly a principle founded in politics, not science.

7. The EPA could never convince a Federal Court, operating under Federal Rules of Evidence 702 and the court dicta for expert and scientific testimony that the EPA air pollution health effects science is valid proof of anything. The Pope, Dockery and Lipfert or Samet studies cannot be massaged or misrepresented enough to create any proof of air pollution health effects. The studies show trends within an insignificant range and "associations," that are not evidence of proof of health effects.

8. Precautionary principles that are used by the EPA as stand-alone policy justification are nothing more than a dressed up version of anxiety, cannot pass muster for admissible scientific evidence in a Federal Court and ignore the reality of risk/benefit analysis.

9. Based on the information reviewed in this critique, the EPA must revisit old rigs, forgo new, more onerous and expensive regulatory interventions, and the EPA must suspend its rulemaking in air pollution until it can find valid and reliable science on health effects.

Toxic air pollution existed in the past, and still may occasionally occur in some places on the planet as a local phenomenon, as particulate and other noxious air pollution in industrial areas, from various sources. Certainly air in big cities, Pittsburg, Los Angeles, Houston, New York was fouled in the past by air pollutants and even when not toxic, was smelly and visible, but trends in air pollution in the past 30 years as reported and confirmed by the EPA, have all been positive, attributable to changes in industrial processes, regulatory efforts and cleaner petroleum and coal consumption. Any study or discussion of air pollution is focused on a moving, improving problem. However the public thinks the air is worse than ever and there is an air pollution health effects crisis, and that is the fault of the EPA, its favorite researchers, and the mass media, who love to scare the public, since EPA budgets and environmental organization budgets depend on the anxiety of the public.

The death and illness rates during smog and air pollution catastrophe periods in the past were affected by less effective medical management and heavier cigarette smoking but also significantly higher air pollution than exists anywhere in the United States today, for many reasons. Deaths from acute respiratory failure in the past were more common and less preventable, but that is an independent factor related to medical advances and not due to air pollution itself. Airway diseases, the main effect of any air pollution, were less treatable before the 1970s. Pulmonary Medicine has changed dramatically for the better since 1970. Many airway diseases were more dangerous in the past and medical therapies frequently failed to control disease and death. Medical expertise in respiratory illness and cardiovascular disease is changed, but Pope and Dockery still yearn for the good old days of killer air because it scares the public. Their research ignores the trends of the last 20 years and below I will discuss a conscious deception in the second half of the Pope research from NCI data. In addition the EPA air pollution researchers continue to ignore the weakness of their findings, hoping to keep alive the "deadly air" panic talk alive.

People die for lots of reasons in America, but not due to air pollution. Air pollution health effects researchers know that, but act as though nothing has changed. The EPA should carefully reevaluate the number of deaths that researchers claim are due to air pollution in the last 20 years, but the EPA has a conflict of interest. No air pollution crisis might mean reduced EPA funding. No air pollution crisis might mean no funding for the researchers and their support organizations.

The air pollution health effects studies are based on weak epidemiologic relationships and trends carelessly described without definition as "associations," or "trends." Well ice cream consumption and drowning or boating accidents are associated by season, but ice cream eating doesn't cause water accidents. Associations are not proof, they are observations of phenomena--clusters of events that may or may not mean something. Epidemiologists know these things and should be careful when describing data associations and trends within insignificant ranges like less than relative risk of 2, so that the reader or reporter won't mislead the public or a politician. However, the definitions are not forthcoming from the scientists and researchers because saying that there is no crisis of air pollution means no publications for air pollution researchers, no

invitations to swell events, no funding, no chance to pursue a political agenda and change the world, making your mother proud.

The uncertainties of the air pollution health effects studies, the weak relative risks and the methodological problems of the most influential of the health effects studies are so noticeable and remarkable that during this comment period the EPA should reassess what has gone wrong in air pollution health effects research. The EPA should assess how these weak studies have affected EPA policy and rule making. The EPA doesn't have the right to panic the public and political leaders with deceptive junk science in the service of religious and fanatic environmentalism.

DISCUSSION OF THE STATISTICAL AND METHODOLOGIC PROBLEMS OF THE SAMET, POPE, AND DOCKERY HEALTH EFFECT DEATH STUDIES.

Author's comments are in bold. Studies referenced are underlined and the cite is in the endnotes by name and year. Sorry to disappoint those who want numbered endnotes—not a formal paper.

J. Samet (Samet 2000) published in the New England Journal of Medicine, a study modeled after the studies of Pope (1995) and Dockery (1993). He compiled and studied deaths in twenty American cities over a period of years, and compared them with air pollution monitor reports for those cities.

Samet in this 2000 paper asserts the following:

--"the relative rate of death from all causes was 0.51 percent increase for each increase in the PM 10 (10 micron size particulates) of 10 micrograms per cubic meter." This effect is not proof of anything, and Dr. Samet knows it. Less than a 1-% death effect is a nonsense result in a big cohort study.

--"the relative rate of death from cardiovascular and respiratory diseases rises 0.68 percent for each increase of 10 micrograms per cubic meter" Trends of less than 1% inside of a meaningless range of relative risk less than 1.05? A serious epidemiologist would snicker?

--"we also analyzed the effects of levels of carbon monoxide, sulfur dioxide, and nitrogen dioxide in a fashion similar to that of the analysis of pm 10 levels. After adjustment for pm 10 and ozone levels we found little evidence that these pollutants had a significant effect on the relative rate of death." Hold it, hold it, Samet says that he can't find an effect, even itsy bitsy effects from ozone precursor and carbon monoxide, something the other EPA favorite researchers say are killing thousands? Samet is not helping the EPA here. What about those dastardly pollutants? We scientists and particularly toxicologists are smiling to see Samet make a fool of himself and by adoption of this weak and deceptive epidemiology, the EPA doesn't look too good either. This is the kind of research the EPA has been using in air pollution regulatory policy now for years.

--"We did not find an effect of ozone levels on the overall rate of death from all causes or from cardiovascular and respiratory causes during the full year periods. Ozone levels were positively associated with mortality rates during the summer months when ozone levels were highest, although the 95 percent posterior interval extended into the range indicating no effect of ozone levels on mortality." Might this non-Johns Hopkins man who owns no jacket with arm patches translate for the benighted—Samet says even ozone doesn't have a death effect in his study. Score so far on this paper—rational skeptics for people in search of truth 3, EPA and Samet 0.

--"We found no evidence that key socioeconomic factors such as low socioeconomic status affect the association between PM10 and the risk of death in linear regression models." Some might be surprised to know that Samet works at a School of Public Health and all Public Health research for the last 20 years has shown clearly that there is a socioeconomic effect that produces premature deaths. Skeptics now 4 and running away, EPA and Samet still 0. Socioeconomic noise cancels out air pollution effects; that's the way the epidemiologists put it.

--"Our analysis also did not address the extent to which life is shortened in association with daily exposure to the various pollutants." Well golly Dr. Samet, everyone dies, how can you talk about death effects if you don't measure whether deaths are premature? Skeptics 5, Samet and EPA still 0.

Additional comments by this author:

1. The rate of death changes in Samet's studies are less than 1%, which is epidemiologically meaningless and shows no respect for the relative risk of 2 (100%) or more, that all cohort studies have to show in order to be able to assert effect. Little effects, even in studies with good confidence intervals and lots of power, are still empty studies, make work exercises. Samet's study was a nothing, yet it got published in the New England Journal, so one must wonder about political and environmentalist agendas up in Boston. I suppose they are neutral on the environment and always demand valid research in support of political agendas. I suppose.

2. The study fails to age/sex adjust for the important analysis—premature death. How did Samet get published? Samet is asserting proof of effect at less than one two hundredth of what is required in epidemiology. Then he says he didn't bother with measuring whether air pollution caused premature deaths. This research is about acute death affects? At non-toxic pollution levels? There is no plausible biologic science to support the idea that non-toxic air pollution kills people. Samet is beyond redemption. He's in scientific denial, or he works for the EPA agenda and he will be funded until he is old and gray.

3. Low relative risks, below 1.2, are the results in Samet's studies and all the other EPA health effects studies. One study goes above 1.2, the Dockery 1993 smaller study at 1.26, since recalculated by Enstrom in his article, Enstrom 2005 to 1.13. Such weak and minimal findings are unacceptable for publication, much less serious EPA policy making. The EPA and the studies misuse the term statistical significance, trends or association if they mean proof. There is no proof in any of these studies of an air pollution health effect. These studies prove nothing in the relative risk ranges of less than 1.3, particularly in cohort studies of death certificates that are subject to serious confounding.

4. The failure by Samet to find any effect, even these minimal effects, from other air pollutants like nitrous and sulfur oxides (ozone precursors), ozone, and carbon monoxide should give the EPA cause to wonder about any further attempts to impose new ambient air standards. The EPA has noticeably ignored Samet conclusions about these pollutants, why?

5. Samet's assertion that socio economics do not effect death rates is a an extraordinarily faulty conclusion for a public health researcher, since his study only looked at average area incomes for the twenty cities; and there is a vast body of public health research that shows that socioeconomics independently are a significant factor in life expectancy. (Wong 2002, Fitzpatrick 2001, Lantz 1998).

6. Socioeconomics is a factor and would nullify the signal from air pollution effect, and could even be a cofactor in another way by causing poor indoor air quality from substandard housing and a higher rate of

smoking along with a higher rate of underreported smoking. For example the poor have outdoor jobs where they can smoke more, and culturally they may be much heavier smokers with more inhaling, a potential confounder. Such confounding might explain the Ohio and West Virginia data from Pope 1995. That's why relative risk has to be set high, to avoid the effect of confounders not seen or understood.

The Samet article includes cautionary notes on the limitations of the study's methodology. His caveats are applicable to the all the previously mentioned Pope and Dockery, favorite EPA studies on air pollution health effects:

1. "For the pollutants measured on an hourly basis we calculated the 24-hour average." Toxicologists cringe at that one.

2. "If the pollutants were measured at multiple locations in a metropolitan area, we averaged the data." Remember the basic principles of toxicology, if you're downwind from an air pollutant you're safe, how can he say these things with a straight face. You have to know the patient and the toxin and the dose to know anything much about the science. Population studies are very crude at non-toxic levels of exposure.

3. "Since the Environmental Protection Agency requires levels of PM 10 to be measured only every six days, data for ozone and other pollutants were generally more available on more days." Good grief, this is a sham, a toxicology study with exposures every so often in sub toxic ranges.

4. "We analyzed the effect of the day on which the pollution data were obtained (the current day, the day before, or two days before) on the association with mortality rates. The overall effect did not vary with the lag interval selected. We report data for a one day lag between pollution variables and mortality." This is the place where Dr. Samet shows he doesn't know anything about death. You could be sick to death in a hospital and I can keep you alive indefinitely until the family gives up—where do those cases fit in Dr. Samet's arbitrary lag time of one day? What about people who die in a bed at a nursing home and haven't been outside in two years? These public health wonks and economists who hate dirty air do research as if a death certificate signed by the local GP is a piece of reliable data on the health effects of air pollution. They are in dreamland.

Then Samet says they found a temporal-causal relationship -- astounding! He didn't find a causal relationship, but he can find a temporal relationship. Did he dredge and dredge until he found something to point at? What's he talking about? Who's to know when the blips in the data are differences of less than 1%? That's not about cause of death, that's about political agendas and a polemic dressed up as science that causes public anxiety.

The good Doctor continues.

5. "Data on levels of PM 2.5 (small particulates) are not yet available nationally, since a monitoring network for particles in this size range is currently being implemented." This writer believes that Dr. Samet is working the agenda for the "annuity." Small particulates are an annuity for the EPA and air pollution researchers because, along with ozone, dust will never go away. Those air pollution demons assure EPA power into the distant future and more regs and anxiety. Dust is bad. Dust is always going to be there. It's the perfect air pollutant for the EPA.

Samet and others in the air pollution junk science club just use the PM 10-micron data that is measured every six days as a surrogate for PM 2.5. The supportive press and academic colleagues forgive such a lapse since they are working on the agreed upon agenda.

6. "Our analyses also did not address the extent to which life is shortened in association with daily exposure to the various pollutants."

Extraordinary. If the endpoint is a death effect, then the study must analyze premature death in mortal man and assess acute events as a measure of effect and endpoint for acute and/or chronic disease. To determine premature death effect, age and sex adjusted death rates are the accepted methodology, but Samet is just doing death rates and he gets published in the New England Journal of Medicine? Politics and the right agenda trump science and peer review?

7. "The finding that the association between PM 10 levels and the risk of death was strongest for cardiovascular and respiratory causes of death is consistent with the hypothesis that persons made frail by advanced heart and lung disease are more susceptible to the adverse effects of air pollution."

Again they didn't show that at all, they showed less than a 1% effect on death rates. I thought these people were dying of air pollution caused illness, not acute effects of air pollution, which at current levels couldn't kill a canary. What gives? What gives is that Dr. Samet is clueless because he's a numbers cruncher for the EPA in cahoots with his friends in the spic and span air society. I know why people die and it isn't from air in America, or even from Air America. Air pollution comes in many forms but we are obligated to live with toxicology science, not anxiety. Living organisms don't die for the thought of a smoggy day or from a bad smell. Dr. Samet and his cottage clack of air pollution hand wringers should go to a hospital and see how and why people die before they do these desk analyses of death certificates.

Despite these caveats the Samet research group asserts in the conclusion of their paper:

"Our analyses provide evidence that particulate air pollution continues to have an adverse effect on the public's health and strengthen the rationale for limiting levels of respirable particles in outdoor air." Samet says nothing about the significance of their research showing no death effect from ozone, carbon monoxide, sulfur and nitrous oxides. That would certainly disrupt current EPA policy, and he avoids an admission that the relative risks and death rate changes he found do not reach epidemiologic significance.

This study by Samet is sham epidemiology/science, junk science with lipstick, and the deception and "newspeak" harkens back to junk science in the service of the King or the current tyrant. Pope, Dockery and Samet are the officials/magicians/astrologers/conjurers in the EPA court, providing the EPA regent with needed "expertise" to justify the latest edict.

Briefly we will discuss below Dr. Samet's mentors, the EPA's favorite air pollution haters, Drs Dockery and Pope, who work together and change places on the authors lists of their papers.

The Six City and Pope Studies?

Dockery (1993) and Pope (1995) did studies that were the model for the Samet study discussed above. The studies did do better than Samet, in that they measured relative risk of premature death by studying death rate with age sex adjusting. Both Dockery and Pope were unable to show significant relative risk of health effect. The Pope and Dockery studies were used in the mid 1990s to justify EPA Director Browner's "emergency" new ambient air quality standards on ozone and other pollutants. The resulting cost was

estimated by the Center for Study of American Business at Washington University, St. Louis, at more than 100 billion. The Browner action was taken unilaterally, in spite of protests from many agencies within the government and without the approval or support of EPA internal experts. This action was taken without proof of a health effect, since Pope and Dockery never showed an acceptable relative risk. They were limited again to Samet's "associations" and trends within meaningless ranges below a relative risk of 1.3.

There is a greater relative risk of whole milk causing lung cancer than the relative risk that the EPA has shown for air pollution. One might say that's because of some confounder—well duuuh, that's why relative risk has to be above a threshold of 2 and some say 3, so confounders don't make the epidemiologist look confounded. Samet, Pope, Dockery don't care, they're on a roll and have the support of the environmentalist zealots, and the EPA (whoops, that's redundant). Call public relations, the research shows air pollution is killing thousands. It causes CANCER.

This paper points out that the EPA and the researchers are cheatin', and Dr. K. Popper, famous philosopher of science favorably cited by the Supreme Court in the Daubert decision, says that science must be more serious and reliable than politics. Popper asserts that science must be based on proofs that are reliable. Popper even talks about what the air pollution research by Pope, Dockery and Samet and the spic and span society is—Popper says some "science" is so bad it can't be falsified. How does one falsify something that means nothing? Associations at the edge of or in the midst of nothingness is what Pope's and the other health effects studies assert should be the basis for society wide regulatory regimes. Breathtaking—no pun intended.

The EPA says that air pollution kills thousands, because air pollution kills thousands. That is a tautalogy, a common tool for junk scientists. IT IS BECAUSE IT IS. I write here to tell the EPA that their anxious pursuit of clean air is more about politics and power and anger with modern industrial society that is already cleaning up the air, more about the religion of environmentalism. That's why the crisis, without the deaths or the science is a political or a polemic tool, not science. Not nice to fool with science that way, particularly when there is a Federal mandate that the EPA insist on scientific integrity for policy making. The EPA should not be in the business of ginning up false crises and scaring mothers that their kids are going to suffer from the air just so that the bureaucracy will thrive at the Federal and State level.

The EPA cannot claim to be unaware of the failure to prove health effects by the insignificant level of relative risk in the Pope and Dockery studies. These are the most basic of epidemiologic rules. And no subsequent studies have rehabilitated the failures of the Pope and Dockery studies. Samet, as described above, just repeated the same mistakes and came to up with the same lack of proof of health effect, unjustified conclusions and excessive and activist recommendations.

The barriers to a good study on health effects of air pollution for Dockery and Pope were the same as for Samet,

1. mobile populations,

2. unreliable, non-continuous and fixed monitor information,

3. no monitor information on some pollutants all the time (2.5 micron particles for example) or part of the time (10 micron and others),

4. an attempt to assess long term chronic health effects of air pollution by death studies, an acute phenomenon,

5. death certificates and raw death data used without autopsies,

6. inside air quality ignored for populations living indoors, particularly during old age, advanced medical illness, and terminal illness,

7. But most of all, no biological plausibility because the deaths are in the setting of non-toxic levels of air pollution (the inane straight line effect toxicology of the EPA cannot continue to get a pass—it is advocacy at the expense of science).

The EPA in assessing the air pollution effects studies must revive Bradford-Hill Criteria for toxicology.

The Bradford Hill (BH) criteria for toxicology are elementary, and establish biological plausibility for toxin effects. They require the toxicologist to establish plausibility, dose effect, reproducibility, time relationship, and a pattern of predictable and observable effects. Sounds like good science, but that's only part of it. Karl Popper was referenced above as the guru of the philosophy of science, and master or curator of scientific principles. The Popper legacy of science rules are referred to reverently in the Supreme Court opinion in the Daubert v. Merrill Dow Case [509 U.S. 579 (1993)] on admissibility of scientific testimony. Falsifiability is the key. To be true science one must submit to the test of being proven wrong. Pope and Dockery study results can't be falsified because they don't even allow a legitimate assertion of proof. They are tools in the game of politics, not in the game of toxicology. The EPA is required by common sense and federal statute to apply the BH criteria in air pollution studies, and all other toxicology work, but instead this wildly deceptive use of small changes within insignificant ranges of effect is souped-up to become the reason the EPA must act, now, immediately, to save lives. The EPA is saving itself, but the air pollution regulations are not saving any lives because the research would show the lives lost with valid epidemiology, and it doesn't.

The only reason that the EPA can create a crisis from the Pope or Dockery studies if it holds its nose and just projects to the whole population of the United States, then relative risk of less than 5% becomes thousands of deaths, even though it fails to show proof of one death caused by the toxicity of air pollution. Not one death.

If the biological plausibility of air pollution causing disease and death consistent with the BH criteria was established or could be established, then EPA and air pollution health effects researchers like Pope, Dockery and Samet could rest with their laurels. If air really were a killer or a toxin, we wouldn't see these weak cohort studies from the EPA with itsy-bitsy relative risks, and the argument would be over.

The EPA is not the national agency or institute for the arts, culture, pleasantness and good smells, it has a serious public health responsibility and a federal mandate to find toxins with legitimate science, promulgate appropriate solutions for the public benefit and then assess the effectiveness of what it has done. None of those steps are being taken in the air pollution policy making of the EPA.

The air pollution health effects studies in America will never be able to show the required relative risk of 2 or 3. What was the EPA role in such deception?

The idea that seems to control the EPA policy making on air pollution in the past 15 years is--ignore methodology and statistical problems, science be damned, move on to the grand program of air purification.

Find the ultimate terrible pollutant that will never go away, even with all our regulations. That is why small particulates are so promising for the EPA, enough so that these health effects studies talk about small particulates without measuring them, or measuring them in only one part of the study and not everywhere. The project of demonizing small particulates is reflected in the Samet study. He makes strong assertions with extraordinarily weak evidence, but he goes to the meetings, he knows what the EPA is concerned about. With EPA leading and frequently funding the crusade—science and truth casualties are acceptable. Small particulates are the worst crisis in the history of air pollution, they might cause CANCER.

I grew up and still live on a farm. I consider dust a reality that cannot be regulated away, just like ozone is part of the Smoky Mountains. There is a form of air pollution that is now being generated by the EPA in its ozone and small particulates crisis project—it is composed of dust, water, methane, and biological particulates.

Joseph Shumpeter said that the first casualty of a commitment to an ideal is the truth. The second casualty, this author asserts, is the unwary taxpayer and public that depends on responsible government. Solzhenitsyn said "The simple step of a courageous individual is not to take part in the lie. One word of truth outweighs the world." The EPA has become a slave to the lie of junk science in health effects research because the agency is devoted to its own importance and the importance of its religious and political agendas. EPA dredges up and makes icons of the precautionary principle, the small numbers/large projections lie, small trends within meaningless relative risks in populations studies, the refusal to recognize basic toxicology concepts. The EPA is a rogue agency in need of a stand down and close internal inspection with regards to bad policy making on the basis of bad science.

The Killer Smog

In The New England Journal of Medicine, Dr. C. Arden Pope, clean air activist, and one of the EPA's all time favorite air pollution health effects researchers, describes killer air in Belgium in 1930, Pennsylvania in 1948, and London in 1952 -- and uses those incidents as examples of why he thinks there is good reason to pay attention to a study in that issue of the Journal that claims to show a causal relationship between non-toxic air pollution and children's pulmonary functions. Again the study he is supportive of shows no epidemiological proof, just "associations," which are nothing more than statistical cluster puffs in population studies subject, as pointed out above, to bias and confounders. But the key is the study includes two important things for environmentalist zealots, children, and air pollution. Most importantly this study, like all the air pollution health effect studies, is working in insignificant causation ranges of effects so Pope and the EPA can talk about little bitsy trends and associations and urge that something be done before children die on playgrounds. They talk of these numbers exercises like they foretell an apocalypse. Gather the elderly and children and go seek shelter from the air, says Dr. Pope, an economist who got in the air pollution health effects business because he hated the air in Utah—imagine if he had lived in New Jersey. Dr. Pope advises---Stop breathing, if you must.

People do not go out into the streets of America, choke and die. The days of the people of London and Pittsburgh wearing dark clothes to mask the effect of soot and smoke are gone. The public health hanky battalion wants Americans to think air is killing their children and old folks, but in America ambient air pollution did not kill anyone, last week, last year, or in the last ten years. The panicky talk has to stop and the EPA must stop being the sponsor of the lie. The medical journals have to put their scientist hats back on and stop wringing their hands about nonsense environmental crises. The EPA is so busy these days frightening people about their rat studies and the imagined effects of so many things. Hardly enough time in

the day to pursue air pollution, except the EPA has lots of staff and lots of money and much energy and religious devotion to the cause.

EPA Policy and Regulation Activity

Fredrick Bastiat is known for his "law of unintended consequences," best exemplified as the analysis of the Paris shopkeeper's broken window. Bastiat made a common sense observation that when government or individuals choose to spend money or act, it produces desired and undesired effects, always making a ripple within the society and economy.

Let us propose to the EPA that if asthma deaths are predominately in young adult black males in America because of poor compliance (McFadden 1997), due to cost and availability of asthma treatment for disadvantaged adult black males or some other socio-economic or political problem, the EPA would be foolish to work on parsing senseless air quality regulations in preference to better asthma health care. The EPA would not be a party to such nonsense, would it, to relieve the anxiety of anxious environmentalists or satisfy the EPA staff's need for power and control?

There are no free regulatory actions. Every choice has multiple consequences, and government interventions have effects unforeseen. The EPA takes taxpayer dollars for every jot and tittle, every phone call, every new grand idea of every zealous bureaucrat. Every dollar spent for the EPA's ideal of pure air comes from somewhere and is taken from somewhere else.

The EPA is charged with responsible health effects research and policy making. The questions raised in the mid 1990s and now are the same:

1. If relative risk is a well known measure of cause and effect in epidemiology, why does the EPA allow relative risk below acceptable levels of proof to influence policy making?

2. Considering that EPA regulatory activity is tremendous burden to the economy, and the air regulations have a cost effect measured in billions per year taken from the taxpayer. If socioeconomic factors are an undeniable influence on quality of life and life expectancy, then can weak and unacceptable health effects epidemiology as described above, be excused for some abstract ideal of pure air?

3. Can studies that measure acute events in any way be considered studies of cumulative health effects? Are these death studies that Pope and the other air pollution researchers insist on basically flawed and deceptive. The answer is yes.

4. If some of the studies can't eliminate confounders, does the EPA have the authority to impose an onerous regulatory regime on the American society on the theory that cleaner air is a worthwhile, even if it doesn't have any effect on health?

Enstrom Particulate Air pollution Health Effects Study of 50,000 elderly Californians. 2005

Dr. James Enstrom, in the attached article found in appendix A, studied deaths in elderly Californians in 25 counties. He found that the relationship between fine particulates and mortality was very weak during the 1973-2002, particularly after 1982. He also reviewed the cohort studies on health effects of fine particulates and mortality by Pope, Dockery, McDonnell, and Lipfert, and found that their results were fairly similar to his, with the weakest health effects being present during the most recent years.

Enstrom finds:

1. The relative risks, age and sex adjusted and homogenized, are close to 1.00 in his and the other death studies (Pope, Dockery, McDonnell, Lipfert) he reviews in Table 10—there is no proof of health effect shown from particulate air pollution in his or the other studies.

2. Pope's year 2000 16 year follow up to the earlier (Pope 1995) study of the same cohort (Pope 2002) shows a declining cumulative risk from 1.07 to 1.04, first half to second That means to all but the innumerate that the relative risk in the second decade is well below 1.04. Hello Dr. Pope, Helloooo EPA.

3. Enstrom points out there are substantial geographic variation between the California populations of his study and Pope's Ohio, Kentucky and West Virginia data. The potential for confounders should be considered. I know something about that, and people in those states aren't the same as people in Enstrom's study. They might live different lives from their fellow citizens in Lala land. That's what homogenizing and sampling in epidemiology is all about. Without the data from those three states, Pope's studies would be more epidemiologically insignificant than they are, if that were possible. So much for avoiding cherry picking and the admonition to chip off the edges of the data to norm a cohort analysis.

The important points of the Enstrom study: .

1. Deaths and air pollution relative risks were assessed for 25 California counties, a cohort of 50,000 elderly Californians, and 39,000 dead before the end of the study in 2002. The relative risks were measured with proper confidence and homogeneity.

2. Relative risk found was extremely small and insignificant, 1.04 in the first part of the study (1973-1982), then relative risk of death from air pollution disappeared altogether in the second part of the study (1983-2002). Which will it be EPA, a crisis or salvation from killer air.

3. For the entire period the relative risk was 1.01 Pulleeez, 1-% risk? That's a relative risk of 1.01. I am closer than that to being rich and good looking, like Michael Jordan. The results would have to be 2.00 to be proof of any health effect, 1.00 is no effect.)

4. This Enstrom study, like all the other studies that the EPA uses to analyze health effects, and supposedly to study small particulate effects, is limited by the lack of PM 2.5 micron monitors before 1979 and only limited monitors after.

5. No increased death effects of any kind were shown in the counties with higher levels of air pollution, eliminating any dose response effect (a favorite rhetorical tool of the EPA researcher group), that, some of the higher pollution counties had lower relative risks. So is air pollution good for you if you live in California? In this range of relative risk absence of trend is meaningless but Dr. Enstrom does the

prescribed exercise, since the air pollution cabal likes to do trending and associations. The idea of a trend within an insignificance is interesting to consider, for fun, but not for science.)

6. Table 10 in Enstrom's paper shows a comprehensive review of comparable relative risks from large (Pope, Enstrom) and small (Dockery, McDonnell, Lipfert) studies, showing that only the Dockery study published in 1993 in a small cohort shows a relative risk above 1.1 at 1.15. All the other studies show relative risk similar to Enstrom, in the range of 1.07 or less.

7. In table 10 a number of the confidence intervals cross 1.0, the cumulative relative risk of the Pope study for the second half is lost in the failure to separate out the second half, indicating there is a reason to believe that in the second half of his study 1990-98, Pope had a relative risk approaching an insignificant 1.01. I worry, sort of, about Pope hiding this bad trend downward of an already weak relative risk. Could one suppose he has revealed this problem to his friends at the EPA?

Suresh Moolgavkar comments

It would not be practical here to cover all the writings of Suresh Moolgavkar on the epidemiologic and methodology problems he identifies in the EPA air pollution health effects research and policy making, and this writer does not understand some of the subtleties. Dr. M's brain and pen are too capable for an adequate treatment here, by a mere emergency physician. Dr. Moolgavkar's recent in depth review and critique of EPA particulate and air pollution research and policy making is in Appendix B.

Moolgavkar 2005 wrote a commentary on Enstrom's paper for Inhalation Toxicology discussed above (see second part of App. A). He asked the rhetorical question "Can contemporary epidemiological and statistical tools reliably detect miniscule risks, particularly with strong risk factors as potential confounders?" (Dr. Moolgavkar is too kind. He politely avoids exposing the junk science, the obvious, that miniscule risks in a cohort study like the results in the Pope, Dockery and other studies show no health effects at all and talking about trends in those ranges is silly.)

Moolgavkar objects to the methodology of proportional hazards modeling because "it is highly unlikely that proportionality of hazards would hold over the entire period of time covered by these studies." (The long term air pollution health affects studies). He asserts that it can be argued that "the SO 2 effect wipes out the PM signal in joint pollutant models." He does not even address the Samet study showing no SO 2 effect, so even that problem may ignore the more basic one that is so apparent—there is no detectable causal effect between air pollution and death. Dr. M is operating with the assumption that SO2 still is on the top of the list of bad pollutants. No doubt it is more toxic than others, but again, we must repeat the toxicology commandment—the dose makes the toxin. The air pollution health effect studies relied on by the EPA are ridiculously weak and are used as silly substitutes for a lack of laboratory proof that the current air conditions cause disease. The health effects research of Pope Dockery and Samet is just an exercise in the traditional deception of the "data dredge," the tool of crisismongers.

What is the point of quibbling about miniscule, below threshold of proof, differences in a cohort death study, some slavish devotion to arithmetic? I benefit, I suppose from not liking higher math, in this circumstances, that's why I focus on the medicine and the proper analysis of death studies and why people die.

Moolgavkar (2005 See App. B) wrote a lengthy review and criticism of EPA policy in Regulatory Toxicology and Pharmacology that exposes the epidemiologic and toxicological problems of the EPA air pollution health effects research discussed above.

Moolgavkar asserts: "evidence fell far short of supporting a causal association between particle mass concentration and human health." He goes on "the results of observational epidemiology studies can be seriously biased, particularly when estimated risks are small, as is the case with studies of air pollution. The Agency (EPA) has largely ignored these issues." "I conclude that a particle mass standard is not defensible on the basis of a causal association between ambient particle mass and adverse effects on human health."

Although Moolgavkar allows that the EPA may be bending the science in an attempt to pursue the precautionary principle on particulates, the precautionary principle under a mandate of good science in the public interest is not good policy. It is the default position for making concerns, feelings and aesthetics into the basis for regulatory actions that cost society billions for compliance. However no sandal-footed environmentalist gang of enviro-religious concerned citizens can allow the EPA to reject science.

The EPA is prohibited by federal mandate from ignoring science in the pursuit of the precautionary principle. The precautionary principle is anti-science and irrational by definition. Health effects not showed scientifically trumps feeling, concern and governmental overreach. The EPA is mandated by federal law to halt the overreach of the air pollution crisis crusade until it can resuscitate science in the public interest.

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App. A

Abstract only with one table added.

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Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973–2002

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Fine particulate air pollution has been associated with increases in long-term mortality in selected cohort studies, and this association has been influential in the establishment of air quality regulations for fine particles (PM2.5).However, this epidemiologic evidence has been questioned because of methodological issues, conflicting findings, and lack of an accepted causal mechanism. To further evaluate this association, the long-term relation between fine particulate air pollution and total mortality was examined in a cohort of 49,975 elderly Californians, with a mean age of 65 yr as of 1973. These subjects, who resided in 25 California counties, were enrolled in 1959, recontacted in 1972, and followed from 1973 through 2002; 39,846 deaths were identified. Proportional hazards regression models were used to determine their relative risk of death (RR) and 95% confidence interval (CI) during 1973–2002 by county of residence. The models adjusted for age, sex, cigarette smoking, race, education, marital status, body mass index, occupational exposure, exercise, and a dietary factor. For the 35,789 subjects residing in 11 of these counties, county-wide exposure to fine particles was estimated from outdoor ambient concentrations measured during 1979–1983 and RRs were calculated as a function of these PM2.5 levels (mean of 23.4 μg/m 3). For the initial period, 1973–1982, a small positive risk was found: RR was 1.04 (1.01–1.07) for a 10-μg/m 3 increase in PM2.5.For the subsequent period, 1983–2002, this risk was no longer present: RR was 1.00 (0.98–1.02). For the entire follow-up period, RR was 1.01 (0.99–1.03). The RRs varied somewhat among major subgroups defined by sex, age, education level, smoking status, and health status. None of the subgroups that had significantly elevated RRs during 1973–1982 had significantly elevated RRs during 1983–2002. The RRs showed no substantial variation by county of residence during any of the three follow-up periods. Subjects in the two counties with the highest PM2.5 levels (mean of 36.1 μg/m 3) had no greater risk of death than those in the two counties with the lowest PM2.5 levels (mean of 13.1 μg/m 3). These epidemiologic results do not support a current relationship between fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly before 1983.

Table ten is present as originally published in a pdf file of the article. Attached.

TABLE 10 Relative risk (RR) and 95% confidence interval (CI) for long- term all- cause mortality per 10- μ g/ m 3 increase in PM 2 . 5 for U. S. cohort studies based on PM 2 . 5

data, circa 1980

PM 2 . 5 Study characteristics

Study (author, year)

Data period/ Mean (range)/ (μ g/ m 3)/ Cohort geographic definition/ Follow- up period/

Mean entry age for period/ Number entered in cohort/ Deaths in follow-up period/ RR (95% CI)

Males

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 3671 a 830 a 1.15 (1.02– 1.30) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 130,310 a _ 12,400 a 1.07 (1.03– 1.11) b

McDonnell et al., 2000 1973– 1977 32 (17– 45) 9 CA airsheds 1976– 1992 58 _ 1347 _ 375 1.09 (0.98– 1.21) b

Lipfert et al., 2000 1979– 1981 24 (6– 42) 42 U. S. counties 1975– 1981 51 26,067 _ 4600 c 0.95 (0.89– 1.01) c

1982– 1984 22 (8– 41) 1982– 1988 57 _ 21,467 _ 6100 c 0.94 (0.90– 0.98) c

1982– 1984 22 (8– 41) 1989– 1996 63 _ 15,367 _ 5765 c 0.89 (0.85– 0.95) c

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 159,000 a _ 36,000 a 1.05 (1.01– 1.10)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 66 15,573 4701 1.03 (0.99– 1.07)

1979– 1983 24 (11– 42) 1983– 2002 74 10,872 8831 0.97 (0.95– 1.00)

Females

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 4440 a 599 a 1.12 (0.96– 1.30) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 164,913 a _ 8365 a 1.06 (1.01– 1.12) b

McDonnell et al., 2000 1973– 1977 32 (17– 45) 9 CA airsheds 1976– 1992 58 _ 2422 _ 568 _ 1.00 (assumed)

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 200,000 a _ 24,000 a 1.02 (0.98– 1.06)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 65 20,210 4094 1.05 (1.01– 1.10)

1979– 1983 24 (11– 42) 1983– 2002 73 16,116 10,815 1.02 (0.99– 1.04)

Both Sexes

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 8111 1430 1.13 (1.04– 1.23) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 295,223 20,765 1.07 (1.04– 1.10) b

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 359,000 _ 60,000 1.04 (1.01– 1.08)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 65 35,783 8795 1.04 (1.01– 1.07)

1979– 1983 24 (11– 42) 1983– 2002 73 26,988 19,646 1.00 (0.98– 1.02)

a Obtained from supplementary data (Krewski et al., 2000).b Recalculated from published data (US EPA, 2004).c Obtained from the author.

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Commentary

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Fine Particles and Mortality

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In an interesting paper in a recent issue (vol 17, issue 14)

of the journal, Enstrom examined the association between fine particulate matter (PM) pollution and mortality in a cohort of elderly Californians. The analyses used proportional hazards

regression and after adjusting for age, sex, cigarette smoking, and other potential confounders, Enstrom concluded, "These epidemiologic results do not support a current relationship between

fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly

before 1983." Enstrom's analyses were based on a sub-cohort of individuals enrolled in the first Cancer Prevention

Study (CPS I) conducted by the American Cancer Society (ACS). Enstrom's conclusion is consistent with the conclusions of a cohort study among veterans conducted by Lipfert et al.

(2000), but is at odds with the results from analyses of the second ACS cohort (CPS II) by Pope and others (Pope et al., 1995, 2002; Krewski et al., 2000), which reported statistically

significant associations between fine particulate pollution and mortality.

Every epidemiological study has weaknesses and limitations and, undoubtedly, both proponents and skeptics of the 'fine par-ticles cause death' thesis will find much to criticize in the studies

that do not support their conclusions. These discrepant results raise an important question, however. Can contemporary epidemiological

and statistical tools reliably detect miniscule risks, particularly with strong risk factors as potential confounders? All the cohort studies referred to above use proportional haz-ards modeling for data analyses. But is proportional hazards really the appropriate tool for these analyses? First, it is highly unlikely that proportionality of hazards would hold over the en-tire period of time covered by these studies. Statistical tests for departures from proportionality of hazards have low power. En-strom states that, in his analyses, these tests failed to reject pro-portionality of hazards. However, his finding of a higher relative risk associated with fine particles over the period 1973–1982 is inconsistent with proportionality of hazards over the entire

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I have discussed the original CPS II study (Pope et al., 1995)

and reanalyses (Krewski et al., 2000; Pope et al., 2002) in de-tail

elsewhere (Moolgavkar, 2005). I note here, however, that

the reanalysis by Krewski et al. (2000) of the original (Pope

et al., 1995) study (which considered no pollutant other than

PM), showed quite clearly that the pollutant most strongly as-sociated

with mortality was not PM but SO2.In fact, when SO2

was considered along with PM in the model for all-cause mor-tality, the coefficient for sulfates was reduced to less than a third of its original value, that for fine particles was reduced to a sixth of its original value, and both became statistically insignif-icant. It is also of interest to note that consideration of spatial correlations attenuated the PM coefficients to a much greater extent than the coefficients for SO2.Given the much stronger and more robust association of SO2 with mortality in the CPS II reanalyses, I find it surprising that this study continues to be taken as providing strong support for the PM mortality asso-ciation. It can be plausibly argued on biological grounds that SO2 could not be causally associated with mortality. But that still does not explain why SO2 wipes out the PM signal in joint pollutant models. This awkward fact has simply been dismissed as being irrelevant. In a more recent study of the CPS II cohort that doubles the follow-up time and triples the number of deaths, Pope et al (2002) reported significant associations between fine particles and oxides of sulfur with all-cause, cardiovascular and lung cancer mortality. Surprisingly, despite the findings in the Krewski analyses that SO2 was the pollutant most strongly as-sociated with mortality, no joint pollutant analyses were carried

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App. B

Abstract only

A review and critique of the EPA's rationale for a fine particle standard

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Received 18 November 2004

Available online 24 March 2005

Abstract I review the rationale for the Environmental Protection Agency_s 1996 fine particle standard, which was based almost entirely on the epidemiological data with neither support from Toxicology nor understanding of mechanism. While many epidemiological papers available in 1996 reported associations between ambient particles and adverse effects on human health, many others did not and the evidence fell far short of supporting a causal association between particle mass concentration and human health.

The literature appearing after 1996 further complicates the picture. The large studies that have appeared after 1996, such as National Mortality Morbidity and Air Pollution Study, and the reanalyses of the American Cancer Society II study, report risks that are substantially smaller than the risks reported in the 1996 Criteria Document and Staff Paper. Moreover, concerns about confounding by weather, temporal trends and co-pollutants remain unresolved. Other issues having to do with model choice have resurfaced as a result of reanalyses of critical data to address a glitch in a widely used software package for time-series epidemiology studies of air pollution. Finally, contemporary examples show that the results of observational epidemiology studies can be seriously biased, par-ticularly when estimated risks are small, as is the case with studies of air pollution. The Agency has largely ignored these issues. I conclude that a particle mass standard is not defensible on the basis of a causal association between ambient particle mass and adverse effects on human health. Such a standard may be justifiable on the basis of the precautionary principle, however. The Agency could argue that the Science raises concerns about current levels of air pollution, and that reduction of ambient fine par-ticulate matter mass, if it could be achieved without an increase in the level of the ultrafines, could have positive effects on human health. If the Agency justifies a particulate matter mass standard on these grounds then the debate over the form and level of the standard will, for all practical purposes, belong strictly in the Policy arena.

Keywords: Air Pollution; Particulate matter; Criteria document; Staff paper

4. Dunn submission on Ozone October 8, 2007

Subject: Comments on Ozone Standards 2007

Submitted via the a-and-r-docket@EPA.gov 10-9-07

Docket ID No. EPA-HQ-OAR-2005-0172

Comments by John Dale Dunn, MD, JD, Civilian Emergency Medicine Faculty, Carl R. Darnall Army Medical Center, Fort Hood, Texas, Policy Advisor, Heartland Institute, Chicago, IL. Member, Board of Scientific and Policy Advisers, American Council on Science and Health, New York, NY.

Corrected and revised final draft submitted 0915 CDT 10-9-07.

1. The EPA ozone science does not justify continued aggressive ozone regulation and a new lower 8-hour standard.

2. The observational air pollution studies and the weak exercise/ozone inhalation studies cited by the EPA show weak associations and relative risk less than 1.5, as well as lab results best described as non adverse. The study evidence cited by the EPA would not be admissible in a Federal Court because it violates basic epidemiology and toxicology scientific rules.

3. The EPA's own Clean Air Scientific Advisory Committee advised in the past that ozone effects research did not show adverse effects and the ozone standard should be left as is.

4. There is no EPA research that shows any benefits from the air quality improvements of the past 20 years. Is it that the EPA doesn't want to report any improvement, for fear it will jeopardize agency funding? Is it evidence that the air pollution wars of the past 20 years were against a PHANTOM MENACE? Are the weak population studies on air pollution weak for a reason--there was no killer air in America?

DISCUSSION

The EPA cited health effects studies are weak on adverse ozone health effects and weak generally on air pollution adverse effects.

The Scientific studies discussed in the proposal document are reviewed below. Although the studies are cited by the EPA to justify the ozone standard, they are not what the EPA commentary says they are. They do not excuse the old standard, or justify the new proposed ozone standards because they are a combination of weak observational studies and no-effect intense exercise/high ozone studies.

Commentary on some of the prominent studies:

1 Dockery DW, Pope CA 3d, Xu X, et. al. An association between air pollution and mortality in six U.S. cities. N Engl J Med 1993;329:1753-9.

Weak observational study that mentions, but does not control confounders. The results are small effects with relative risks of an insignificant magnitude that is proof of nothing.

2 Pope CA, Thun MJ, Namboodiri MM, et.al. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am J Respir Crit Care Med 1995;151:669-74.

Like the Dockery study above, one of the EPA's most important studies for justifying air pollution regulations. This study is another example of weak epidemiology with weak relative risks and no correction for confounders.

Even after the congress passed a law sponsored by Senator Shelby, requiring Pope and Dockery to produce their data sets, they still dodge and feint, and have not complied. Pope and Dockery are still in the inside clique of EPA favored and sponsored epidemiologists. They continue unhindered and well funded by the EPA and other governmental grant sources friendly to an aggressive regulatory agenda.

3 Hrostman DH Ozone concentration and pulmonary response relationships for 6.6 hour exposures with five hours of moderate exercise to 0.9, 0.10, and 0.12 PPM. American Review of Resp Dis Nov, 1990; 142: 1158-63.

Even heavy exercise with ozone inspired above current limits shows little ozone effect and no disease. The effect shown was mostly subjective respiratory mechanical effect. Ozone makes air heavy and increases its suspended/solute load.

4 Samet JM, Dominici F, Curriero FC, et.al. Fine particulate air pollution and mortality in 20 U.S. cities, 1987-1994. NEJM 2000; 343:1742-9.

Study of cities that claims to know how many days it takes for air pollution to kill someone, then proceeds to find no kill effect from all the air pollution factors, including ozone and ozone precursors, except small particulates, but then admits that the small particle monitor information is not available for the study and that big particles were used as a surrogate. Breathtaking, but published by Dr. Samet's friends in Boston. Incidentally the EPA on its air web site now has announced that large particles are no longer monitored or controlled because they do not cause adverse effects, but the old studies that concluded the dangers of small particles admit they used large particle monitor data as a surrogate for the small particles, since small particle monitors only became available in the late 1990s.

5 Wong JD, Shapiro MF, Boscardin WJ, et. al. Contribution of major diseases to disparities in mortality. N Engl J Med 2002;347:1585-92.

Discussion of confounders in death studies. Apparently has not been read by EPA sponsored and in-house epidemiologists, since the proposal documentation of the EPA makes little mention of he problem of the studies that are relied on—they make assertions without caveats like they were environmental gurus.

6 Fitzpatrick R. Ed. Social status and mortality. Ann Intern Med 2001 134;10:1001-2.

Lantz 1998 Lantz PM, Lepkowski JM et. al. Low income was an independent risk factor for premature death after controlling for health behaviors. JAMA 1998; 279:1703-8.

None of the studies used by the EPA for air pollution regulatory strategies control well for socio-economic status. Some of the studies do nothing more than mention that average income and education were used over large areas. Very similar to the casual use of wide-area, even regional monitors as measures of exposure to pollution.

7 McFadden ER jr., Warren EL. Observations on asthma mortality. Ann Intern Med 1997;127:142-7.

Shows that asthma mortality is in a select group of patients and caused by under-treatment and socioeconomic factors.

8 Mcconnell R, Berhane KT Gilliland F, "Asthma in exercising children exposed to ozone: a cohort study, Lancet 359 (2002) 386-91.

Selective reporting of this study ignored the protective effect of ozone, (yes, protective) in the whole cohort while making much of a minimal evidence of detrimental effects in one group--kids who were in three sports. McConnell is part of the Gauderman group that specializes in studying air in Southern California and always finds detrimental effects, even though many times the methodology and the evidence of risk are questionable and weak.

9 Gauderman WJ, Vora H, McConnell R, et al. Effect of exposure to traffic on lung development from 10 to 18 years of age: a cohort study. Lancet (on line) Jan 26, 2007. www.thelancet.com.

This study by the Southern California group had two major problems--1. Very small pulmonary function differences, less than 5%, which is insignificant, and no real negative trend, since the trend line only existed because of one outlier. There was also a high drop out rate. 2. The study measured differences in groups up to 1500 meters, dividing by 500 meters except for a group within 300 meters. Research shows that air quality from roadways is at background by 300 meters. The air quality on Southern California roadways was reported by H. Zhu in Atmospheric Environment 2002; 36: 4325-35 and in Environmental Science and Technology 2006; 40: 2531-36. Gauderman's group is well sponsored by a division of the California EPA. Imagine their funding stream if they reported no roadway effects?

Studies and analysis ignored by the EPA

The EPA also refuses to recognize the research and analysis that contradicts the EPA air regulation proposals.

Lipfert FW, Perry HM, Miller JP, et.al. The Washington University—EPRI veteran's cohort mortality study: preliminary results. Inhal. Toxicol. 2000, 12 S4:41-73. (Insignificant air pollution health effects.)

Enstrom J. Fine particulate air pollution and total mortality among elderly Californians, 1973-2002. Inhalation Toxicology 2005; 17:803-16. (Very large and long term study shows no air pollution death effect, in fact a counter intuitive protective effect of air pollution in many California cities. This study essentially nullifies the weak studies of Pope and Dockery as well as other death studies that are used by the EPA to push tighter NAAQS)

Moolgavkar S. Let. Fine particles and mortality. Inhalation Toxicology 2006;18:93-4. (Refutes the EPA air pollution project dogma. Discussion of EPA overreach and excessive regulatory zeal.)

Moolgavkar S. A review and critique of the EPA's rationale for a fine particle standard. Reg Tox Pharm 2005; 42:123-44. (Expose' of the EPA's failure to use good science to justify its agenda to make current ambient air pollution appear to be a serious health risk for Americans.)

Schwartz, J. No Way Back: Why Air Pollution Will Continue to Decline, (Washington: American Enterprise Institute, 2003). (Discussion of declining air pollution and improving air quality.)

The situation is so bad that the EPA and its sponsored epidemiologists and public health toxicologists control the literature and the journals. Journal editors now ignore toxicology and relative risk rule breaking. A recent poll by the National Institute for Statistical Science indicates that epidemiology journal editors no longer require data set production, p value calculation adjustments for multiple testing, and compliance with the rule on relative risk. The epidemiology journals have become political commentary on the hot environmental and social issues of the day—a mirror on the mental state of the academy.

Federal Rules of Evidence

The persistent failure of research on ozone and other air pollution observational studies to meet the requirement for relative risk of 2 and the p valued calculations without adjustment for multiple testing are examples of pseudo-science. The measure of scientific integrity, however, goes outside the academic and journal community. The Federal Courts have a stake in reliable evidence and the Federal Trial Court Judge makes the call on admissible scientific evidence.

The Federal Judicial Center's *Reference Manual on Scientific Evidence*, 2nd Edition (2000, West Group), also free on line at http://www.fjc.gov) Chapter on Epidemiology, written by highly esteemed experts, including Leon Gordis, the former Chair of epidemiology at Johns Hopkins School of Public Health deals with various matters of admissibility. The Manual states, at page 384:

> The threshold for concluding that an agent was more likely than not the
>
> cause of an individual's disease is a relative risk greater than 2.0. Recall that a
>
> relative risk of 1.0 means that the agent has no effect on the incidence of disease. When the relative risk reaches 2.0, that implies that the agent is responsible (with certain qualifications noted below) and implies a 50% likelihood that an exposed individual's disease was caused by the agent.
>
> A relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. Thus, a relative risk of 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent.

There are no major studies of ozone health effects relied on by the EPA that show a relative risk 2 or more. In fact there is not, at this time, a way to design a study on ozone that will show evidence of any relative risk, because there is no end point to measure. Ozone is a benign molecule, and doesn't cause death or disease. Exercise studies with excess exposure are a house of scientific cards for any EPA effort to build a toxicology argument against ozone.

The only reason the EPA can use these studies with relative risk of 1.5 or less, and not blush or apologize, is a political climate of panic about the environment and collusion in the academic and journal community collecting around the non-scientific social science concept of the precautionary principle. Discarding the relative risk rule is necessary to the survival of the precautionary principle, since the scientific evidence on ozone and most other pollutants cannot be shown to reach the relative risk of 2.

Expanding the effect of the EPA with "susceptibility."

The EPA also misuses the concept of sensitive or susceptible groups to make any exposure a concern for regulation. Susceptibility allows the EPA extraordinary latitude. There is always someone who is really, really sensitive—therefore the EPA plans to play the sensitive game and will make the society pay, eliminating any target toxin, regardless of the cost of the ablution. The rational regulatory regime does not adopt such a nonsensical approach, but the EPA embraces the concept as an excuse to overdo.

Reviewing the EPA United States air quality map, there are presently very few unsafe air quality areas, but that map will deceptively and dramatically change if the new ozone standard is implemented, along with the nonsense of the susceptibility. It will make no difference whether the standard is 0.06 ppm or .07 ppm, the non-compliance expansion guarantees that the EPA will exist into eternity.

The EPA is no longer in the business of protecting the public health and preserving the environment, the new range of ozone standards is an example of an EPA attempt to redefine what the environment should be and assure itself agency immortality. The EPA wants the world to be a scrubbed down bubble with no dust and no ozone for its own purposes, with no consideration of the rules of scientific integrity or even the mission of the agency to protect the environment and the public. Next the EPA will be regulating nitrogen, which is toxic if found at too high a percentage in the air. Really toxic.

The EPA is consciously and intentionally pushing the limits of scientific concepts of toxicity and epidemiology and cheating on the margins with the help of aggressive and flexible toxicology and epidemiology research. At this point a responsible Federal Judge, properly informed by the Federal Judicial Center Reference Manual on Scientific Evidence, chapters on toxicology and epidemiology, would throw out the "evidence" the EPA is using for this round of ozone standards.

The EPA refuses to study the health effects of the air quality improvements of the past 20 years. Why?

The EPA, like most government agencies or political advocacy groups, lives or dies by the old H.L. Mencken maxim about practical politics, that the public must be frightened, and anxious to be led to safety. False ozone fears and air pollution anxiety prop up the EPA. The EPA and its allies in the environmental movement feed the irrational and uninformed concern that the public has about a declining air quality, in the face of contrary evidence of improving air.

Why is there no research from the EPA that shows a public health benefit from the 20-year improvement in the quality of the air in the United States? Is the health benefit there and not shown or is it possible that the ambient air of 20 years ago, including the ozone levels, was not toxic? Generally even a blind toxicologist can prove a toxic effect by showing that the removal of a toxin caused a benefit. If there are air quality improvements that the EPA documents in its monitor information, then there should be a corresponding improvement in the health of the public.

Los Angeles and Houston air have improved—why no research to show the benefits? Is the EPA a one trick pony—they can only talk panic and crisis and bad air. Good air is not in the lexicon, only bad air and assertions of people dying from bad air? The proof of benefit would be the logical scientific inquiry to show the value of EPA activity and tighter air standards. Where are those studies of benefit?

If there is no real change in life expectancy or quality of life from air quality improvements, what will the EPA do, more importantly what should the country and the society do? Fire the EPA for lying or malpractice? The EPA and its allies in state and local government agencies, and in the non-governmental

environmental advocacy sector would be decimated by reports that there is no crisis in the environment, never was. They would also be, incidentally, unemployed and unemployable as pollution sheriffs.

Air Pollution Trends and Policy

Some places in America will be naturally dusty; some places will have natural background ozone levels that create haze. West Texas exemplifies the first, the Smoky Mountains the second. Trends in air pollution, control of ozone and ozone precursors in the past 30 years have all been positive, yet the EPA does not and will not report any benefit or improvement and continues to aggressively and energetically pursue every opportunity to increase its regulatory empire and authority. The EPA even sponsors and funds non-governmental entities like the American Lung Association and other rabid environmental groups that sue the EPA to push more environmental intrusions. That raises a question about conflicts and influence peddling, and contaminates the very important debate about EPA responsibilities to protect health and preserve the environment and maintain a high level of integrity in its science and research.

The blow back on the latest round of EPA overreach in ramming down the ozone standard is the protest of reasonable people confronting a new regulatory burden based on weak science. Ten years ago the EPA Clean Air Scientific Advisory Committee advised the EPA that ozone could not be shown to produce adverse health effects at the standard then, 0.12 PPM. Even then the CASAC, which is inclined to favor EPA policy proposals as a creature of the agency, was reluctant to support the ozone standard reduction from 0.120 ppm to a lower number. Chairman George Wolff said " although the panel member's opinions differed, none supported the lower end of EPA staff's recommendations, and a majority of members stated a position which included . . . the present standard."

EPA Clean Air Scientific Advisory Committee

The EPA Clean Air Scientific Advisory Committee (CASAC) in the late 1980s pointed out that ozone respiratory effects were not "adverse" health effects, and the CASAC in the 1990s refused to support using the Pope and Dockery studies to justify new NAAQS in 1997, but now the EPA is less scientific or objective in its analyses. The CASAC of today has become an advocacy committee committed to EPA agendas, even advocating more aggressive EPA activity. The CASAC of today has not and cannot be objective about ozone issues, and the current CASAC commentaries are not objective science but advocacy for aggressive environmentalism, now and forever.

There is no explanation for the CASAC conduct of the past few years other than political commitment to the environmental movement and the precautionary principle. In the past the CASAC and other agencies were the only chance that fanatic EPA officials would be brought under control, but now the CASAC has gone to the political side and cannot be trusted to show objectivity. Any argument for more regulation is supported. They represent the politicization of environmental science. CASAC commentary on small particulates last year was over the top.

Only 6 of 21 CASAC members supported the small particulate standards in 1996, the CASAC in 1996 advised in favor of the standard for ozone remaining at 0.120 ppm. Times have changed, the CASAC is now no restraint on junk science, and the CASAC of today is predictably in favor of any new and more stringent standard.

There are many in America who believe that the air quality is worse now than ever. That is because they get no reliable information from the EPA. The EPA is no longer a public agency that protects the public, but a

political propaganda mill, intent on panicking the public and working an environmentalist agenda. Informing the public of the improvements in air quality would reduce public anxiety and EPA and environmental group funding. Environmentalism would suffer a setback as a movement. The EPA is intentionally giving the public incorrect information about the current air quality, creating more anxiety, pollution warnings and claims about deaths.

This proposed new ozone standard is part of the deception, since the day the standard goes into place the American Lung Association, the EPA and the usual environmentalist organizations like Sierra Club will announce a new dirty air crisis. This latest round for ozone standard setting appears to be an effort by an EPA and its allies to reinvigorate their position as protecting the innocent public from killer air. They offer the naïve members of he public the proposal to create a pristine environment, more pristine than even Mother Nature could produce.

Consider, instead the reality as described by an environmental regulation expert:

> The United States has made tremendous progress in reducing air pollution during the last forty years. Air pollution has declined dramatically since the 1960s and 1970s, and virtually the entire nation now meets federal health standards for carbon monoxide (CO), sulfur dioxide (SO2), and nitrogen dioxide (NO2). Many areas of the country still exceed health standards for ground-level ozone ("smog") and airborne particulate matter (PM), but both of these pollutants continue to decline as well. Half of the nation's ozone-monitoring locations exceeded the federal one-hour ozone standard in the early 1980s, but only 13 percent exceeded the standard by the end of 2002. PM measurement methods have changed a number of times during the last forty years, but all trend data show PM levels dropping. Average levels of PM2.5—the form of PM now of greatest regulatory concern—have declined by a third during the last twenty years. (Joel Schwartz, 2003)

A good example of irrational panic mongering is in the September 9, 2004 issue of New England Journal of Medicine, in which C. Arden Pope, an economist cum environmentalist, describes as a companion piece to another children are victims of bad air article, describes killer air in Belgium in 1930, Pennsylvania in 1948, and London in 1952 and proposes those incidents as examples of why he thinks there is good reason to be worried. Pope is always worried, although he can't show me one person in his studies who really died from air pollution. They died as members of the cohort and he counted them as dead from air pollution after he looked at their death certificates. That's not a proper toxicologic analysis, that's an association. People don't die on epidemiologist's desks from associations.

In America ambient air pollution did not kill anyone, last week, last year, or in the last ten years. The crisis of bad air is long past, and the real health effects from air are non existent, but won't go away because the EPA is too big and too influential and too aggressive to go silent.

I agree with the Chairman of the Texas Commission on Environmental Quality, Buddy Garcia, who said in his letter of September 25, 2007 to EPA Administrator Johnson that ozone non-compliance will be the rule rather than the current exception, if the new standard is put in place. Mr. Garcia points out that 0.06 is well

known to the EPA as a background level in many environments—and that such a standard is irrational and cannot be complied with in places like the Gulf Coastal Plain.

Chairman Garcia also points out a little problem that the EPA ignores, that ozone precursors are mostly a product of mobile sources, not point/stationary sources, so the penalties and costs will be imposed on cities and communities for things they can't fix. Why is it that the EPA appears to care little about Mr. Garcia's concerns and his appeals for sensible science and policy making?

Summary

The research used to justify the proposed new ozone standard does not demonstrate results that meet the basic rule for proof of detrimental health effects. In fact the consistent findings of the EPA ozone research is insignificant ambient ozone pollution relative risk and laboratory evidence of fleeting effects if humans or animals are forced to breath high levels of ozone and exercise.

Research studies have shown that low relative risk results and pervasive confounders make it very unlikely that the proposed new ozone rules will have measurable beneficial or protective health effects. The EPA has failed to show the previous reduction in ozone levels has produced any benefits.

The EPA should abandon this precautionary-principle driven and junk science justified new standard, and retreat from continued aggressive tightening of ozone and other air quality standards.

Conclusion and recommendation.

There is no health effects science that justifies the current ozone standard of 0.08 ppm, so I urge the EPA to reset the ozone standard at the more reasonable 0.12 ppm, pending evaluation of the ozone control program for termination. Ozone should go the way of large particles, no longer on the list of EPA targets.

Imagine a government control program that has an end.

Economic and political effects of adoption of the recommendation.

I project that billions of taxpayer dollars and compliance costs could be returned to the citizens as soon as the EPA gives up chasing ozone, a benign component of the natural world.

I also project that a chastened and re-dedicated EPA might,fter the end of the ozone campaign, eschew future goose chases, and focus on serious, non-political, scientific inquiries in the public interest.

11-15-07

5. Dunn Presentation to the Health Risk Assessment Subcommittee of the and Executive Committee of the US EPA Board of Scientific Counselors 2007, 2008

John Dale Dunn MD JD

November 15, 2007 in person Bethesda, Maryland

Committee members and staff,

My name is John Dale Dunn. I am an inactive attorney. I teach emergency medicine at the Carl R. Darnall Army Medical Center, Fort Hood, Texas.

I asked for more time to present in early October, but I will do the best I can with the 3 minutes allotted. Dr. Stan Young from the National Institute for Statistical Science, and Dr. James Enstrom, epidemiologist from UCLA, will follow my presentation on the phone. We are not professionally or financially affiliated, but we share a concern about EPA scientific activity and integrity. In the future we will ask for more time to discuss our concerns with the BOSC.

H.L. Mencken made the prescient observation that the goal of practical politics is to create a hobgoblin, and make the public clamorous to be led to safety.

1. The Federal Judicial Center's Reference Manual on Scientific Evidence, published in 2000, and provided to the committee, was written by experts like Leon Gordis and Bernard Goldstein.

2. The scientific advice and rules provided to judges in the Manual are generally held and well known to the committee.

3. My concern is that EPA research repeatedly violates the Reference Manual rules on observational study relative risk as proof of causation and the rules on toxicology. I think well established and reliable scientific rules should govern EPA research.

4. The Manual insists on Relative Risk of at least 2 for proof of causation in observational studies. The EPA sponsored and funded research repeatedly and flagrantly violates that rule and claims small effects are reliable.

5. The Manual recites the traditional rules of toxicology, including the concept of threshold. The EPA violates those rules by arguing for high-dose toxin experiments on hybrid homogeneous rats and mice, combined with linear modeling as proof of toxicity.

EPA Administrator Browner had the chutzpah to claim that the adoption of ambient air standards proposed in 1995, that were based on Pope and Dockery small effects results, would prevent 20,000 deaths.

The quality of air and the environment is better now, but Americans think the environment is worse due to EPA public relations and research activities.

The BOSC is charged with assuring reliable and credible EPA research and policy making. EPA science should not risk a sensible judge applying the rules and finding EPA research inadmissible. It should be research and that does not panic the public with weak and incredible claims, like those made by Ms. Browner.

The BOSC should prevent the EPA shouting "consensus," intimidating the academic and journal community into breaking the rules and creating unjustified public anxiety.

Respectfully,

John Dale Dunn MD JD

Previous submissions:

Dunn Comments on small particle standards--2006.

Dunn Comments on ozone standards--2007.

Reference Manual on Scientific Evidence 2nd Ed. (2000)

Submission with this email:

2001 Editorial by Drs. Samet and Burke in American Journal of Public Health defending use of small effects studies.

Amicus brief submitted on behalf of Drs. Wogan, Eaton and 29 other distinguished Scientists criticizing EPA Linear Modeling on dioxin.

DUNN PUBLIC COMMENT SUBMISSION

MEETING OF THE EXECUTIVE COMMITTEE

Board of Scientific Counselors (BOSC) OF THE EPA

JANUARY 24-25, 2008 by phone with written submission emailed.

In the recent months I have provided materials and commentary on scientific integrity issues that fall within the BOSC Mission. The submissions and commentary were to the HHRA meeting and NERL meetings.

I renew for the Executive committee, my concerns about the following:

1. EPA sponsored scientists have repeatedly used relative risk in the negligible range as proof of health effects causation, in spite of epidemiology rules to the contrary, as recited in the Reference Manual on Scientific Evidence, published by the Federal Judicial Center.

2. The same is true of EPA sponsored science on the issue of hi dose rodent toxicology combined with linear modelling with no threshold. Again, I submitted the Reference Manual chapter on toxicology.

3. In addition to the Reference Manual materials, I submitted the brief filed on behalf of the American Council on Science and Health and many distinguished scientists criticizing EPA linear modelling and no threshold toxicology.

I will not resubmit these materials today, since they are already available to the Executive Committee, in addition to submissions by Dr. Stan Young on multiple testing unreliability and Dr. James Enstrom's submissions on his concerns about conduct in the scientific community that stifles inquiry and penalizes legitimate scientists.

The Executive Committee is composed of members much more expert than in the problems of data dredging in small effects science. The EPA is also embarked on a new series of toxicology projects that will increase the chance for problems, the genomic effects toxicology and small effects chemical toxicology research projects that increases the risk of more uncertain and unreliable research in health effects.

I ask the Executive Committee to begin to make more inquiries in these areas, and hold the EPA to a higher standard of reliability. The BOSC represents the interests of the public in assuring EPA science does not just promote interests and agendas of the EPA, but a balanced and reliable effort on behalf of the public interest and deserving of the public's trust.

Thank you for your consideration.

6. Essay by John Dale Dunn for congressional Aides of the Space, Science and Technology Committee of the House, on matter of Science and the Law

10-10-11

Introduction to fallacious and erroneous science and the law.

In addition to reviewing the Reference Manual on Scientific Evidence of the Federal Judicial Center, txt and links in this folder, there are also some excerpts from a book by Peter Huber, PhD and attorney, and Ken Foster PhD on the meaning of the new rules of admissibility for scientific evidence and testimony.

The section of the book excerpted focuses on fallacies in science and the intellectual, epistemological, political, social and psychological aspects of bad science.

First, however, anyone attempting to understand the current state of affairs should read the folder file on Angelo Codevilla, the essay on scientific pretense, along with the farewell speech by Dwight D Eisenhower in 1960 that discussed after the military-industrial complex, the government-research complex and in that section Ike warns of the danger of big government funding research programs and how such developments might corrupt the scientific process, which is not about authority and consensus, but skepticism and humility, the self-questioning that is essential for good science.

After reviewing the essay by Codevilla, one might expand on the problem of oligarchies in the other essay by Angelo Codevilla on the Ruling Class in America, that discusses the problem of elitist oligarchy dominated government tainted by group think and statist agendas. That is critical to the development of science in the service of politics.

Peter Huber, Kenneth Foster *Judging Science* (1997 MIT Press)

The chapters of importance in this book discuss the judicial articulation of what is good science, then essays and discussion on '

Testability and Falsification—Chapter 3

Errors in Science—Chapter 4

Reliability—Chapter 5

Scientific Validity—Chapter 6

That's enough for this folder material and will be summarized with the excerpts from the book including in the materials of the folder.

The materials are valuable, because they include original essays by many of the important figures in the philosophy of science. This summary is by John Dunn, but the original writers are better in their original discussion for more in depth inquiry.

1. Karl Popper is quoted and his teaching on good science is adhered to in the Blackmun Daubert opinion. Popper, a philosopher, emphasizes the importance of the deductive method of development of scientific concept and solutions, which is heavily focused on evidence and testing theories developed for evidence that might falsify the theory. Falsifiable is essential to a good scientific theory, otherwise Popper considers the theory non science. Pp. 35- 55

2. Weinberg proposes a concept of trans-science that is not practically verifiable or it may exceed the sensitivity of the instruments and methodology. Pp 55, 56.

3. An example of trans-science is epidemiology in the range below proof of effect, for example uncertain methodology or Relative Risk of less than 2. P 57.

4. Another concept of trans-science that is rhetorically in widespread use is to prove no risk, to prove the negative. P 58.

5. Reliability and validity are not the same, for example a reproducible and reliable measure may be invalidated because of a poor instrument or methods or bad underlying science. The first error is easier to identify and correct than the second, which looks valid. P 69-71.

6. Confounders produce validity errors and are the reason observational studies require effects of 100 percent—there are many confounders, listed at p 71, migrations or maturation of the study group, attrition, selection, regression to the mean, sequence of effects, experimenter and subject biases and behavior, even simple things like recall bias and overreliance on recall.

7. Confidence interval is another form of measure of reliability of the data, providing a range of accuracy or reliability around a result. P 79, 81. But some say that confidence interval is too loose. One important consideration is that if a confidence interval includes 1.0, there is no basis to argue for an effect. STUDIES RELIED ON BY US EPA THAT INCLUDE 1.0 IN THE CONFIDENCE INTERVAL (CI) ARE NOT RELAIBLE TO SUPPORT AN ASSERTION OF TOXICITY. A CONFIDENCE INTERVAL THAT INCLUDES 1.0 SHOWS A NULL EFFECT.

8. When the signal (results) is in the range of the noise (background natural variability) the reliability of the research is compromised by the signal to noise confusion. In studies with small effects like the US EPA air pollution premature death studies, confirmation bias (also called tunnel vision) energized by intellectual passion and commitment to a political agenda produce studies that do not justify the policies proposed and pursued or the regulatory regimes imposed. P 84.

9. Fallacies and fallacious thinking and research derive from reliance on authority, consensus, acceptance of a vote of those present, obfuscation or cover and selection bias in the service of intellectual passion or ambition, or the "gold effect" which is another form of intellectual passion combined with social

pressure consensus bias. All these biases and prejudices and fallacies of thinking are in contravention to the gold standard for scientific inquiry—skeptical experimentation by researchers who are the most strict judge of the nature and reliability of their research and disciplined in analyzing whether their evidence is proof of a theory. P 85.

10. Intellectual passion and ego of the researcher are sources of bad science and one of the most important conflicts of interest. Ego produces a failure to test one's theory adequately and produces confirmation bias—gathering supportive evidence and rejecting dissent or disagreement and evidence that falsifies the theory in favor. All researchers tend to mythologize themselves and their research, and lack the humility to recognize their own fallibility or see the limits or weakness of their research. Their investment in their career and stature make them rigid and uncritical in their assertions of theory or positing of solutions or answers. P 86

11. Sick science is characterized by:

a. The maximum effect is produced by a phenomenon of barely detectable intensity.

b. Observations are made near the threshold of visibility of the eyes or instruments.

c. There are claims of great accuracy (and significance).

d. Ad hoc excuses are used to nullify any dissent or criticism.

e. The supporters rise and then fall.

12. Another characteristic of sick science is the cargo cult syndrome—pretense of scientific methodology that has no substance. P 89.

13. Another characteristic of sick science is the reports of effects that are considered ominous are in the range of background. E.g. EMG that was proposed to cause terrible carcinogenic effects in the range of the earth's magnetic fields.

14. The pattern of error that goes to policy making, for example ignoring opportunity benefits, fear of introducing new technologies on the precautionary principle, ignoring safety risks associated with a proposed regulatory regime or remedy, ignoring large existing benefits in favor of fear of risk or the precautionary principle, or MOST IMPORTANT, IGNORING THE UNINTENDED CONSEQUENCES OF PROPOSED SOLUTIONS, EITHER IN TERMS OF COMPLIANCE COSTS OR DIRECT AND KNOWN RISKS AND DETRIMENTS.

15. Procrustean data torturing is not different from opportunistic data torturing, and certainly no less pernicious and deceitful. P 99.

16. The seven deadly sins of knowledge or the cognitive illusions that are nefarious;

a. overconfidence

b. magical thinking

c. predictability in hindsight

d. anchoring or tunnel vision

e. ease of deception

f. probability blindness or chance ignorance

g. the game of conjuring of linkages and ignoring the weak links in a chain P 118, 119

17. Reliability refers to the reproducibility of the data. Reliability is measured in terms of sensitivity and specificity. Bayes' theorem measures positive and negative predictive values that are both dependent on sensitivity and specificity. P 113-115.

18. Back to Popper, the soundness of a theory depends on

a. the conclusions must be internally consistent

b. avoid tautological statements that prove nothing but just reference the assertion

c. look for scientific advances in a theory

d. test a theory with experiments

19. The theory must be logically consistent, falsifiable, must assert something new, or novel, and it must be verified by experimental evidence (p 138, 139).

20. There are a fistful of fallacies

a. indirect cause asserted

b. necessary causes are not always sufficient cause

c. temporal or post hoc causation is not real causation

d. ecological fallacy transfers observations about populations to individuals

e. the faggot fallacy piles small and suspect items of proof or evidence and attempts to validate by the bundle or the height of the pile

f. weight of evidence fallacy is similar to e. and relies on the pile

g. bellman's fallacy is another form of the pile fallacy

h. fallacy of risk is the confusion of absolute and relative risk and using one or the other to deceive

i. inappropriate extrapolation is the assumption that one knows the trends and can project

j. new syndrome fallacy is novelty to an extreme

k. insignificant significance—overemphasizing the importance of statically significance in proof of a theory

l. Fallacy of ignoring large effects in small studies because hey fail a statistical significance test.

m. Positive results are fallaciously given more significance

n. Denial of medical mistakes (all these are on P 143)

21. There are good rules for reading and evaluating a paper as a reviewer. P 149-150

22. Feinstein dissects fallacious and alarming medical reports on reserpine causing breast cancer, coffee causing pancreatic cancer, and alcohol and breast cancer. Feinstein reviews how the studies on these reports were flawed. P 156.

It is important to note that the book Judging Science is an exceptional effort by extraordinary authors and this writer cannot do them justice. The books sections are excerpted by necessity.

Buying the book will be the best choice for anyone compelled to learn the intricacies of legal management of scientific evidence and the theories of science that underlie any reasonable discussion of scientific reliability and veracity.

7. An abbreviated story of the effort by John D. Dunn MD JD to expose the misconduct of the US EPA in matters of toxicology and epidemiology.

The Environmental Protection Agency's Particulate Matter Rules: One Physician's Crusade against Cargo Cult Science (JPANDS Spring 2014)

John Dale Dunn, M.D., J.D.

http://www.jpands.org/vol19no1/dunn.pdf

The U.S. Environmental Protection Agency has an annual budget of almost $10 billion, and influence and power far beyond that, with U.S. industry and society always subject to EPA orders, regulations, guidelines, fines, and edicts on environmental compliance.

My effort to expose EPA's bad science and policy making began in the early 1990s, and has culminated in the past 2 years in EPA's admissions, in declarations under penalty of perjury, that inadequate and unreliable, even unethical science underlies EPA regulatory regimes under the Clean Air Act (CAA).

In the infamous Tuskegee syphilis experiment, innocent black Americans suffered the depredations of advanced syphilis as federal public health agents denied them treatment. Now EPA-sponsored studies deliberately expose human subjects to pollutants that the EPA claims to be toxic, lethal, and carcinogenic. The Tuskegee experiment was unnecessary—the effects of advanced syphilis had been known for centuries. The EPA claims it already knows how dangerous fine-particulate air pollution is, but the agency is funding human exposure experiments with what EPA-published air quality standards say are toxic levels of fine-particulate air pollution.

Environmental Law Course

I was a small-town emergency physician and inactive attorney when the dean of sciences at the local Howard Payne University asked me to teach environmental law for the new undergraduate major in environmental science. I obtained the federal and state statute books and put the course on the curriculum to

include adult education for community people interested in compliance issues, as well as the environmental science students.

My study of the economics and politics of environmental regulation led to the conclusion that it involved a **form of cargo cult science** (fake science that looks like science), as described by Nobel Prize winner Richard Feynman,1 that develops when government money is lavishly given to people in the academy to support a political agenda built on a false threat of public harm. EPA's cargo cult science was in the area of epidemiology (population studies) and toxicology (study of poisons and harmful substances). It allowed EPA to beat the panic drum and scare people about killer environmental poisons that were not harming anyone in the ambient environment. This coincided with the growth of the radical environmentalist movement, which I would describe as a cult built on pantheism and a commitment to statist control of society.

One of my guest lecturers, an engineer responsible for compliance for Phillips 66 and an alumnus of Howard Payne, said that EPA would eventually take as much as five percent out of the gross domestic product. His predictions didn't seem so exaggerated when, in the mid-1990s, ozone air standards proposed by EPA Administrator Carol Browner under President Clinton were estimated by economists to cost the economy more than $100 billion. Browner pushed ahead in spite of objections and opposition by EPA's in-house Clean Air Scientific Advisory Committee, and all the Democrat administration-controlled executive agency divisions and offices.

Many aspects of junk science in the public health sector promoted by agencies like EPA are explained by biostatistician and lawyer Steve Milloy in his books *Science Without Sense* (Cato, 1995), *Silencing Science* (with Michael Gough, Cato, 1998), and *Junk Science Judo* (Cato, 2001). Other valuable books on bad science are by Peter Huber: *Galileo's Revenge* (Basic Books, 1991); *Phantom Risk: Scientific Inference and the Law* (MIT Press, 1993); and the most extraordinary study of junk science I have read, *Judging Science: Scientific Knowledge and the Federal Courts* (with Kenneth Foster, MIT Press 1997). The last focuses on the question of science as evidence and how rules of evidence should be used to determine admissibility of scientific testimony and evidence in court proceedings.

"Clean" Air vs. Safe Air: Justifying Regulatory Overreach

The cottage industry of air pollution research is committed to the proposition that air pollution panic is justifiable if it allows regulatory reach by the EPA that would satisfy an aesthetic demand for "clean" air. In my opinion, the research community is distorting the intent of the Clean Air Act (CAA), which should have been named the Safe Air Act since it is impossible to make the air"clean" of pollutants (such as dust, for example). The statutory language of the CAA required the EPA to identify harmful air pollution and mitigate the effects, not make the air "clean."

One of the most prominent EPA-sponsored researchers in air pollution is Jonathan Samet, M.D., chair of epidemiology at Johns Hopkins Bloomberg School of Public Health and chair of the EPA Clean Air Scientific Advisory Committee (CASAC). In a 2000 paper in New England Journal of Medicine, 2 he claimed that fine particles were causing deaths. This claim was based on an inadequately small association of fine particulates and deaths in a study of 20 cities. Small associations are not proof of causation and could easily be a random effect or result from data mining and dredging. By the year 2000 EPA had used its junk science to stack up a well-funded and sponsored pile of papers using the same bad methodology and claims

as the Samet paper, going all the way back to the Pope 3 and Dockery 4 foundational air pollution studies that created the EPA air pollution research and regulation crusade of the 1990s.

Samet and his fellow air pollution researchers, who had become advocates, would mine the data to find a small association and then announce a threat and crisis. In his 2000 paper, 2 however, Samet made an admission that I thought very important: he could not find a toxic effect from the other EPA criteria air pollutants, carbon monoxide, sulfur oxides, ozone, or ozone precursors such as nitrogen oxides and volatile organics. Today, however, Samet campaigns against ozone as if he had never written that paper.

After a two-part science and legal critique that I wrote on Samet's 2000 New England Journal of Medicine 20-city study of effects of air pollution at the website of the American Council on Science and Health, 5,6 James Enstrom, Ph.D., research professor at the University of California at Los Angeles, contacted me and asked for assistance with his efforts to stop California government efforts to create more air pollution regulations that would harm business and industry. I submitted public comments opposing proposed EPA particulate and ozone regulations in 20067 and 2007, 8 with no effect on EPA policy or attitude. EPA continued to make absurd claims that this or that air pollution regulation would save lives.

During that same period, I benefited from the statistics expertise of S. Stanley Young, Ph.D., of the National Institute for Statistical Science in Research Triangle Park, North Carolina.

U.S. EPA Board of Scientific Counselors

In 2007 Enstrom, Young, and I decided to approach EPA's Board of Scientific Counselors (BOSC), an outside independent scientific advisory group that was supposed to monitor and critique EPA science and policy making to encourage research compliance with basic scientific rules. BOSC was composed of members of high professional standing who were in private or state activities, and not EPA employees.

We articulated our positions, based on our areas of concern for BOSC subcommittee meetings in late 2007, and then the executive committee in early 2008. Our pleas and arguments were:

1) Irresponsible and false epidemiology and toxicology by EPA researchers claimed an effect that clearly fell well below any threshold needed to show a toxic effect in observational epidemiological population studies. Evidence for claimed air pollution death effects was inadequate to prove any causation and was asserted without a plausible toxicological mechanism.

2) Studies with multiple inquiries exaggerate the chance of false positives. The EPA was misusing the concept of statistical significance by failing to adjust for the multiple inquiries.

3) The EPA and its sponsored researchers and reviewers ignored studies that disproved their theories and suffered from tunnel vision and confirmation bias. Moreover they persecuted researchers like Enstrom who found results that didn't support the EPA agenda.9

I traveled to Maryland to present my concerns in person to the BOSC subcommittee of the Human Health Risk Assessment Committee, and Enstrom and Young presented by telephone. After waiting through hours of presentations by insider EPA officials and researchers before the scheduled public comment period, each of us was allowed only three minutes. Considering the inhospitable reception we received, it was not surprising we were the only outside commenters. Many lectures of an hour or more had been followed by laudatory comments from other EPA employees and officials present. I also noted that the roster of

committee members was clearly made up of people who had previously, or would in the future, want to be grantees of EPA largesse. It was definitely a home game, with home umpires.

I reviewed the Board of Counselors minutes for the previous five years and found there were no public comments at Board of Counselors meetings in those years. Even highly placed people in private industry, who were severely affected by its regulations, had no taste for criticizing EPA or its sponsored researchers. Favoritism and influence peddling are constant factors in governmental programs. Enstrom, Young, and I decided that appeals to the supposedly independent BOSC were worthless. Nonetheless, we made presentations to another subcommittee and then the BOSC executive committee.

The CARB Toxic Air Machine Project of 2007-2008

The battle was over at EPA, since it was a fixed game, but at the same time there was a battle going on in California led by Enstrom, which heated up in 2008 because of a new set of diesel engine rules focused on fine-particulate air pollution. These regulations were proposed and supported by research sponsored by EPA and the California Air Resources Board (CARB), a subdivision of the California EPA.

In 2005 Enstrom published his results of a robust and current study on the effects of fine-particulate air pollution in California. The study (10) involved 50,000 people in the years 1973-2002. It showed no premature death effect in California from fine- particulate air pollution. Moreover, California's air pollution of the 1950s and 1960s had declined for 30 years. Nonetheless, the increasing rate of asthma was misrepresented as a sign of an air pollution crisis justifying more air pollution regulations for no discernible benefit. Enstrom was also concerned that economic hardships would prove to be important causes of deprivation and decreased human life expectancy, as demonstrated in reliable population studies.11

In 2007, the CARB "solicitation" and review process was set up for a document entitled "Methodology for Estimating Premature Deaths Associated with Long-term Exposure to Fine Airborne Particulate Matter in California." The process included three scientific advisors and six "independent" but paid reviewers well known to, and allies of, CARB. Then CARB staff in May of 2008 released a draft report and proposed regulatory regime, claiming that air pollution caused premature deaths in California. A public comment period began, and the CARB business-as-usual process ran into vigorous critiques 12 submitted by Enstrom and other distinguished public health scientists and engineers in July 2008.

Public criticisms of the CARB draft report included:

1) Panel reviewers were reviewing their own or their close colleagues' air pollution studies.

2) CARB had discarded the Enstrom study and ignored geographic and time trend evidence available in the reviewed research that argued against their conclusions of air pollution death effects in California and the need for more regulations.

3) CARB had failed to adjust for changes in engines and emissions that also made older studies invalid.

4) Basic rules of the sciences of epidemiology and toxicology were violated in the CARB research that made claims based on small associations that were inadequate to claim a premature death effect.

My critique 10, pp 129-135 of the comments document discusses basic principles of scientific evidence that the EPA violates in its overreach. According to the Federal Judicial Center's Reference Manual on Scientific Evidence, 13, 14 which discusses the magnitude of toxic effect required in observational studies that are

used in public health toxicology research, an agent was more likely than not the cause of an individual's disease when the relative risk (RR) is 2.0, that is, a 100 percent increase in the disease or effect (e.g. premature death) in the exposed population. For example, the research on effects of cigarette smoking showed the RR of lung cancer in cigarette smokers is 10.

An RR greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. None of the cited foundational and supportive studies EPA or CARB use to justify air pollution regulatory regimes have the minimum RR of 2 needed to assert evidence in associations of causation.

While epidemiologists study population effects, toxicologists study adverse effects. In the early 1950s, Sir Austin Bradford Hill, British icon of public health research, originated nine criteria referred to by the Federal Judicial Center in the Reference Manual for proving toxicity. Hill's first and most important criterion was evidence of a measurable and significant toxic effect. Other criteria include that the toxic effect proposed has to be plausible, has to make temporal and dosage exposure sense, and should be evaluated to make sure some other factor is not in play.15

EPA has consistently disregarded the Bradford Hill criteria, in particular using small associations that fail the test of adequate evidence of effect. There is no real knowledge of actual exposure of individuals alleged to be affected or dead, and certainly no assurance that outside air quality is the exposure that is appropriate to measure, since people spend the majority of their time indoors. A final and important consideration is that EPA research shows no evidence of a current understanding of a plausible mechanism for fine-particle toxicity or lethality.

CARB staff in October 2008 issued a final report that was the same as the preliminary draft report of May 2008. CARB staff admitted that they didn't show the public scientific critiques to the expert panel or request an expert response to those criticisms of CARB research conclusions or policy proposals.

In December 2008, Enstrom and three other prominent California air pollution experts directly contacted CARB board members to urge rejection of the 2008 report. The four also wrote a public letter to CARB to recommend that CARB reassess the report and delay any decision on air pollution and diesel regulations.16

Enstrom and Young checked the credentials of Hien Tran, lead author of the CARB Report on Fine Particles and Premature Death in California, and found that he had a fake Ph.D., purchased for $1,000 from a drop box, Thornhill University.17 Enstrom and others also pursued another scandal—that CARB executive Mary Nichols knew of the Tran fraud and had not reported it to the CARB Board before Dec 12, 2008, when it voted to approve the Truck and Bus Regulation. Enstrom's research into the enabling legislation for CARB also found that most members of the Scientific Review Panel on Toxic Air Contaminants had served in their positions longer than the specified term of 3 years without following the nomination and appointment process of members required by the 1983 enabling statute. Pacific Legal Foundation filed a lawsuit in June 2009 to force compliance with the nomination and appointment process, resulting in the removal of five of the nine members.

A taxpayers' protest was held with speeches and demonstrations at the State Capitol on Aug 28, 2009, reinforced by the sound of a 220-truck convoy sponsored by the California Dump Truck Owners Association (now the California Construction Trucking Association). The convoy circled the Capitol building and, on

cue, sounded truck horns for one minute. The convoy and the Capitol steps rally on California agency overreach were not covered by the press, but the legislators were there.

Business leaders and industry sectors that use diesel engines raised their voices. Dr.Bill Wattenberg, an engineer and influential talk show host from San Francisco's KGO, railed against CARB. Bloggers and other radio hosts joined in. Bryan Bloom, Lee Brown, and Betty Plowman and other trucking industry people were eloquent in public meetings. Jay McKeenan for the California Independent Oil Marketers Association, representatives of the logging industry organizations, Bill Davis with the Southern California Contractors Association, and Shelly Sullivan of the California Manufacturers and Technology Association, all pressed for a CARB suspension of the new diesel rules and a sensible agency retreat from its aggressive stance. Skip Brown, construction executive, was a steady and important participant as a speaker and writer.

California Assemblyman Roger Niello (R-5th Assembly District) presented a bipartisan letter with 52 signers demanding that CARB suspend the new diesel rules. Senator Robert Dutton (R-31st Senate District) and Assemblyman Dan Logue (R-3rd Assembly District) introduced bills to slow down CARB implementation plans on greenhouse gas and global warming regulations. Gov. Arnold Schwarzenegger weighed in to advocate a suspension of any new fine particulate/diesel regulations until the California economy could recover.

As a result of this 2-year campaign, CARB attempted to repair its damaged reputation for reliable research with a full-day scientific discussion and "cage match" debate on Feb 26, 2010 at the California EPA hearing room in Sacramento.

CARB designated three experts from the original scientific review panel: Daniel Krewski, Ph.D., Michael Jerrett, Ph.D., and Arden Pope, Ph.D., well-credentialed and also longtime friends and beneficiaries of CARB and EPA grants, members of the insider air pollution club with senior status. CARB paid for them to appear just as they had paid for previous research and review work.

Krewski has headed a large group that did a national study.18 A close look at the results showed that they found no air pollution "associations" that would support a claim of human health effects in California, but they ignored their own results, which would argue against their basic premise. During the symposium, Jerrett admitted that he couldn't find an air pollution health effect in California, but a year later he manipulated the data to show a minor association in one of his models19 created by a trick in methodology and geographic gerrymandering that he called "conurbation."20 As noted above, the Pope and Dockery group 3,4 have been prolific and always predictably produced studies with very weak associations that they claim support their position that air pollution kills.

For the opposing public critics, James Enstrom, Ph.D., Fred Lipfert, Ph.D., Robert Phalen, Ph.D., Roger McClellan, D.V.M., Suresh Moolgavkar, M.D., Ph.D, and Tom Hesterberg, Ph.D., M.B.A., appeared. These well-qualified researchers urged no more regulations and no more exaggeration of the science on air pollution health effects.

The webcast is seven hours long. 21 The net effect was that the public commenters exposed the nature of the CARB malfeasance on human health effects science, and demonstrated that the CARB research project was a setup that involved conflicts of interest and a failure to objectively evaluate competing data and evidence on the question of California air quality and its effect on health.

No regulatory relief came from the debate and the proof of CARB malfeasance, and CARB proceeded with the originally planned air pollution regulations.

Washington Politics

The Space Science and Technology Committee of the House of Representatives contacted me in 2010, and I provided information from the CARB wars and the previous challenges of EPA air pollution research claims and policy making. Congress had hearings in the fall of 2010 and through 2011 on EPA air pollution research and regulations. In 2011 and 2012, the House Energy and Commerce Committee also had activities and an interest, and in February 2012 former chairman Rep. Joe Barton (R-Texas) gave a speech outlining the perfidy of the EPA on many aspects of science and policy, as well as legal aspects of EPA misconduct.

Barton condemned:

- EPA's refusal to assess risk and benefit on regulations;
- EPA's burdensome and nonsensical power plant regulations;
- EPA's failure to cooperate with congressional oversight;
- Persistent and flagrant conflicts of interest among EPA researchers and advisers who receive tens of millions of dollars in research grants from the agency while serving as reviewers of EPA research;22
- EPA researchers' refusal to comply with basic rules of public health research in toxicology and epidemiology;
- Inappropriate reliance on the precautionary principle;
- Circumvention of congressional oversight; and
- Grant-giving to non-governmental advocacy groups that then enter into collusive lawsuits and aggressive regulatory requests that promote the agency's agenda and expand its regulatory and political power.

As Barton pointed out, "I believe that the American public and taxpayers should not be paying for an agency that manipulates data and funds researchers in the form of exterior grants, who in turn serve on the internal committees within the EPA to create policy and work in an oversight capacity. This is an incredible conflict of interest to the American public."23

Rep. Barton's dressing-down of EPA and its administrator was a first step in the right direction. But now Rep. Barton and his colleagues need to follow through by implementing real solutions that will stop EPA's regulatory excesses.

EPA and the Admissibility of Scientific Evidence

EPA research on human health effects of air pollution consistently violates the rules of science and is not admissible in a federal court under the rules of Daubert v. Merrell Dow, 509 U.S. 579 (1993). The Daubert majority opinion, written by Justice Harry Blackmun, discarded the old rule of "generally accepted" for scientific testimony and evidence, from the 1923 case of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) and adopted new, more rigorous tests for admissibility of science testimony and evidence, under Federal

Rules of Evidence (1975), particularly Rule of Evidence 702 on Testimony by Experts. The rule provides that if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue (Rule 104 test), a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In his written opinion, Justice Blackmun provided an erudite discussion on the philosophy of science, with a strong dose of the theories of a respected philosopher of science, Karl Popper.

Justice Blackmun's major points were as follows:

1) Trial judges were the gate keepers to assure that reliable science was admitted as evidence.

2) Scientific testimony and other scientific evidence had to be consistent with everyday good scientific practice.

3) The science would be assessed generally as follows:

a. The general acceptance rule of Frye did not survive the new Federal Rules of Evidence.

b. Knowledge is more than subjective belief or unsupported speculation; it must be supported by evidence and proven methods.

c. An expert witness is permitted wide latitude under the federal rules of evidence to offer opinions, including those that are not based on firsthand knowledge or observation.

d. Under Federal Rule of Evidence 104, a federal trial judge must determine the threshold question of whether the evidence is relevant and material to the case and will assist the trier of fact.

Justice Blackmun continued that if the threshold test of Rule 104 is satisfied (3d above), then the judge, in applying the rules of Daubert, must assess the admissibility of the scientific evidence and testimony on the basis of four tests under Federal Rule of Evidence 702 on Testimony of Experts:

1) Whether the theory or technique can be and has been tested;

2) Whether the theory or technique has been subjected to peer review and publication (this test is not dispositive, only additive);

3) Whether the technique or method has a known or potential rate of error; and

4) Acceptance of the theory or technique within a relevant scientific community of scholars.

Professor Michael Fenner of Creighton Law School wrote a helpful, in-depth review of the Daubert opinion. 24 In *Judging Science*, 25 Kenneth Foster and Peter Huber (MIT Press 1995) also review and analyze Daubert, providing much background analysis on the problems of junk science and fallacious science and also on the methods that produce reliable evidence and avoid scientific negligence and misconduct.

The Federal Rules of Evidence provide a means to challenge EPA-sponsored research, claims, conduct, actions, and policy-making. The burden of the challenge to an action, or ruling or fine or penalty, is to prove that the agency was arbitrary and capricious in its analysis of the pertinent science and research on human health effects and detriment. A common-sense understanding of those words entails actions taken without good justification or rationale. The courts have been inclined to be excessively deferential and allow agency

hegemony, even refusing to hear arguments on the arbitrary and capricious standard for agency acceptance of scientific research assertions.

Jurisprudence allows for judicial deference to agency discretion in matters of ambiguous statutory provisions, described by Justice Antonin Scalia in *Whitman v. American Trucking Association*. 26 What the erudite Justice Scalia fails to constrain is the inordinate and inappropriate expansion of the deference allowed EPA in reference to interpretation of ambiguous statutory language to include arbitrary and capricious agency acceptance of what would be arguably inadmissible scientific testimony and evidence.

Judges are, however, and always have been, the ones to decide what's admissible as evidence. Agency discretion under the jurisprudence of the Chevron decision 27 should not allow unreliable scientific evidence into the record under the rules of *Daubert*, whether it's a hearing or a trial. The evidence must be admissible for purposes of proving that the agency is or is not being arbitrary or capricious, which makes the decision on evidentiary admissibility and reliability separate from whatever idea the court might have about agency authority and discretion.

Unreliable scientific evidence is inadmissible and therefore cannot be used to justify agency actions. The admissibility rulings on evidence trump some arcane idea about agency discretion that is all tied up in the jurisprudence on congressional delegation. There is no law that Congress has passed that permits agencies to use and promote junk science.

In the excessive support of congressional delegation to agencies under the statutes, and the general deference for agency discretion under Chevron, Scalia allows EPA research to cheat and avoid a challenge under the "arbitrary and capricious" standard. Justice Scalia just plain ignores the commonly and legally understood meaning of "arbitrary and capricious." Proposing inadmissible scientific evidence and testimony on critical research assertions that are foundations for policy and regulatory action would certainly cross the threshold of "arbitrary and capricious" under the Administrative Procedure Act.

The Role of the Administrative Procedure Act (APA)

The Administrative Procedure Act (APA) allows a successful challenge of agency conduct when that action is arbitrary (without good reason) and capricious (on a whim and without a good reason). Violating scientific rules, like the ones that are clearly outlined in the *Reference Manual on Scientific Evidence* 11, 12 to educate judges on science, would certainly raise the question of irrationality that is the fundamental issue for claiming that an agency has acted in an arbitrary and capricious manner.

The courts have, however, been very lenient with the EPA on the violations of scientific rules and provided many opportunities for agencies to violate the rules of science, so legislative actions may be necessary to force better science and policymaking at EPA. The alternative is to find a judge with integrity and an appellate court that doesn't undermine a judgment of inadmissibility, or will entertain and find valid an appeal to reverse an improper judgment on Daubert admissibility.

Legislative Remedies

In the political sphere, Congress can modify standards of administrative and judicial review to demand good science and a better standard for agency conduct, with more reasonable rules on challenges to EPA actions. This is similar to the rules for challenges to actions by the Occupational Safety and Health Administration, which carry a preponderance-of-evidence burden.

The pertinent legislative act is the Congressional Review Act (CRA), found at 5 U.S.C. 801, which allows Congress to jump in when the agencies are involved in misconduct. CRA was enacted as section 251 of the Contract with America

Advancement Act of 1996, also known as the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The law allows Congress to review, by means of an expedited legislative process, new federal regulations and, by passage of a joint resolution, to overrule a regulation.

Another legislative effort to bring the pressure to bear on the federal agency and their sponsored researchers is the **Data Quality Act**, which requires agency-sponsored research to hold to good scientific principles or be subject to review and possible modification or recision.

Even without legislation, responsible, competent, and serious legislators can find reasons to question EPA conduct, and lawyers can frame evidentiary challenges so that the courts and administrative hearings will be required to make clear rulings on admissibility of scientific evidence with an accompanying rationale for appellate review.

A bad evidentiary ruling is a reversible error; a good ruling will nurture good science in the courtroom. No lawyer but a pettifogger would admit to arguing for bad science that violates the public trust.

At present EPA, following Samet, 28 asserts the theory of "no threshold" for a toxic effect of air pollution, allowing EPA to pursue any pollutant to the last molecule. This impossible goal allows for unlimited expansion of EPA power. Chemical toxicology still is based on thresholds. **"No threshold" chemical air pollutant toxicology turns the Clean Air Act (42 USC 7401. 1963, amended 1970, 1990) on its head and nullifies and abandons the strategy Congress intended.**

Human Experimentation Scandal

As previously described in this journal, 29 EPA has been sponsoring research in which human subjects are exposed to air pollutants at levels far exceeding those EPA declares to be toxic or lethal. It is illegal, unethical, and immoral to expose experimental subjects to harmful or lethal toxins.30 The Reference Manual on Scientific Evidence, 3rd ed. (2011), [12, p 555] declares that exposing human subjects to toxic substances is "proscribed" by law, and cites case law. The editor of Environmental Health Perspectives (EHP) refused a request by Steve Milloy of JunkScience.com to withdraw a paper based on one such study and conduct an investigation.31

According to information obtained by Milloy from a Freedom of Information Act (FOIA) request, a University of North Carolina research study exposed 42 people to what EPA says are harmful or lethal levels of fine particles, with some receiving 10 times EPA's declared safe level of 35 micrograms per cubic meter of air. The EPA human experiments described were conducted from January 2010 to June 2011, and ended three months before then-EPA Director Lisa Jackson's congressional testimony, during which she still asserted dramatic claims of the lethality of small particulates less than 2.5 microns in diameter (PM2.5), claiming thousands of deaths and hundreds of billions of dollars in economic consequences from the deaths and disabilities caused by fine particles.

There have been no publications of toxic effects as declared by the authors of the paper, other than the one case report of a cardiac arrhythmia described earlier; 29 the researchers failed to report that none of the other

subjects had any adverse effects, despite the obligation of researchers to report results both for and against their hypothesis.

Did EPA risk the deaths of 42 subjects? Or are EPA officials lying in their testimony about the dangers of small-particle air pollution and deliberately misleading Congress and the public?

After filing complaints with EPA officials and the editor of EHP, Milloy and I filed complaints with the North Carolina Board of Medicine and the University of North Carolina (UNC) School of Medicine. The North Carolina medical board found no violation of the Medical Practice Act by the physicians, and no action was taken by the UNC School of Medicine.

A lawsuit was filed in Federal District Court in Arlington, Va., to ask for injunctive relief or a remedy that would stop the human experiments. The Court said it didn't have the authority or jurisdiction to stop the human experiments, but declarations under penalty of perjury obtained from officials of the EPA research team at UNC Chapel Hill School of Medicine were revealing.

Eugene Cascio, M.D., a lead EPA physician in the research team, declared that 10 domestic medical schools and six foreign medical schools were doing human exposure experiments. They included some of the most prominent medical schools in the United States—Rutgers, Rochester, Ohio State, University of Michigan, Michigan State, University of Washington, University of California at Los Angeles, University of Southern California, and Lovelace Clinic affiliated with the University of New Mexico. The foreign medical schools included three in Europe, one in Canada, and two in the UK.32

Two other declarations produced by EPA officials in the lawsuit were critical to understanding EPA misconduct. Martin Case, program administrator, declared that he told the subjects they could die from the exposures, but he did not write that warning in the consents obtained.33 Milloy has obtained the consent forms from UNC and other medical schools involved in the project for human experimentation, and none of programs warned subjects of EPA's position that fine particles were toxic, lethal, and carcinogenic, and that the subjects might suffer the consequences.34

Robert Devlin, Ph.D., senior research official for EPA and part of the UNC team, stated in his declaration under penalty of perjury that the EPA was sponsoring the human experimentation because the results of epidemiological studies are not reliable enough and do not establish a strong enough case for toxicity of air pollution.35

In paragraph 8, Devlin states:

> Controlled human exposure studies conducted by EPA scientists and EPA-funded scientists at multiple U.S. universities fill an information gap that cannot be filled by large population studies. In 1998 the Committee on Research Priorities for Airborne Particulate Matter was established by the National Research Council in response to a request from Congress. The committee was charged with producing four reports over a five- year period which describe a conceptual framework for an integrated national program of particulate-matter research, and identified the most critical research needs linked to key policy-related scientific uncertainties.

The committee states on page 36 of its report:

> Controlled human exposure studies offer the opportunity to study small numbers of human subjects under carefully controlled exposure conditions and gain valuable insights into both the relative deposition of inhaled particles and the resulting health effects. Individuals studied can range from healthy people to individuals with cardiac or respiratory diseases of varying degrees of severity. In all cases, the specific protocols defining the subjects, the exposure conditions, and the evaluation procedures must be reviewed and approved by institutional review boards providing oversight for human experimentation. The exposure atmospheres studied vary, ranging from well-defined, single- component aerosols (such as black carbon or sulfuric acid) to atmospheres produced by recently developed particle concentrators, which concentrate the particles present in ambient air. The concentrations of particles studied are limited by ethical considerations and by concern for the range of concentrations, from the experimental setting to typical ambient concentration, over which findings need to be extrapolated.

Controlled human exposures studies have been conducted for decades on important pollutants such as ozone, particulate matter, nitrogen dioxide (NO2), sulfur dioxide (SO2), VOCs [volatile organic compounds] emitted [in] new homes, and carbon monoxide (CO).

In paragraph 9 of his Declaration, Devlin states: "Controlled human exposure studies assess the biological plausibility of the associations observed in the large-population epidemiological studies."

So we have come full circle. For 20 years I have argued that EPA is involved in corrupted, invalid, unreliable epidemiology. Now, under pressure from a lawsuit for unethical conduct, it admits what we knew already, that epidemiology is being misused as a false portfolio of evidence of air pollution toxicity. The most astounding aspect of this human experiments scandal is the refusal of state boards of medicine, institutional review boards (IRBs), deans of medical schools, and EPA officials to investigate and stop the misconduct. This is in spite of the well-known and remembered Tuskegee and horrific wartime

Nazi/Japanese medical experiments on prisoners.

What we have discovered with EPA misconduct and that of the grantees at numerous medical schools is very sobering. These are not trivial violations of the ethical rules on human experimentation with which the IRBs are familiar. The rule is that one cannot perform harmful human exposure experiments— period. In only a very few circumstances where significant benefit is anticipated could subjects be exposed to harmful substances, after they are informed of the risks.

Conclusion

For 20 years or more EPA has promulgated bad epidemiology and bad toxicology that eventually evolved into research with unethical human exposure experiments. There is no easy way to excuse unethical human experiments to substantiate claims made in congressional hearings, despite lack of evidence, that air pollution or other forms of pollution are toxic and lethal.

If EPA is lying about the toxicity, the regulations fall. If it isn't, a federal agency is committing battery and unethical research that is criminal, unethical, and violates agency rules on human research. Either way, innocent experimental subjects are victimized.

Daubert and the *Reference Manual* guidelines could be used to restore sanity and objectivity to EPA regulatory activities so that they would improve public health policy-making rather than serving a political agenda.

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7. Dunn and Milloy on EPA sponsored Human Experiments using small particles emissions.

Environmental Protection Agency's Air Pollution Research: Unethical and Illegal?

Steve Milloy, M.H.S., J.D., L.L.M., John Dale Dunn, M.D., J.D (JPANDS Winter 2012)

- www.jpands.org/vol17no4/dunn.pdf

"First, do no harm"is a fundamental precept of medical ethics. So how do U.S. Environmental Protection Agency physicians explain their non-therapeutic experiments in which they exposed health-impaired people to high levels of concentrated diesel exhaust and other air pollutants?

A federal court may soon help clarify this dilemma.

Since at least 2004, EPA physicians have been intentionally exposing human beings to various forms of concentrated airborne particulate matter (PM), including diesel exhaust, at an EPA laboratory at the University of North Carolina School of Medicine (UNC). The diesel exhaust is generated by idling a diesel truck with its exhaust pipe located right under the air intake for the exposure chamber.

The university not only houses the EPA facility, but also provides on a contract basis the mandatory institutional review board (IRB) intended to serve as the last line of defense for human study subjects.

Although these experiments materially violate every law, regulation, and standard developed since World War II for the protection of human subjects, there are two primary violations.1

First, these experiments should never have been approved by UNC or conducted by EPA given the allegedly lethal nature of PM as determined by EPA.

Since 1997, the agency has regulated PM on the basis that it kills people. In 2004, EPA clarified its views of PM's lethality by concluding that any inhalation of PM could result in death within hours of exposure.2 The EPA reiterated this view in its 2009 scientific assessment of PM.3

In July 2011, Dr. Jon Samet, chairman of EPA's Clean Air Scientific Advisory Committee, wrote in the New England Journal of Medicine that there is no safe exposure to PM.4 This view was repeatedly echoed by EPA air chief Gina McCarthy in a February 2012 letter to House Energy and Commerce Chairman Fred Upton (R-Mich.).5

EPA Administrator Lisa Jackson testified before Congress in September 2011: "Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should. She added,"If we could reduce particulate matter to levels that are healthy we would have an identical impact to finding a cure for cancer."6 Cancer kills about 570,000 in the U.S. annually, according to the American Cancer Society.

In addition to the EPA-determined lethal nature of PM, EPA also says there is strong evidence that PM is carcinogenic.7

These characterizations of PM essentially portray it as one of the most toxic substances known to man—at least according to EPA. Though every poison has a lethal dose, any exposure to PM can kill, and kill quickly (within hours), EPA claims. Although exposure to carcinogens like asbestos, benzene, and vinyl chloride may cause cancers decades after exposure, or after decades of exposure, these risks obviously pale in comparison to that of PM in the view of EPA.

EPA, then, is experimenting on human beings with what it views as one of the most toxic substances known to man for the simple (and illegal) purpose of evaluating what would happen, apparently in an effort to bolster its epidemiological (i.e. statistical) claims.8,9 Worse, many of the study subjects are health-impaired, suffering from metabolic syndrome, asthma, old age, or combinations thereof.

The idea of a government agency deliberately exposing sick people to what it portrays as an extremely toxic substance is shocking. This is, however, only part of the story.

Second, informed consent is the cornerstone of medical practice and human testing protocols. Failure to obtain informed consent, among other misconduct, resulted in the execution of 16 of 23 Nazi doctors at the Nuremberg tribunal. The so-called "Common Rule" has been adopted by American medical researchers, including EPA, as a standard for conducting human experiments, and it prohibits harmful human experiments.10

Although EPA went through the motions of having its study subjects read and sign consent forms, the forms never mentioned that any exposure to PM could result in death within hours of the experiment. Study subjects were instead told, for example, "You may experience some minor degree of airway irritation, cough or shortness of breath or wheezing. These symptoms typically disappear two to four hours after exposure, but may last longer for particularly sensitive people."10

At least hundreds, and possibly thousands of human subjects have been so experimented upon by EPA physicians or EPA- grantee physicians at universities around the country. These experiments continue even as these concerns have been pointed out to EPA in recent months.

Has anyone been harmed? At least one 58-year-old obese woman with a personal and family history of heart problems had her experiment terminated early when she developed atrial fibrillation/flutter. The case was reported, 11 and it was said to be "the first case report of cardiovascular disease after exposure to elevated concentrations of any air pollutant." The rhythm resolved spontaneously about 2 hours after termination of the exposure. The authors concluded: "The resolution of the arrhythmia with termination of the particle exposure further supports a causal relationship between the two."They made this strong inference even while acknowledging evidence of a high frequency of supraventricular ectopy prior to exposure, numerous preexisting risk factors, and the fact that an

electrophysiologic study 6 weeks later revealed a re-entrant circuit, which was ablated. The authors suggested a potential mechanism of "disruption of the normal cardiac autonomic control," without

acknowledging the confounding factor of a potential emotional reaction to being in a setting resembling a gas chamber and being the subject of an exposure to an inhaled air mixture in a lab.

Although EPA physicians attributed the subject's arrhythmia to her PM exposure, they nevertheless did not modify the consent forms for subsequent human test subjects to reflect this risk.

As a result, the American Tradition Institute, a nonprofit public policy group, has filed suit in federal court against the EPA seeking an end to this illegal experimentation (American Tradition Institute Environmental Law Center v. U.S. EPA, Case 1:12- cv-01066-AJT-TCB, U.S. District Court for the Eastern District of Virginia—Alexandria Division).

Complaints have been filed with the North Carolina Medical Board concerning three of the North Carolina-licensed EPA physicians involved in the illegal experimentation. This investigation continues. The University of North Carolina School of Medicine has announced an internal review.

Congress has gotten involved, too. Sen. Jim Inhofe (R-Okla.) has requested that the Senate Environment and Public Works Committee, the committee responsible for overseeing EPA, schedule hearings on the scandal. Spearheaded by Rep. Paul Broun,

M.D. (R-Ga.-10), the House Science Committee has requested that the EPA Office of Inspector General conduct an investigation.

The lawsuit has already produced a notable admission of sorts from an EPA employee. In his declaration,12 EPA Clinical Studies Coordinator Martin W. Case asserted that he verbally informs human subjects in an ongoing trial that, "There is the possibility you may die from this." In addition to the shocking nature of this"warning,"even if it were acceptable to risk the lives of human study subjects for the sake of science—and it's not—such a warning would need to be in writing, according to federal regulations.

It's clear that "first, do no harm" was not a high priority concern of EPA physicians involved in this shocking experimentation. EPA and UNC are now in defensive postures, and the medical community needs to hold them accountable. Given past outrages of medical science, like the Nazi experiments and the Tuskegee syphilis experiments to name just two, what will the medical, political, and legal communities do to stop this ongoing research sponsored by a United States federal agency and funded with taxpayer dollars?

Another possibility is that the EPA does not believe its own testimony to Congress, and that oppressive, costly regulations have been imposed on American industry on the basis of flawed epidemiologic studies, unwarranted extrapolations, and contrived estimates of benefits. The experiments may be designed to find a potential mechanism of harm, like the one suggested in the case report by Ghio et al.11 If so, the very purpose of the experiments is to cause harm to human beings in an effort to justify false testimony.

[Editor's Note: In a letter from the Environmental Protection Agency Office of Inspector General, dated October 22, 2012, Assistant Inspector General for Program Evaluation, Carolyn Copper, indicated the agency "plans to begin an evaluation of the Environmental Protection Agency's (EPA's) Research on Human Subjects...to determine whether EPA: 1) Obtained sufficient approval to expose subjects to specific levels of diesel exhaust emissions or concentrated airborne particles; 2) Obtained adequate informed consent from human study subjects before exposing them to diesel exhaust emissions or concentrated airborne particles; 3) Adequately addressed any adverse events that occurred, including notifying the University of

North Carolina at Chapel Hill's Institutional Review Board (IRB), the Human Studies Review Board, and the Human Subjects Research Review Official, revising consent forms as needed, and providing clinical follow- up in accordance with the approved protocol." See http://junksciencecom. files.wordpress.com/2012/11/new-assignment-memorandum-on-oig- evaluation-on-epas-research-onhuman-subjects.pdf] .

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8. ESSAYS and ARTICLES THAT EMPHASIZE THE NATURE OF US EPA SCIENTIFIC MISCONDUCT

Hyperlinks to essays on correcting EPA science Abuses

- Science and the Toxic Scare Machine
- The EPA's Faulty Science Can Be Stopped
- A Strategy to Stop EPA Science Abuse

Hyperlinks to essays on the EPA human experiments scandal and legal and administrative review of the conduct of EPA

- http://www.americanthinker.com/articles/2012/06/epas_unethical_air_pollution_experiments.html
- The EPA Uses Children (and Adults) as Guinea Pigs
- http://www.americanthinker.com/articles/2016/08/epa_whitewashes_illegal_human_experiments.html
- http://www.americanthinker.com/articles/2017/04/swamp_diving_the_epas_secret_human_experiment_regime.html

  National Research Council Human Experiments investigation panel
- EPA Whitewashes Illegal Human Experiments

Arnett review of EPA misconduct on air quality research 2012

Politicized science, Enstrom v. environmental activists – 17(4):118-119, 2012

http://www.jpands.org/vol17no4/arnett.pdf

Enstrom study on small particles in Dose Response

https://junkscience.com/2017/04/epidemiologist-accuses-prominent-epa-funded-researchers-of-deliberate-misrepresentation-on-key-air-pollution-studies/

Dunn letter on Enstrom paper.

http://journals.sagepub.com/doi/full/10.1177/1559325817749414

CA study of small particles and ozone effects in 2017 by Young, Smith, Lopiano

Young S, Smith R, Lopiano K. Air quality and acute deaths in California, 2000-2012.
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JAMA DI small particles article 2017

https://junkscience.com/2018/02/dr-john-dunn-blasts-jama-over-harvard-pm2-5-fraud/

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9. 2018 Enstrom reviews and exposes EPA air quality epidemiological misconduct 2017

https://junkscience.com/2018/05/pope-fails-to-find-error-in-enstroms-2017-reanalysis-of-pope-1995-pm2-5-study/

The study below is a reanalysis of earlier studies relied on by the US EPA.

Dr. Enstrom shows that the studies not only show small associations that are proof of nothing, but in some cases reanalyzing the data shows Confidence Intervals that include Relative Risk of 1.0 so the studies failed in every way to show an effect. Dr. Enstrom also provides information on a systematic effort by journals to suppress his expose'.

James E. Enstrom, Original Article Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis

Enstrom J. Fine particulate matter and total mortality in cancer prevention study cohort reanalysis. Dose-Response: January-March 2017 1-12 DOI: 10.1177/1559325817693345
https://www.ncbi.nlm.nih.gov/pubmed/28473741

Abstract

Background: In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter ($PM_{2.5}$), largely because of its positive relationship to total mortality in the 1982 American Cancer Society Cancer Prevention Study (CPS II) cohort. Subsequently, EPA has used this relationship as the primary justification for many costly regulations, most recently the Clean Power Plan. An independent analysis of the CPS II data was conducted in order to test the validity of this relationship.

Methods: The original CPS II questionnaire data, including 1982 to 1988 mortality follow-up, were analyzed using Cox proportional hazards regression. Results were obtained for 292 277 participants in 85 counties with 1979-1983 EPA Inhalable Particulate Network $PM_{2.5}$ measurements, as well as for 212 370 participants in the 50 counties used in the original 1995 analysis.

Results: The 1982 to 1988 relative risk (RR) of death from all causes and 95% confidence interval adjusted for age, sex, race, education, and smoking status was 1.023 (0.997-1.049) for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ in 85 counties and 1.025 (0.990-1.061) in the 50 original counties. The fully adjusted RR was null in the western and eastern portions of the United States, including in areas with somewhat higher $PM_{2.5}$ levels, particularly 5 Ohio Valley states and California.

Conclusion: No significant relationship between $PM_{2.5}$ and total mortality in the CPS II cohort was found when the best available $PM_{2.5}$ data were used. The original 1995 analysis found a positive relationship by selective use of CPS II and $PM_{2.5}$ data. This independent analysis of underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the $PM_{2.5}$ NAAQS. These findings provide strong justification for further independent analysis of the CPS II data.

James E. Enstrom

Here is another article in 2018 that describes Enstrom's efforts to expose US EPA air quality effects research misconduct.

http://www.jpands.org/vol23no1/enstrom.pdf

Scientific Distortions in Fine Particulate Matter Epidemiology
James E. Enstrom, Ph.D., M.P.H.

ABSTRACT
The theoretical prevention of premature deaths from the inhalation of fine particulate matter is being used by the U.S. Environmental Protection Agency (EPA) to justify the National Ambient Air Quality Standard (NAAQS) and multibillion dollar regulations across the U.S., including the EPA Clean Power Plan and the California Air Resources Board (CARB) Truck and Bus Regulation. The epidemiology is severely flawed. Fine particulates probably make no significant contribution to premature mortality in the U.S. The publication of null findings has been blocked or marginalized and studies claiming excess mortality need to be reassessed.

Basics of Fine Particulate Matter

Fine particulate matter (PM2.5) is defined by its size (≤2.5 μm diameter), not its composition. Major sources in the U.S. are forest fires, commercial and residential burning, and diesel engines. In California, a major source is China; on some days up to 30% of fine particulates had crossed the Pacific Ocean.
Of these invisible particles, the average adult in the U.S., based on actual 2015 exposure levels, would inhale about 1 gram in an 80-year lifespan, assuming that he breathes about 10,000 liters of air a day at rest. For comparison, the amount inhaled while smoking 100 cigarettes is about 4 grams.1

In 1997, the EPA established the NAAQS for PM2.5 as 15 μg/ m3. This was lowered to 12 μg/m3 in 2012. This standard has been largely justified on the basis of secret science epidemiology. These regulations are very powerful and impose huge costs on American businesses. The PM2.5 NAAQS, has been used to justify several multi-billion-dollar rules, such as the EPA Clean Power Plan and the CARB Truck and Bus Regulation.

Although a significant effect from such extremely low levels is on its face highly implausible, the stringent EPA regulations are justified primarily by a claim of preventing premature deaths, assuming a value of $10 million per statistical life saved. The controversy over the issue was brought to general attention in 2002 by Professor Robert Phalen.2

Epidemiology of Fine Particulate Matter

The EPA claim that PM2.5 causes "premature deaths" is based on epidemiologic cohort studies purporting to show that the relative risk (RR) for total mortality is slightly greater than 1.0 in U.S. populations exposed to higher levels of PM2.5. No etiologic mechanism has been established, and there is no experimental evidence that inhalation of 1 g or 5 g of PM2.5 can cause death. Weakly positive RRs do not prove causality. Major difficulties include: (1) geographic and temporal variation in PM2.5 mortality risk; (2) exaggeration of actual human exposure by PM2.5 monitors, which measure ambient outdoor levels

far from the subjects; and (3) confounding variables such as co-pollutants. Moreover, the key study relied on by EPA, the American Cancer Society (ACS) 1982 Cancer Prevention Study (CPS II)3 is seriously flawed.

Reanalysis of the American Cancer Society Cancer Prevention Study II (ACS CPS II)

CPS II began in 1982 and is similar to the original CPS I, which began in 1959. The seminal paper published by Pope et al. in 19953 was so controversial that the Health Effects Institute (HEI) sought applications from teams consisting of two to four epidemiologists, statisticians, and airpollution exposure experts to conduct a reanalysis, including "sensitivity analyses to test the robustness of the original findings and interpretations to alternative analytic approaches."4 The HEI Reanalysis published in 2000 did not complete the mandated sensitivity analysis to assess the effect of alternate data.5 HEI published a report in 2009,6 which extended the mortality follow-up of the study from 1989 to 2000, but it did not incorporate the EPA Inhalable Particulate Network (IPN) PM2.5 data7,8 that I had called to the authors' attention in my 2005 paper.9

In 2016 I was able to obtain access to data in an original 1982-1988 version of CPS II. The data had been previously inaccessible since 1995 despite a congressional subpoena and repeated requests by different agencies. I am the only independent scientist who has gained access to the individual level data in both CPS I and CPS II. I was able to reproduce the same key results as Pope et al. by doing exactly what the authors did in 1995.3 However, their results were sensitive to the PM2.5 data that they used and to their particular analysis.

HEI did not follow its own mandate to conduct a comprehensive reanalysis. In particular, their sensitivity analysis was not done properly. Of the 13 teams that submitted reanalysis applications, HEI selected a 31-member team based in Canada, headed by statistician Daniel Krewski. It included a geographer, Michael Jerrett, and another statistician, Richard Burnett, but only had one epidemiologist, Yue Chen. Chen's degree was from Shanghai Medical University, and he was not a coauthor on either the 2000 HEI report5 or the 2009 HEI report.6 Thus, to reanalyze a major U.S. epidemiological study, HEI used a Canadian team that had essentially no epidemiologist.

An early clue to the existence of problems is seen in Figure 21 in the 2000 HEI Reanalysis Report.5 (Figure 1 in this article.) This map shows that in 50 cities across the U.S. the level of PM2.5 mortality risk varies. Higher risks were found mainly in the Rust Belt or the Ohio Valley, and levels were actually reasonably low

in California and throughout most of the western part of the U.S. Beginning in 2002, I asked the head of HEI, Daniel Greenbaum, and its principal scientist, Aaron Cohen, to send me the underlying data for that map. For 16 years, they have consistently refused to reveal this data to me.

Fine Particles and Mortality Risk
Figure 1. PM2.5 Levels and Mortality Risk in the U.S. [Reprinted from 2000 HEI Reanalysis Report,5 with permission.]

Thus, using the HEI PM2.5 data of Pope et al., 3 there is a statistically significant slight increase in RR of 1.082. That means that if the PM2.5 level increases by 10 μg/m3, the risk of dying goes up by about 8%. But, using the IPN PM2.5 data, the effect is nonsignificant, RR = 1.025 (95% CI, 0.990-1.061). Note that if one divides the U.S. into the Ohio Valley (Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia) and the rest of the country, the RR is indistinguishable from 1.0, no matter what PM2.5 data is used. Only by combining the Ohio Valley, which has both a higher mortality risk and a higher level of PM2.5, with the rest of the country can HEI show a statistically significant effect.

My reanalysis10 has been published online since Mar 28, 2017, and so far its validity has not been challenged. The selection of data by HEI was also very interesting, as seen in Table 2. There were actually 11 counties in California that were part of the IPN network, and the HEI analyses omitted 7 of the 11 counties for reasons the authors have not explained. HEI had data from 50 different cities, and the only ones they included from California were Fresno, Los Angeles, San Francisco, and San Jose (in Santa Clara County). Two other counties that represent the extremes in PM2.5 levels are highlighted in the table. The Pope 1995 paper3 was based primarily on these extremes. HEI had Albuquerque, N.M., at 9 μg/

My analysis of the CPS II data revealed that the county of residence of subjects could be approximated based on the ACS Division and Unit numbers. The CPS II data were collected by about 70,000 researchers, including myself, who enrolled 1.2 million subjects in Fall 1982. I performed an analysis comparable to the HEI Reanalysis, as shown in Table 1. The PM2.5 data labeled IPN in the table was published in EPA reports from the Inhalable Particulate Network (IPN) by David Hinton et al. in 19847 and 1986.8 Because of the evasions that I have experienced in attempting to obtain information from HEI, I took a closer look at the 2000 HEI Reanalysis Report and found it actually contains the data that I used, although in a mislabeled and somewhat altered form. I have designated that data as HEIDC, which is labeled PM2.5 DC in the 2000 Report. This data was indirectly referred to in a couple of places in the 2000 HEI report, although it was not analyzed.

m3, as the lowest value, and Huntington, W.V., at 34.4 μg/m3, as the highest value. This is curious because the data that comes from the IPN network actually shows different high and low values. In fact, there is no measurement in the IPN for Huntington, W.V., but rather for Wheeling, W.V., listed in the IPN column. From the table, both the low and the high values are in California, both of which omitted from the HEI analysis. The low value is 10.6 μg/m3 in Santa Barbara County, and the high value is 42.0 μg/m3 in Riverside County. The PM2.5 DC data that I found in the 2000 HEI Report appendix table, labeled HEIDC by me, had more than 50 cities, but only five of the 63 total cities were from California. The IPN network as a whole has about 85 cities. These major inconsistencies need to be addressed by these investigators. And so far, there is nothing but silence. This is only one of the issues that must be addressed if the investigators want to maintain any credibility.

Table 1. Enstrom Analyses of ACS CPS II Data Using Three Sources of PM2.5 Data

Table 2. Comparison of Data on PM2.5 and Mortality from Enstrom and HEI9

Relationship between PM2.5 and Mortality in California

Because of the Feb 26, 2010, conference in Sacramento, which I attended along with Professor Robert Phalen, other prominent scientists, and impacted business groups, we were able to get an analysis done by HEI that dealt with the California portion of the national CPS II results. The California data was partitioned out from the national analysis in the 2009 HEI Report.6 Based on the four HEI California counties shown in Table 2, the RR is about 0.9, significantly below 1.0, as shown in Table 3. This inverse relationship was reproduced using either the HEI data or the IPN data. Of course, this relationship cannot be etiologically correct, but it shows what can result from data omission and manipulation.

Table 3. Relative Risk for PM2.5 and Mortality in California Based on Four Counties

Table 4. PM2.5 and Total Mortality in Six California Cohorts Both my analysis and that by Thurston et al. on the NIH
AARP cohort,14 summarized in Table 5, show no effect nation- wide or in California.

There are actually six California cohorts that have been used to analyze the relationship between PM2.5 and total mortality, as shown in Table 4. The cohort that I initially used is labeled CA CPS I;9 the cohort used by Jerrett et al.11 is labeled CA CPS II. The Adventist Health Study of Smog (AHSMOG) was the original cohort study in California.12 There are also the California Teachers Cohort,10 the "West" portion of the Medicare Cohort Air Pollution Study (MCAPS),13 and the National Institutes of Health-American Association of Retired Persons (NIH AARP) cohort, which was published in 2016 by Thurston et al.14 The NIH AARP cohort is supposed to be an open access database, but is apparently currently controlled by Thurston. I have been able to get access to only the California portion of the data, and my analysis shows no effect in California. Averaging all six cohorts gives an RR of exactly 1.00, which means no relationship between PM2.5 and total mortality.
The lack of an effect in California might explain why Pope et al.3 omitted seven California cities from the national analysis. As Figure 1 shows, there is tremendous variation across the country. Yet the most severe regulations are in California, despite the clear absence of mortality risk there!

Table 5. Comparison of Enstrom and Thurston Analyses for
U.S. and California

An International Perspective on PM2.5

Despite the null effect shown by their own data and analyses, prominent advocates of drastic measures to reduce PM2.5 levels state in a major paper in the May 13, 2017, Lancet that ambient PM2.5 was the fifth-ranking mortality risk factor worldwide in 2015. Aaron J. Cohen, until recently HEI Principal Scientist, is the lead author, and Pope is a coauthor. The study is part of the World Health Organization (WHO) Global Burden of Disease (GBD) Project and was largely funded by HEI. The article claims that PM2.5 causes 4.2 million deaths annually worldwide, with 88,000 deaths in the U.S. (see Table 6). The mean PM2.5 level is

8.4 μg/m3 in the U.S. and 58.4 μg/m3 in China. Clearly, the PM2.5 level and premature deaths are low in the U.S. and high in China, India, and Africa.

Table 6. Global Deaths Attributed to PM 15

Agenda-driven Science

Since publishing my 2005 critique of the relationship between PM2.5 and total mortality9 and my 2017 critique,10 I have sent numerous requests to Pope, ACS, HEI, and others, inviting a rebuttal. I have received no response that confirms or refutes any of my analyses. It has, however, been incorrectly asserted that, "The study by Enstrom does not contribute to the larger body of evidence on the health effects of PM2.5." ACS has criticized me for having CPS II data that they have deliberately tried to keep secret. My invitations to authors and ACS officials to attend meetings, teleconferences, and symposia have simply been ignored. They even ignored an August 1, 2013, subpoena from the U.S. House Science, Space, and Technology Committee.

The control over air pollution research and assessments that is recognized by EPA is not based on special expertise in epidemiology. Pope, the self-proclaimed "world's leading expert on the effects of air pollution on health," is a professor of economics at Brigham Young University and holds a 1981 Ph.D. in agricultural economics from Iowa State University, where he studied the dynamics of crop yields. Michael Jerrett, who is one of the most prolific publishers and a member of the HEI reanalysis team, has a 1996 Ph.D. in geography from the University of Toronto, and no formal training in epidemiology. Aaron J. Cohen, until recently HEI's Principal Scientist, does hold a 1991 D.Sc. degree in epidemiology from Boston University, but he has badly misused the principles and standards of epidemiology. Although he supervised the 1998-2000 HEI Reanalysis Project, he has refused to clarify findings from this project and has refused to confirm or refute the findings in my 2017 CPS II reanalysis. It is very disturbing that ACS has allowed CPS II data to be used for more than 20 years for research that misuses the principles and standards of epidemiology and that has nothing significant to do with cancer.

The principal qualification for admission to the elite circle of influence appears to be dedication to the agenda of global controls on economic activity via air pollution regulations. The conclusion reached by researchers is apparently predetermined, as stated in the last paragraph of the GBD study on ambient air pollution: "As the experience in the U.S. suggests, changes in ambient PM2.5 associated with aggressive air quality management programmes, focused on major sources of air pollution including coal combustion, household burning of solid fuels, and road transport, can lead to increased life expectancy over short timeframes."15

What is the state of scientific integrity? It is very dangerous to one's career to criticize views backed by powerful interests, and I do it only because I believe current trends are anti- science and dangerous to our country. Simply being a passive observer is no longer acceptable.

To disclose my own background, I obtained a Ph.D. in physics in 1970, but I became an epidemiologist starting in 1973 in order to apply the rigorous principles of physics to observational epidemiology. I had a long career as a research professor and researcher at the UCLA School of Public Health. My research has examined the influence of environmental and lifestyle factors on mortality, and has on occasion reached politically incorrect conclusions. My research in air pollution epidemiology has been strongly influenced by Dr. Frederick Lipfert and Professor Robert Phalen. In February 2010 I was terminated from UCLA without warning and told that my "research is not aligned with the academic mission of the Department." In

February 2015 I settled a three-year federal whistleblower retaliation lawsuit against UCLA and my termination was reversed. My case and some of the issues related to my air pollution epidemiology research have been discussed in this journal.16

My background and publications, including rejections of my research, often without peer review, are documented on my website, www.scientificintegrityinstitute.org. I believe that major journals simply will not accept articles that challenge the established view. Moreover, authors of the papers promoting PM2.5 premature deaths omit null results, even their own. For example, Jerrett is the lead author of a 2007 study that shows no increased mortality associated with PM2.5 in the CPS II cohort if the results are divided into five time periods.17 Although researchers are paid millions of dollars, they're not under any obligation to address any of the concerns about their work. Those who disagree with the agenda are denied research funding.

We must prevent American science from following historical examples like that of Trofim Denisovich Lysenko. He was a phony plant geneticist, who gained the favor of Joseph Stalin because he didn't believe in Mendelian genetics. Lysenko's views controlled much of Soviet agriculture in the 1930s, 1940s, and 1950s, with devastating effect. False crop statistics were published, and dissenting scientists were purged. Nikolai Vavilov, a renowned plant geneticist, was imprisoned by Stalin and died of malnutrition.
Concerns about integrity in Western science are being raised. Richard Horton, editor of The Lancet, writes: "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness."18

A U.S. House of Representatives bill called the Secret Science Reform Act was passed in 2014 and 2015 in order "to prohibit the Environmental Protection Agency from proposing, finalizing, and disseminating regulations or assessments based upon science that is not transparent or reproducible." The bill was revived in 2017 as the Honest and Open New EPA Science Treatment (HONEST) Act, labeled H.R. 1430, and was passed by the U.S. House of Representatives.
American science needs to guard against the heirs of Sinclair Lewis's protagonist in his 1927 novel Elmer Gantry, an itinerant preacher who is able to sell false religion to gullible people. We have prominent scientists who have successfully sold the notion that inhaling 1 g of invisible particles over an 80-year lifetime can cause premature death.

Conclusions

There is strong evidence from two large national cohorts that PM2.5 does not cause premature deaths in the US. There is strong evidence that this relationship has been falsified by EPA, the Health Effects Institute, and leading researchers for more than 20 years. Better oversight to assure scientific integrity, such as access to data, transparency, and consideration of opposing views, is imperative.

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10. Dunn on US EPA Linear No Threshold Misconduct 2018.

This is a paper by the submitter Dunn that is intended to be an abstract as a presentation to a conference of the American Nuclear Society and the Health Physics Society on the problem of Linear No Threshold toxicology. The Conference is scheduled for early October 2018.

AN ENVIRONMENTAL NOBLE LIE,
LINEAR NO-THRESHOLD Radiation Biophysics Toxicology,
IT NEEDS TO GO

John Dale Dunn MD JD
American Nuclear Society/Health Physics Society Conference
Sept 30-Oct 3, 2018
Pasco, Washington

Abstract
The United States Environmental Protection Agency (USEPA) is charged with identifying and mitigating environmental risks. This article will discuss US EPA misguided decision to use Linear No Threshold as the template for Radiation Biophysics and Toxicology.
The Health Physics Society (HPS) has stated that reliance on the LNT model "...tends to foment the public's fear of all types of radiation . . . reliance on the LNT model, especially at very low doses and dose rates, is inappropriate and can exaggerate the risk." (Kirner 2017) (Ring et al. 2017). The HPS also condemns "collective" (cumulative) dose as a measure of biological radiation risk.
One hit or linear no threshold (LNT) radiation biophysics makes no sense as a theory for carcinogenesis. Most cancer cell types are hyper/multiploid due to telomeric mitotic dysfunction, not mutations of genetic code. Carcinogenesis is also enabled by immune system failure to eliminate malignant cell lines. Both phenomena are associated with aging.

The US EPA acceptance of the assertions on LNT of Biological Effects of Atomic Radiation (BEAR), Biological Effects of Ionizing Radiation (BEIR) and National Academy of Science (NAS) committees, has been so irrational as to assume there is no safe level of ionizing radiation. Nonsense.
The LNT cancer theorists ignore protective biological processes, even hormetic, certainly no effect evidence of low level radiation. (Ulsh 2010; Sacks and Siegel 2017; Welsh et al. 2017), Scott 2017), acknowledged by the National Council on Radiation Protection and Measurements (NCRP) over 15 years ago (NCRP 2001). "These experimental observations are not compatible with a single hit mechanism. . . hypothesis." (Trott and Rosemann 2000)
The fruit fly research by Hermann Muller and Curt Stern founded the LNT model, but the research actually showed a threshold, misrepresented by Muller, a committed advocate of LNT (Siegel et al. 2015; Calabrese 2017a, 2017b). Muller was a deceitful, relentless advocate of LNT, and, as a Nobel Laureate, very influential. (Calabrese 2017c)
The American Association of Physicists in Medicine (AAPM) strongly objects to the LNT approach as creating harm from adverse attitudes about imaging procedures. They consider the risks at or below 50 mSv [5 rem] for single procedures or 100 mSv [10 rem] for multiple procedures not detectable.
The USEPA use of LNT causes harm with no evidence of worthwhile benefit. US EPA claims that LNT is "conservative" and "cautious," translated as adoption of the misbegotten precautionary principle. The Fukishima mitigation, for example, was excessive, harmful and expensive, applied at doses far below the range of any negative public health consequences (Siegel et al. 2017c; Welsh et al. 2017).

Conclusions
The US EPA has been irresponsible and unscientific in its application of the Linear No Threshold template for radiation biophysics and toxicology. US EPA risk management is unscientific, unreliable and unjustified, wrongly derived from high dose rate environments and bench experimentation. Rat and mouse studies with exposures at lethal levels have created a long list of "carcinogens" that are then part of the LNT toxicology deception. (Calabrese 2018)
Society has become so fearful of radiation and chemicals that unnecessary steps are taken, and other risks are accepted, compliance costs are tolerated and are pursued energetically and expensively in a risk management environment of zero tolerance.
From the 1979 Three Mile Island to Fukishima in 2011, radiation incidents impacting large areas repeatedly show potential, variable risk for the immediate plant area, but, for example, even the terrible Chernobyl explosion, a stunningly limited harm from radiation beyond that.
The Fukishima event caused no radiation-related deaths (UNSCEAR 2013b), however the scare and the evacuation increased mortality, particularly in the elderly (Nomura et al. 2013; Yasumura et al. 2013; Uchimura et al. 2014, Ichiseki 2013) and the evacuations were scientifically unethical as a risk management strategy (Akabayashi and Hayashi 2012).
Changes, long overdue, on the matter of LDDR radiation risk management must go forward with the knowledge that adverse health effects are not detectable and that radiation exposures have a no effect, a harmful threshold of effect and even a sweet spot where radiation produces hormetic beneficial effects. (Calabrese 2013, Scott, 2017)
The USEPA Scientific Advisory Board (SAB) properly recommended a "change in the agency culture, change in how the agency works, and increased support for scientists and managers in programs and regional offices responsible for science integration." (Swackhamer and Burke 2012)
The radiation biophysics and toxicological precautionary principle needs a retirement in favor of rational risk assessment and mitigation.

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Below is my abstract/monograph for a presentation to the Gulf Coast Geophysical Societies conference scheduled for late September of 2018. Here I summarize much of the research on human health impacts from warmer temperatures—that shows the benefits of warming. That debunks the catastrophic and ominous claims of the US EPA. There are certainly other reasons to object to US EPA clams that CO 2 is a pollutant and dangerous, but underlying those claims is their fraudulent and unsupported claim that warming would be deleterious to human health—when the opposite is true.

This if offered as just one exhibit that shows the US EPA has been irresponsible in its claims about the impact of CO2 rise and warming—there are other scientific research studies that show the claims about

11. Dunn on Global Warming and Climate Change EPA misconduct—the scam of making Carbon Dioxide a pollutant.

Warming is a Benefit to Humans and the Biosphere

John Dale Dunn MD JD

The Intergovernmental Panel on Climate Change (IPCC) predicts a global temperature increase of 3C or more by 2100, but other experts believe the best guess is 1C or less. We assert that increases in average temperature of the planet from the current 60 degrees F. will be beneficial to human health and the biosphere.

IPCC's alarms have led to widespread fear of the health effects of global warming (Schulte, 2008) and even political attack ads claiming people are dying of "carbon pollution" (WMC, 2015). These statements have no basis in scientific research and in fact and based on the evidence, warming will be a benefit to all living things. Carbon Dioxide that increases to even 1000 PPM will be beneficial to the biosphere and make the planet more hospitable and arable.

In fact, the litany of climate extremes postulated by the IPCC has been falsified by the actual record of climate measurements and observations. None of the environmental disasters, human displacements and disruptions predicted have come to pass during the past ten years, even as atmospheric carbon dioxide has continued to increase. We all know of the temperature "pause" that has accompanied an increase in atmospheric Carbon Dioxide.

In this document the benefits of fossil fuel use, and even warming, if it did occur, are explained in greater detail.

A warmer planet is beneficial to humanity as warmer temperatures lead to decreases in temperature-related mortality, premature deaths due to cardiovascular and respiratory disease, and stroke occurrences, and has little if any influence on vector-borne diseases such as malaria and dengue fever since vectors generally are not respectful of the definition of "tropical diseases.

Cool and colder temperatures kill while warmer temperatures are beneficial. It is troubling that, in the face of this evidence, environmentalists and politicians continue to frighten people with predictions of "killer heat waves" in a slightly warmer world. And yet, such claims are made. Severe heat waves are a weather phenomenon, not causally linked to average global temperature. Deaths from heat waves are most dramatic in areas with lack of adaptation—or general medical care for the disabled—who suffer from poor housing and medical problems that make them more susceptible.

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Global Warming and Mortality Rates

- Medical research confirms and explains why cooler, colder temperatures cause increased disease and death rates. Warmer temperatures are associated with health benefits and decreased deaths.

- Population studies around the world show that warmer temperatures lead to a net decrease in mortality worldwide, even in those areas described as tropical.

- Carbon dioxide (CO2) is invisible, odorless, nontoxic, and does not seriously affect human health until the CO2 content of the air reaches approximately 15,000 ppm, more than 37 times greater than the current concentration of atmospheric CO2 (Luft et al., 1974). There is no reason to be concerned about any direct adverse human health consequences of the ongoing rise in the air's CO2 content now or in the future,

currently at about 400 parts per million (0.04%) since even extreme model predictions by warming advocates are for less than 2000 parts per million (2%).

The Intergovernmental Panel on Climate Change (IPCC), however, sees looming health threats. The Summary for Policymakers of IPCC's Working Group II's report for the Fifth Assessment Report (AR5) identified eight "key risk factors" regarding the effect of climate change on human wellbeing, all of them allegedly "identified with high confidence" (IPCC, 2014, emphasis in original). They are:

i) Risk of death, injury, ill-health, or disrupted livelihoods in low-lying coastal zones and small island developing states and other small islands, due to storm surges, coastal flooding, and sea level rise. 37[RFC1-5]

ii) Risk of severe ill-health and disrupted livelihoods for large urban populations due to inland flooding in some regions. 38 [RFC 2 and 3]

iii) Systemic risks due to extreme weather events leading to breakdown of infrastructure networks and critical services such as electricity, water supply, and health and emergency services. 39 [RFC 2-4]

iv) Risk of mortality and morbidity during periods of extreme heat, particularly for vulnerable urban populations and those working outdoors in urban or rural areas. 40 [RFC 2 and 3]

v) Risk of food insecurity and the breakdown of food systems linked to warming, drought, flooding, and precipitation variability and extremes, particularly for poorer populations in urban and rural settings. 41 [RFC 2-4]

vi) Risk of loss of rural livelihoods and income due to insufficient access to drinking and irrigation water and reduced agricultural productivity, particularly for farmers and pastoralists with minimal capital in semi-arid regions. 42 [RFC 2 and 3]

vii) Risk of loss of marine and coastal ecosystems, biodiversity, and the ecosystem goods, functions, and services they provide for coastal livelihoods, especially for fishing communities in the tropics and the Arctic. 43 [RFC 1, 2, and 4]

viii) Risk of loss of terrestrial and inland water ecosystems, biodiversity, and the ecosystem goods, functions, and services they provide for livelihoods. 44 [RFC 1, 3, and 4]

There is no scientific basis for believing global temperatures will rise to levels high enough to bring about any of these risks. Indeed, there is sound scientific support for believing warming will be a net positive rather than negative.

Here, we summarize only research on the effects of rising global temperatures on human health and the medical literature shows warmer temperatures and a smaller difference between daily high and low temperatures that results from some rising temperatures as occurred during the twentieth and early twenty-first centuries, reduce mortality rates (the subject of this section) as well as illness and mortality due to cardiovascular and respiratory disease and stroke occurrence.

Similarly, the research is quite clear that climate has exerted only a minimal influence on recent trends in vector-borne diseases such as malaria, dengue fever, and tick-borne diseases. Other factors, many of them related to economic and technological setbacks or progress and not to weather, are far more important in determining the transmission and presence of these "tropical" diseases that are not so tropical at all.

Warmer Temperature Impacts on Human Health

- Warmer temperatures lead to a decrease in temperature-related mortality, including deaths associated with cardiovascular disease, respiratory disease, and strokes. The evidence of this benefit comes from research conducted in every major country of the world.

- In the United States the average person who died because of cold temperature exposure lost in excess of 10 years of potential life, whereas the average person who died because of extreme heat related event lost no more than a few days or weeks of life because heat has a greater effect on more seriously debilitated and ill persons.

- In the U.S., some 4,600 deaths are delayed each year as people move from cold northeastern states to warm southwestern states. Between 3 and 7% of the gains in longevity experienced over the past three decades was due simply to people moving to warmer states.

- Cold-related deaths are far more numerous than heat-related deaths in the United States and the world. Coronary (heart attack) and cerebral thrombosis (stroke) account for about half of all cold-related mortality, events that are directed related to blood vessel and blood viscosity effects of cool or cold environments.

- Global warming, if it did occur, even to the degree predicted in the extreme, will reduce the incidence of cardiovascular diseases related to low temperatures and wintry weather by a much greater degree than the warming might increase the incidence of deaths or illness attributable to heat. Heat illness primarily produces fluid and electrolyte disturbances, loss of core temperature control and organ dysfunction from dehydration, circulatory failure and heat caused stress, not clotting events.

- The heat wave deaths of 1995 in Chicago and 2003 in Europe are pointed to by advocates of the claim that heat stress deaths will increase with any warming that might occur, but a closer look at heat event death rates in some of the studies below show acclimation increased awareness have blunted any heat stress death increases. In the case of Chicago and Europe temps rose to over 100 but the availability of air conditioning and ventilation along with attention to the needs of elderly and disabled individuals was determined to be a major reason for heat deaths.

- The heat deaths that occur during severe heat events are the result of stress and inability to acclimate to maintain normal core temperature control and avoid dehydration. Acclimatization and proper attention to the vulnerable populations failed in Chicago in 1995 and Europe, particularly France in 2003, for example with hundreds of heat deaths in the former and 20,000 or more deaths in the later.

- A large body of scientific examination and research contradicts and disproves the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming. Malaria is historically a disease that was endemic to cool and even cold climates like Finland and Russia but has been suppressed by hygienic and vector control

measures.
- Concerns over large increases in vector-borne diseases such as dengue as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue disease. The Aedes Aegypti Anopheles and Asian Tiger mosquitos all have been found at higher latitudes.
- While temperature and climate effect the geographical distribution of ticks, they are not among the significant factors determining the incidence of tick-borne diseases. Moreover the effect of small increases in climate temperature, if does occur with certainly not impact the range of ticks that now live in the high latitudes, even in the mountains of those high latitudes.

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Basis in Medical Science

Medical science explains why colder temperatures often cause diseases and sometimes fatalities whereas warmer temperatures are associated with health benefits.

Wang et al. collected daily mortality and meteorological data from 66 communities across China over the period 2006-2011. They then subjected these data to a series of analyses to elucidate the relationship between cold spell characteristics and human mortality. And what did those analyses reveal?

Not surprisingly, cold spells significantly increased human mortality risk in China. As indicated in Figure 1 below, the combined cumulative excess mortality risk (CER) for all of China when defining cold spells with a 5th and 2.5th percentile temperature intensity threshold was 28.5 and 39.7 percent, respectively. However, there were notable geographic differences; CER was tempered and near zero in the colder/higher latitudes, but increased to 58.7 and 92.9 percent at the corresponding 5th and 2.5th percentile temperature intensity

thresholds for the warmest and most southern latitude. Such geographic differences in mortality risk, according to the authors, are likely the product of better physiological and behavioral acclimatization of the northerly populations to cold weather.

Clearly, cold spells kill; and as has been found in almost every study of the subject, the risk of death from cold spells far exceeds that from heat waves (see the many reviews we have posted on this topic confirming this fact in our Subject Index under the heading Health Effects of Temperature: Hot vs, Cold Weather). As such, therefore, a little global warming would likely result in a net saving of lives by reducing the number of deaths that occur at the cold end of the temperature spectrum.

Antonio Gasparinni (2015) was lead author for a large international group of researchers who studied the effect of temperature extremes on death rates. Gasparrini and his co-authors analyzed data from 384 locations including the countries of Australia, Brazil, Canada, China, Italy, Japan, South Korea, Spain, Sweden, Taiwan, Thailand, the United Kingdom and the United States of America. By fitting a standard time-series Poisson model to the data obtained for each location, while controlling for trends and day of the week, they estimated temperature-mortality associations with a distributed lag non-linear model with 21 days of lag, after which they pooled the results they obtained in a multivariate meta-regression that included country indicators and temperature averages and ranges.

This work allowed them to calculate the number of human deaths attributable to heat and cold -- defined as temperatures above and below the optimum (minimum mortality) temperature -- for both moderate and extreme temperatures, the latter being defined "using cutoffs at the 2.5th and 97.5th temperature percentiles." And what did they thereby learn?

Based on data pertaining to a total of 74,225,200 human deaths that occurred between 1985 and 2012, the 23 researchers determined that 7.71% of the lives lost were caused by non-optimum temperatures; and among this group they found that "more temperature-attributable deaths were caused by cold (7.29%) than by heat (0.42%)" which makes cold in excess of seventeen times more deadly than heat. And they add, in this regard, that moderate "hot and cold temperatures represented most of the total health burden." Consequently, it seems pretty clear that any successful attempt to reverse or slow any potential increase in Earth's mean global temperature would likely come at a net cost of many human lives the world over, not a savings. The Gasparrini research provides a compelling confirmation of the reality that warmer temperatures are better for human welfare than cooler or colder temperatures. (Gasparrini Lancet 2015)

Keating and Donaldson (2001) explain that "cold causes mortality mainly from arterial thrombosis and respiratory disease, attributable in turn to cold-induced hemoconcentration and hypertension [in the first case] and respiratory infections [in the second case]." McGregor (2005) notes "anomalous cold stress can increase blood viscosity and blood pressure due to the activation of the sympathetic nervous system which accelerates the heart rate and increases vascular resistance (Collins et al., 1985; Jehn et al., 2002; Healy, 2003; Keatinge et al., 1984; Mercer, 2003; Woodhouse et al., 1993)," adding, "anomalously cold winters may also increase other risk factors for heart disease such as blood clotting or fibrinogen concentration, red blood cell count per volume and plasma cholesterol."

Wang et al. (2013) write, "A large change in temperature within one day may cause a sudden change in the heart rate and circulation of elderly people, which all may act to increase the risk of cardiopulmonary and other diseases, even leading to fatal consequences." This is significant for the climate change debate because, as Wang et al. also observe, "it has been shown that a rise of the minimum temperature has occurred at a rate three times that of the maximum temperature during the twentieth century over most parts of the world, which has led to a decrease of the diurnal temperature range (Karl et al., 1984, 1991)."

Robeson (2002) demonstrated, based on a 50-year study of daily temperatures at more than 1,000 U.S.

weather stations that daily (diurnal) temperature variability declines with warming and at a very substantial rate, so this aspect of a warmer world would lead to a reduction in temperature- related deaths.
Clearly, cold spells kill; and as has been found in almost every study of the subject, the risk of death from cold spells far exceeds that from heat waves. As such, therefore, a little global warming would likely result in a net saving of lives by reducing the number of deaths that occur at the cold end of the temperature spectrum.

Keatinge and Donaldson (2004) report coronary and cerebral thrombosis account for about half of all cold-related deaths, and respiratory diseases account for approximately half of the rest. They say cold stress causes an increase in arterial thrombosis "because the blood becomes more concentrated, and so more liable to clot during exposure to cold." As they describe it, "the body's first adjustment to cold stress is to shut down blood flow to the skin to conserve body heat," which "produces an excess of blood in central parts of the body," and to correct for this effect, "salt and water are moved out from the blood into tissue spaces," leaving behind "increased levels of red cells, white cells, platelets and fibrinogen" that lead to increased viscosity of the blood and a greater risk of clotting.
Keatinge and Donaldson also note "cold spells are closely associated with sharp increases in mortality rates," and "deaths continue for many days after a cold spell ends." On the other hand, they report, "increased deaths during a few days of hot weather are followed by a lower than normal mortality rate," because "many of those dying in the heat are already seriously ill
and even without heat stress would have died within the next 2 or 3 weeks."
With respect to the implications of global warming for human mortality, Keatinge and Donaldson state "since heat-related deaths are generally much fewer than cold-related deaths, the overall effect of global warming on health can be expected to be a beneficial one." They report, "The rise in temperature of 3.6°F expected over the next 50 years would increase heat-related deaths in Britain by about 2,000 but reduce cold-related deaths by about 20,000."
Keating and Donaldson's reference to deaths that typically would have occurred shortly even without excess heat is a phenomenon researchers call "displacement" or "harvesting." A study from Germany found "cold spells lead to excess mortality to a relatively small degree, which lasts for weeks," while "the mortality increase during heat waves is more pronounced, but is followed by lower than average values in subsequent weeks" (Laschewski and Jendritzky, 2002). The authors say the latter observation suggests people who died from short-term exposure to heat possibly "would have died in the short term anyway." They found the mean duration of above-normal mortality for the 51 heat episodes that occurred from 1968 to 1997 was 10 days, with a mean increase in mortality of 3.9%, after which there was a mean decrease in mortality of 2.3% for 19 days. Hence, the net effect of the two perturbations was an overall decrease in mortality of 0.2% over the full 29-day period.
The US EPA web site discussion of heat wave deaths referenced below reveals that the EPA recognizes heat wave deaths are not reliably counted because of loose death certificate definitions of heat caused versus heat related. Cardiovascular deaths is used as a catch all descriptor Although the deaths attributed to severe heat waves are described as Cardiovascular, the mechanism is metabolic and physiologic dysfunction and a collapse of the systems that maintain temperature equilibrium in endotherms like humans. The victims don't die of a heart attack, a coronary ischemic event caused by clots and narrowed coronary arteries, an occlusive event, they die of temperature effects and the failure of internal systems, including lung and cardiovascular system, solid organ, and brain malfunctions in the face of heat stress, dehydration, and rising core temperatures, along with dehydration and loss of mechanisms to maintain normal temperature. The victims are debilitated, and live in a stressfully hot environment and succumb for failure to acclimate and maintain normal body physiology.

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Observational Research in Asia

Behar (2000) studied sudden cardiac death (SCD) and acute myocardial infarction (AMI) in Israel, concentrating on the role temperature may play in the incidence of these health problems. Behar notes "most of the recent papers on this topic have concluded that a peak of SCD, AMI and other cardiovascular conditions is usually observed in low temperature weather during winter." He cites an Israeli study by Green et al. (1994), which reported between 1976 and 1985 "mortality from cardio-vascular disease was higher by 50% in mid-winter than in mid-summer, both in men and women and in different age groups," even though summer temperatures in the Negev, where much of the work was conducted, often exceed 30°C and winter temperatures typically do not drop below 10°C. Behar concludes these results "are reassuring for populations living in hot countries."

Kan et al. (2003) investigated the association between temperature and daily in Shanghai, China, finding a V-like relationship between total mortality and temperature that had a minimum mortality risk at 26.7°C. Above this optimum temperature, they observe, "total mortality increased by 0.73% for each degree Celsius increase; while for temperatures below the optimum value, total mortality decreased by 1.21% for each degree Celsius increase." The net effect of a warming in Shanghai, China, therefore, would likely be reduced mortality on the order of 0.5% per degree Celsius increase in temperature, or perhaps more.

Guo et al. (2012) examine the nonlinear and delayed effects of temperature on cause- specific and age-specific mortality employing data from 1999 to 2008 for Chiang Mai, Thailand with a population of 1.6 million people. Controlling for season, humidity, ozone, and particulate matter (PM10) pollution, the three researchers found "both hot and cold temperatures resulted in immediate increase in all mortality types and age groups," but "the hot effects on all mortality types and age groups were short-term, while the cold effects lasted longer." The cold effects were greater, with more people dying from them than from the effects of heat.

Lindeboom et al. (2012) used daily mortality and weather data for the period 1983–2009 pertaining to Matlab, Bangladesh, to measure lagged effects of weather on mortality, controlling for time trends and

seasonal patterns. The four researchers report "mortality in the Matlab surveillance area shows overall weak associations with rainfall, and stronger negative association with temperature." They determined there was "a 1.4% increase in mortality with every 1°C decrease in mean temperature at temperatures below 29.2°C," but only "a 0.2% increase in mortality with every 1°C increase in mean temperature."

Wang et al. (2013) evaluated the short-term effect of diurnal temperature range (DTR) on emergency room (ER) admissions among elderly adults in Beijing. The nine researchers report "significant associations were found between DTR and four major causes of daily ER admissions among elderly adults in Beijing." They state "a 1°C increase in the 8-day moving average of DTR (lag 07) corresponded to an increase of 2.08% in respiratory ER admissions and 2.14% in digestive ER admissions," and "a 1°C increase in the 3-day and 6-day moving average of DTR (lag 02 and lag 05) corresponded to a 0.76% increase in cardiovascular ER admissions, and a 1.81% increase in genitourinary ER admissions, respectively.

Wu et al. (2013) assessed the health effects of temperature on mortality in four subtropical cities of China (Changsha, Kunming, Guangzhou, and Zhuhai). The 11 researchers report a U-shaped relationship between temperature and mortality was found in the four cities, indicating "mortality is usually lowest around a certain temperature and higher at lower or higher temperatures." Although "both low and high temperatures were associated with increased mortality in the four subtropical Chinese cities," Wu et al. state the "cold effect was more durable and pronounced than the hot effect."

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Observational Research in Europe

Keatinge and Donaldson (2001) analyzed the effects on human mortality of temperature, wind, rain, humidity, and sunshine during high pollution days in the greater London area over the period 1976–1995. They observed simple plots of mortality rate versus daily air temperature revealed a linear increase as temperatures fell from 15°C to near 0°C. Mortality rates at temperatures above 15°C, however, were

"grossly alinear," as they describe it, showing no trend. Only low temperatures were found to have a significant effect on immediate and long-term mortality. They conclude "the large, delayed increase in mortality after low temperature is specifically associated with cold and is not due to associated patterns of wind, rain, humidity, sunshine, SO2, CO, or smoke."

Kysely and Huth (2004) calculated deviations of the observed number of deaths from the expected number of deaths for each day of the year in the Czech Republic for the period 1992– 2000. They found "the distribution of days with the highest excess mortality in a year is clearly bimodal, showing a main peak in late winter and a secondary one in summer." Regarding the smaller number of summer heat-wave-induced deaths, they also found "a large portion of the mortality increase is associated with the harvesting effect, which consists in short-term shifts in mortality and leads to a decline in the number of deaths after hot periods (e.g. Rooney et al., 1998; Braga et al., 2002; Laschewski and Jendritzky, 2002)." For the Czech Republic, they report, "the mortality displacement effect in the severe 1994 heat waves can be estimated to account for about 50% of the total number of victims." As they describe it, "people who would have died in the short term even in the absence of oppressive weather conditions made up about half of the total number of deaths."

Diaz et al. (2005) examined the effect of extreme winter temperature on mortality in Madrid, Spain for people older than 65, using data from 1,815 winter days over the period 1986– 1997, during which time 133,000 deaths occurred. They found that as maximum daily temperature dropped below 6°C, which they describe as an unusually cold day (UCD), "the impact on mortality also increased significantly." They also found the impact of UCDs increased as the winter progressed, with the first UCD of the season producing an average of 102 deaths/day at a lag of eight days and the sixth UCD producing an average of 123 deaths/day at a lag of eight days.

Laaidi et al. (2006) conducted an observational population study in six regions of France between 1991 and 1995 to assess the relationship between temperature and mortality in areas of widely varying climatic conditions and lifestyles. In all cases they found "more evidence was collected showing that cold weather was more deadly than hot weather." These findings, the researchers say, are "broadly consistent with those found in earlier studies conducted elsewhere in Europe (Kunst et al., 1993; Ballester et al., 1997; Eurowinter Group, 1997; Keatinge et al., 2000; Beniston, 2002; Muggeo and Vigotti, 2002), the United States (Curriero et al., 2002) and South America (Gouveia et al., 2003)." They also say their findings "give grounds for confidence in the near future," stating even a 2°C warming over the next half century "would not increase annual mortality rates."

Analitis et al. (2008) analyzed short-term effects of cold weather on mortality in 15 major European cities using data from 1990–2000, and found "a 1°C decrease in temperature was associated with a 1.35% increase in the daily number of total natural deaths and a 1.72%, 3.30% and 1.25% increase in cardiovascular, respiratory, and cerebro-vascular deaths, respectively." In addition, they report "the increase was greater for the older age groups," and the cold effect "persisted up to 23 days, with no evidence of mortality displacement." They conclude their results "add evidence that cold-related mortality is an important public health problem across Europe and should not be overlooked by public health authorities because of the recent focus on heat-wave episodes."

Wichmann et al. (2011) investigated the association between the daily three-hour maximum apparent temperature (which reflects the physiological experience of combined exposure to humidity and temperature) and deaths due to cardiovascular disease (CVD), cerebrovascular disease (CBD), and respiratory disease (RD) in Copenhagen over the period
1999–2006.

Monthly deaths in the Castile-Leon region of Spain attributable to cardiovascular disease.

Source: Adapted from Fernandez-Raga et al. (2010).

During the warm half of the year (April–September), they found a rise in temperature had an inverse or protective effect with respect to CVD mortality (a 1% decrease in death in response to a 1°C increase in apparent temperature). This finding is unusual but also has been observed in Dublin, Ireland, as reported by Baccini et al. (2008, 2011). Wichmann et al. found no association with RD and CBD mortality. At the other end of the thermal spectrum, during the cold half of the year, all three associations were inverse or protective. This finding, according to the researchers, is "consistent with other studies (Eurowinter Group, 1997; Nafstad et al., 2001; Braga et al., 2002; O'Neill et al., 2003; Analitis et al., 2008)."
Matzarakis et al. (2011) studied the relationship between heat stress and all-cause mortality in the densely populated city of Vienna (Austria). Based on data from 1970–2007, and after adjusting the long-term mortality rate to account for temporal variations in the size of the population of Vienna, temporal changes in life expectancy, and the changing age structure of Vienna's population, the three researchers found a significant relationship between heat stress and mortality. However, over this 38-year period, "some significant decreases of the sensitivity were found, especially in the medium heat stress levels," they report. These decreases in sensitivity, they write, "could indicate active processes of long-term adaptation to the increasing heat stress." In the discussion section of their paper, they write such sensitivity changes "were also found for other regions," citing Davis et al. (2003), Koppe (2005), Tan et al. (2007), and Donaldson and Keatinge (2008). In the conclusion of their paper, they refer to these changes as

"positive developments."
Kysely and Plavcova then examined "temporal changes in mortality associated with spells of large positive temperature anomalies (hot spells) in extended summer season in the population of the Czech Republic (Central Europe) during 1986–2009." They found declining mortality trends in spite of rising temperature trends, just the opposite of what IPCC claims will occur in response to global warming. The Czech scientists add, "the finding on reduced vulnerability of the population remains unchanged if possible confounding effects of within- season acclimatization and mortality displacement are taken into account," and "neither does it depend on the changing age structure of the population, since similar (and slightly more pronounced) declines in the mortality impacts are found in the elderly (age group 70+ years) when examined separately."

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Observational Research in North America

Goklany and Straja (2000) examined trends in United States death rates over the period 1979– 1997 due to excessive hot and cold weather. They report there were no trends in deaths due to either extreme heat or cold in the entire population or in the older, more-susceptible age groups, those aged 65 and over, 75 and over, and 85 and over. Deaths due to extreme cold in these older age groups exceeded those due to extreme heat by as much as 80% to 125%. With respect to the absence of trends in death rates attributable to either extreme heat or cold, Goklany and Straja say this "suggests that adaptation and technological change may be just as important determinants of such trends as more obvious meteorological and demographic factors."
Davis et al. (2003) evaluated "annual excess mortality on days when apparent temperatures—an index that combines air temperature and humidity—exceeded a threshold value for 28 major metropolitan areas in the United States from 1964 through 1998." They found "for the 28-city average, there were 41.0 ± 4.8 excess heat-related deaths per year (per standard million) in the 1960s and 1970s, 17.3 ± 2.7 in the 1980s, and 10.5 ± 2.0 in the 1990s," a remarkable decline. They conclude, "heat-related mortality in the United States seems to be largely preventable at present."
Davis et al. (2004) examined the seasonality of mortality due to all causes, using monthly data for 28 major U.S. cities from 1964 to 1998, and then calculated the consequences of a future 1°C warming of the conglomerate of those cities. At all locations studied, they report "warmer months have significantly lower mortality rates than colder months." They calculate "a uniform 1°C warming results in a net mortality decline of 2.65 deaths (per standard million) per metropolitan statistical area" (emphasis added). The primary implication of Davis et al.'s findings, in their words, "is that the seasonal mortality pattern in US cities is largely independent of the climate and thus insensitive to climate fluctuations, including changes related to increasing greenhouse gases."
Deschenes and Moretti (2009) analyzed the relationship between weather and mortality, based on "data that include the universe of deaths in the United States over the period 1972– 1988," in which they "match each death to weather conditions on the day of death and in the county of occurrence." They discovered "hot temperature shocks are indeed associated with a large and immediate spike in mortality in the days of the heat wave," but "almost all of this excess mortality is explained by near-term displacement." As a result, "in the weeks that follow a heat wave, we find a marked decline in mortality hazard, which completely offsets the increase during the days of the heat wave," so "there is virtually no lasting impact of heat waves on mortality." In the case of cold temperature days, they also found "an immediate spike in mortality but "there is no offsetting decline in the weeks that follow," so "the cumulative effect of one day of extreme cold temperature during a thirty-day window is an increase in daily mortality by as much as 10%."

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Global Warming and Cardiovascular Disease

The key findings are that

- Global warming, if it does occur, would reduce the incidence of fatal coronary events related to low temperatures and wintry weather by a much greater degree than it increases the incidence of death or serious heat related events associated with high temperatures and summer heat waves.

- Non-fatal myocardial infarction is also less frequent during unseasonably warm periods than during unseasonably cold periods.

- Any cost-benefit analysis that attributes an increase in cardiovascular events to warming is incorrect. Heat illness injures and kills by other means and has a much lesser death toll proportionately than cold related events. Heat illness injury and death in heat waves affects the debilitated and chronically ill in hot unventilated environments and the mechanism is dehydration and loss of core body temperature control.

Cardiovascular diseases affect the heart and or the blood vessels. They include arrhythmia, arteriosclerosis, congenital heart disease, and coronary artery disease, diseases of the aorta and its branches, disorders of the peripheral vascular system, endocarditis, heart valve disease, hypertension, orthostatic hypotension, and

shock. According to IPCC, exposure to rising temperatures and especially heat waves can cause premature deaths due to heat-induced illness. The claims that it causes stroke or myocardial infarctions are not correct except to concede that ultimately most deaths are cardiovascular in nature.
Empirical research suggests that heat illness can cause collapse and death, but the mechanism is fluid and circulatory collapse, not stroke or heart attack. Heat stroke is severe heat illness with loss of temperature control that produces brain dysfunction; it's not a cerebral thrombosis or hemorrhage, a true stroke.
That aside, the IPCC overlooks the fact that cooler temperatures cause an even larger number of premature deaths, with the result that a warmer world would experience fewer deaths in total due to cardiovascular disease.

Global Warming and Respiratory Disease

The key findings of this section include the following:

- Global warming, if it did occur would reduce incidence of death due to respiratory disease around the world, for example the Americas, Spain, Canada, Shanghai, and even on the subtropical island of Taiwan.

- Lower minimum temperatures are a strong risk factor for outpatient visits for respiratory diseases. Warmer temperatures reduce rates of respiratory disease.

- Any cost-benefit analysis that attributes increases in deaths or disease and disability or loss of work/school time to warming is incorrect and not a reliable guide for public policy.

Respiratory diseases are diseases affecting the organs and tissues that make gas exchange possible in humans and other higher organisms. They range from the common cold, allergies, asthma, and bronchiolitis to life-threatening conditions including pneumonia, pulmonary embolism, and lung cancer. Acute respiratory disease is a condition in which breathing becomes difficult and oxygen levels in the blood drop lower than normal. Respiratory diseases are widespread. For example, childhood asthma affects more than 300 million people worldwide (Baena-Cagnani and Badellino, 2011). Non-fatal respiratory diseases impose enormous social costs due to days lost from work and school (Mourtzoukou and Falagas, 2007).
According to IPCC, rising atmospheric carbon dioxide concentrations due to the combustion of fossil fuels causes global warming, and this temperature increase causes increased deaths due to respiratory disease. However, examination of real-world data reveals unassailable evidence that colder temperatures cause more deaths and hospital admissions due to respiratory disease than do warmer temperatures.
Some of the studies cited earlier in this chapter on lower death rates due to warmer temperatures and cardiovascular disease also identified specific reductions in fatalities due to respiratory diseases, so their research also appears in this section. Keatinge and Donaldson (2001), for example, studied of the effects of temperature on mortality in people over 50 years of age in the greater London area over the period 1976–1995. Simple plots of mortality rate versus daily air temperature revealed a linear increase in mortality as the air temperature fell from 15°C to near 0°C. Mortality rates at temperatures above 15°C, on the other hand, showed no trend. The authors say it is because "cold causes mortality mainly from arterial thrombosis and respiratory disease, attributable in turn to cold-induced hemo-concentration and hypertension and respiratory infections" (emphasis added).
Nafstad et al. (2001) studied the association between temperature and daily mortality in citizens of Oslo, Norway over the period 1990 to 1995. The results showed the mean daily number of respiratory-related

deaths was considerably higher in winter (October–March) than in summer (April–September). Winter deaths associated with respiratory diseases were 47% more numerous than summer deaths. They conclude, "A milder climate would lead to a substantial reduction in average daily number of deaths." Read milder as warmer.

Hajat and Haines (2002) examined the relationship between cold temperatures and the number of visits by the elderly to general practitioners for asthma, lower respiratory diseases other than asthma, and upper respiratory diseases other than allergic rhinitis as obtained for registered patients aged 65 and older from several London practices between January 1992 and September 1995. They found the mean number of consultations was higher in cool-season months (October–March) than in warm-season months (April–September) for all respiratory diseases. At mean temperatures below 5°C, the relationship between respiratory disease consultations and temperature was linear, and stronger at a time lag of six to 15 days A 1°C decrease in mean temperature below 5°C was associated with a 10.5% increase in all respiratory disease consultations.

Braga et al. (2002) conducted a time-series analysis of both the acute and lagged influence of temperature and humidity on mortality rates in 12 U.S. cities, finding no clear evidence for a link between humidity and respiratory-related deaths. With respect to temperature, they found respiratory-related mortality increased in cities with more variable temperature. This phenomenon, they write, "suggests that increased temperature variability is the most relevant change in climate for the direct effects of weather on respiratory mortality."

Gouveia et al. (2003) extracted daily counts of deaths from all causes, except violent

deaths and neonatal deaths (up to one month of age), from Sao Paulo, Brazil's mortality information system for the period 1991–1994 and analyzed them for effects of temperature. For respiratory-induced deaths, death rates due to a 1°C cooling were twice as great as death rates due to a 1°C warming in adults and 2.8 times greater in the elderly.

Nakaji et al. (2004) evaluated seasonal trends in deaths due to various diseases in Japan, using nationwide vital statistics from 1970 to 1999 and concurrent mean monthly air temperature data. They found the numbers of deaths due to respiratory diseases, including pneumonia and influenza, rise to a maximum during the coldest time of the year. The team of nine scientists concludes, "To reduce the overall mortality rate and to prolong life expectancy in Japan, measures must be taken to reduce those mortality rates associated with seasonal differences."

Bartzokas et al. (2004) "examined the relationship between hospital admissions for cardio-vascular (cardiac in general including heart attacks) and/or respiratory diseases (asthma etc.) in a major hospital in Athens [Greece] and meteorological parameters for an 8-year period." Over the whole year, they found, "there was a dependence of admissions on temperature," and low temperatures were "responsible for a higher number of admissions." Specifically, "there was a decrease of cardiovascular or/and respiratory events from low to high values [of temperature], except for the highest temperature class in which a slight increase was recorded."

Kovats et al. (2004) studied patterns of temperature-related hospital admissions and deaths in Greater London during the mid-1990s. For the three-year period 1994–1996, they found respiratory-related deaths were nearly 150% greater in the depth of winter cold than at the height of summer warmth. They also found the mortality impact of the heat wave of 29 July to 3 August 1995 (which boosted daily mortality by just over 10%) was so tiny it could not be discerned among the random scatter of plots of three-year-average daily deaths from cardiovascular and respiratory problems versus day of year. Similarly, in a study of temperature effects on mortality in three English counties (Hampshire, West Midlands, and West Yorkshire), McGregor (2005) found "the occurrence of influenza ... helps elevate winter mortality above that of summer."

Carder et al. (2005) investigated the relationship between outside air temperature and deaths due to all non-accident causes in the three largest cities of Scotland (Glasgow, Edinburgh, and Aberdeen) between January 1981 and December 2001. The authors observed "an overall increase in mortality as temperature decreases," which "appears to be steeper at lower temperatures than at warmer temperatures," and "there is little evidence of an increase in mortality at the hot end of the temperature range." Specifically regarding respiratory disease, they found "for temperatures below 11°C, a 1°C drop in the daytime mean temperature on any one day was associated with an increase in respiratory mortality of 4.8% over the following month."
Donaldson (2006) studied the effect of annual mean daily air temperature on the length of the yearly respiratory syncytial virus (RSV) season, the virus which causes bronchiolitis, in England and Wales for 1981–2004. Reporting "climate change may be shortening the RSV season," Donaldson found "the seasons associated with laboratory isolation of respiratory syncytial virus (for 1981–2004) and RSV-related emergency department admissions (for 1990– 2004) ended 3.1 and 2.5 weeks earlier, respectively, per 1°C increase in annual central England temperature ($P = 0.002$ and 0.043, respectively)." Consequently, since "no relationship was observed between the start of each season and temperature," he reports, so "the RSV season has become shorter." He concludes, "These findings imply a health benefit of global warming in England and Wales associated with a reduction in the duration of the RSV season and its consequent impact on the health service."
Frei and Gassner (2008) studied hay fever prevalence in Switzerland from 1926 to 1991, finding it rose from just under 1% of the country's population to just over 14%, but from 1991 to 2000 it leveled off, fluctuating about a mean value on the order of 15%. The authors write, "several studies show that no further increase in asthma, hay fever and atopic sensitization in adolescents and adults has been observed during the 1990s and the beginning of the new century," citing Braun-Fahrlander et al. (2004) and Grize et al. (2006). They write, "Parallel to the increasing hay fever rate, the pollen amounts of birch and grass were increasing from 1969 to 1990," but "subsequently, the pollen of these plant species decreased from 1991 to 2007." They say this finding "is more or less consistent with the changes of the hay fever rate that no longer increased during this period and even showed a tendency to decrease slightly." Nearly identical findings were presented a year later (Frei, 2009). Although some have claimed rising temperatures and CO2 concentrations will lead to more pollen and more hay fever (Wayne et al., 2002), the analyses of Frei (2009) and Frei and Gassner (2008) suggest that is not true of Switzerland.
Miller et al. (2012) extracted annual prevalence data for frequent otitis media (defined as three or more ear infections per year), respiratory allergy, and non-respiratory seizures in children from the U.S. National Health Interview Survey for 1998 to 2006. They also obtained average annual temperatures for the same period from the U.S. Environmental Protection Agency. They found "annual temperature did not influence the prevalence of frequent otitis media," "annual temperature did not influence prevalence of respiratory allergy," and "annual temperature and sex did not influence seizure prevalence." They conclude their findings "may demonstrate that average temperature is not likely to be the dominant cause of the increase in allergy burden or that larger changes in temperatures over a longer period are needed to observe this association." They further conclude, "In the absence of more dramatic annual temperature changes, we do not expect prevalence of otitis media to change significantly as global warming may continue to affect our environment."
Xu et al. (2013) examined the relationship between diurnal temperature range (DTR) and emergency department admissions for childhood asthma in Brisbane, Australia, from January 1st 2003 to December 31st 2009. The six scientists report "childhood asthma increased above a DTR of 10°C" and "was the greatest for lag 0–9 days, with a 31% increase in [hospital] emergency department admissions per 5°C increment of DTR," further noting, "male children and children aged 5–9 years appeared to be more vulnerable to the DTR effect than others."

Ge et al. (2013) also investigated respiratory health and DTR. The researchers collected numbers of daily emergency-room visits for RTI at one of the largest medical establishments in Shanghai, China (Huashan Hospital) between 1 January 2008 and 30 June 2009, along with DTR data and data pertaining to possible confounding air pollutants (PM10, SO2, and NO2). After making appropriate statistical analyses, the scientists determined increasing DTRs were closely associated with daily emergency-room visits for RTIs, such that "an increase of 1°C in the current-day and in the 2-day moving average DTR corresponded to a 0.94% and 2.08% increase in emergency-room visits for RTI, respectively."
Lin et al. (2013) used data on daily area-specific deaths from all causes, circulatory diseases, and respiratory diseases in Taiwan, developing relationships between each of these cause-of-death categories and a number of cold-temperature related parameters for 2000–2008. The five researchers discovered "mortality from [1] all causes and [2] circulatory diseases and [3] outpatient visits of respiratory diseases has a strong association with cold temperatures in the subtropical island, Taiwan." In addition, they found "minimum temperature estimated the strongest risk associated with outpatient visits of respiratory diseases."

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Global Warming and Strokes

The key findings of this section include the following:

- Any warming would reduce the incidence of death due to stroke in many parts of the world, including Russia, Korea, Japan, Africa, Asia, Europe, Latin America, and the Caribbean.

- Low minimum temperatures are a stronger risk factor than high temperatures for stroke incidence and hospitalization.

- Any cost-benefit analysis that attributes increased strokes to a prediction of global warming is incorrect and not a reliable guide for public policy.

A stroke occurs when blood flow to an area in the brain is cut off. Ischemic stroke occurs when clots form in the brain's blood vessels, in blood vessels leading to the brain, or in blood vessels elsewhere in the body and then travel to the brain. Ischemic stroke can also occur when too much plaque (fatty deposits and cholesterol) clogs the brain's blood vessels. Hemorrhagic strokes occur when a blood vessel in the brain breaks or ruptures. The result is blood seeping into the brain tissue, causing damage to brain cells. The most common causes of hemorrhagic stroke are high blood pressure and brain aneurysms. An aneurysm is a bulge in a blood vessel caused by a weakness and thinning of the blood vessel wall. Aneurysms are prone to burst and a major cause of hemorrhagic stroke (WebMD, 2015).
According to IPCC, rising atmospheric carbon dioxide concentrations due to the combustion of fossil fuels causes global warming, and this temperature increase causes increased deaths due to strokes. Not true. Examination of real-world data reveals unseasonable cold temperatures cause more deaths and hospital admissions due to stroke than do unseasonable warm temperatures.
Feigin et al. (2000) examined the relationship between the incidence of stroke and ambient temperatures over the period 1982-1993 in Novosibirsk, Siberia, which has one of the highest stroke incidence rates in the world. Based on analyses of 2,208 patients with sex and age distributions similar to those of Russia as a whole, they found a statistically significant association between stroke and low ambient temperature. In the

case of ischemic stroke (IS), which accounted for 87% of all stroke types, they determined "the risk of IS occurrence on days with low ambient temperature [was] 32% higher than that on days with high ambient temperature." They conclude the "very high stroke incidence in Novosibirsk, Russia may partially be explained by the highly prevalent cold factor there." There is no reason to believe that temperature variations would have a discernible effect on hemorrhagic strokes that occur because of vascular pathology, not occlusion.

Hong et al. (2003) investigated the association between the onset of ischemic stroke and prior episodic decreases in temperature in 545 patients who suffered strokes in Incheon, Korea from January 1998 to December 2000. They report "decreased ambient temperature was associated with risk of acute ischemic stroke," with the strongest effect being seen on the day after exposure to cold weather, further noting "even a moderate decrease in temperature can increase the risk of ischemic stroke." They also found "risk estimates associated with decreased temperature were greater in winter than in the summer," which suggests "low temperatures as well as temperature changes are associated with the onset of ischemic stroke." Finally, they explain the reason for the 24- to 48-hour lag between exposure to cold and the onset of stroke "might be that it takes some time for the decreasing temperature to affect blood viscosity or coagulation.

Nakaji et al. (2004) evaluated seasonal trends in deaths due to various diseases in Japan using nationwide vital statistics from 1970 to 1999 together with mean monthly temperature data. They found the peak mortality rate due to stroke was two times greater in winter (January) than at the time of its yearly minimum (August and September).

Chang et al. (2004) analyzed data from the World Health Organization (WHO) Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception (WHO, 1995) to determine the effects of monthly mean temperature on rates of hospitalization for arterial stroke and acute myocardial infarction among women aged 15–49 from 17 countries in Africa, Asia, Europe, Latin America, and the Caribbean. They found among these women, a 5°C reduction in mean air temperature was associated with a 7% increase in the expected hospitalization rate due to stroke, and this effect was relatively acute, within a period of about a month, the scientists write.

Gill et al. (2012) write, "in the past two decades, several studies reported that meteorologic changes are associated with monthly and seasonal spikes in the incidence of aneurysmal subarachnoid hemorrhage (aSAH)," and "analysis of data from large regional databases in both hemispheres has revealed increased seasonal risk for aSAH in the fall, winter and spring," citing among other sources Feigin et al. (2001), Abe et al. (2008), and Beseoglu et al. (2008). Gill et al. identified the medical records of 1,175 patients at the Johns Hopkins Hospital in Baltimore, Maryland (USA) who were admitted with a radiologically confirmed diagnosis of aSAH between 1 January 1991 and 1 March 2009. The six scientists report both "a one-day decrease in temperature and colder daily temperatures were associated with an increased risk of incident aSAH," and "these variables appeared to act synergistically" and were "particularly predominant in the fall, when the transition from warmer to colder temperatures occurred." Gill et al. add their study "is the first to report a direct relationship between a temperature decrease and an increased risk of aSAH," and "it also confirms the observations of several reports of an increased risk of aSAH in cold weather or winter," citing Nyquist et al. (2001) and other sources. Authors' note: This study and others the authors of the study reference are outliers in the sense that they tally aneurysmal sub arachnoid hemorrhage, a different kind of stroke than ischemic strokes, so there is no "mechanism" of coagulation and clot formation that would relate to temperature that might be hypothesized as a cause of cold or cool to cause hemorrhagic stroke.

The reader should be informed that hemorrhagic stroke is because of a different mechanism, the rupture of a weakened wall of a blood vessel, often associated with a bulge called an aneurysm, as opposed to ischemic stroke discussed above that occur because of a blood clot in the brain blood vessel. However the temperature

effect is the same, cold produces an increase in hemorrhagic strokes in addition to its effect on the rate of ischemic strokes.

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Global Warming and Insect-borne Diseases

The key findings of this section include the following:

- Research contradicts the claim that malaria will expand across the globe and intensify as a result of any possible warming.

- Concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever infection rates.

- Climate change has not been a significant factor driving the recent temporal patterns in the epidemiology of tick-borne diseases. Ticks are endemic at many latitudes.

The latest IPCC report, the Fifth Assessment Report (AR5) backs down from previous predictions that global warming would facilitate the spread of insect-borne diseases including malaria, dengue fever, and tick-borne diseases. The full report from Working Group II on the subject (IPCC, 2014a, Chapter 11, pp. 722-726) repeatedly admits there is no evidence that climate change has affected the range of vector-borne diseases including tick-borne diseases. However, the Summary for Policymakers inexplicably warns "Throughout the 21st century, climate change is expected to lead to increases in ill-health in many regions and especially in developing countries with low income, as compared to a baseline without climate change (high confidence)." Among the "examples" given is "vector-borne diseases (medium confidence)" (IPCC, 2014b, pp. 19-20). Such predictions are not supported by the evidence.

In a research report in Science, Rogers and Randolph (2000) note "predictions of global climate change have stimulated forecasts that vector-borne diseases will spread into regions that are at present too cool for their persistence." However, the effect of warmer temperatures on insect-borne diseases is complex, sometimes working in favor of and sometimes against the spread of a disease. For example, ambient temperature has historically not determined the range of insect-borne diseases, hotter weather shortens the lifespan of mosquitos, and human adaptation as well as vector control measures can neutralize any detrimental effect of warming, to overwhelm the role of climate. Even those who support IPCC, such as Marm Kilpatrick, an assistant professor in ecology and evolutionary biology at the University of California, Santa Cruz, admits "It's a little bit tricky to make a solid prediction" (Irfan, 2011).

Gething et al. (2010), writing specifically about malaria, may have put it best when they said there has been "a decoupling of the geographical climate-malaria relationship over the twentieth century, indicating that non-climatic factors have profoundly confounded this relationship over time." They note "non-climatic factors, primarily direct disease control and the indirect effects of a century of urbanization and economic development, although spatially and temporally variable, have exerted a substantially greater influence on the geographic extent and intensity of malaria worldwide during the twentieth century than have climatic factors." As for the future, they conclude climate-induced effects "can be offset by moderate increases in coverage levels of currently available interventions."

This section investigates the reliability of IPCC's claim with respect to the three main kinds of insect-borne diseases: malaria, dengue fever, and tick-borne diseases According to the results of a vast body of scientific examination and research on this topic, there is little support for the claims appearing in the latest IPCC Summary for Policymakers.

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Malaria

A vast body of scientific examination and research contradict the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming.

Jackson et al. (2010) say "malaria is one of the most devastating vector-borne parasitic diseases in the tropical and subtropical regions of the world," noting it affects more than 100 countries.

According to the World Health Organization, Africa carries the highest infection burden of any continent, with nearly 200 million cases reported in 2006, and the Centers for Disease Control and Prevention estimates between 700,000 and 2.7 million people each year die from the dreaded disease (Suh et al., 2004). In addition, Jackson et al. report "the African region bears 90% of these estimated worldwide deaths," and "three-quarters of all malaria related deaths are among African children," citing Breman (2001). According to Reiter (2000), claims that malaria resurgence is the product of CO2-induced global warming ignore other important factors and disregard known facts. A historical analysis of malaria trends, for example, reveals this disease was an important cause of illness and death in England during a period of colder-than-present temperatures throughout the Little Ice Age. Its transmission began to decline only in the nineteenth century, during a warming phase, when, according to Reiter, "temperatures were already much higher than in the Little Ice Age." In short, malaria was prevalent in Europe during some of the coldest centuries of the past millennium, and it has only recently undergone widespread decline, when temperatures have been warming.

Clearly, there are other factors at work in regards to malaria that are more important than temperature. Such factors include the quality of public health services, irrigation and agricultural activities, land use practices, civil strife, natural disasters, ecological change, population change, use of insecticides, and the movement of people (Reiter, 2000; Reiter, 2001; Hay et al., 2002).

Nevertheless, concerns have lingered about the possibility of widespread future increases in malaria due to global warming. These concerns are generally rooted in climate models that typically use only one, or at most two, climate variables in making their predictions of the future distribution of the disease over Earth, and they generally do not include any of the non-climatic factors listed in the preceding paragraph. When more variables are included, a less-worrisome future is projected.

In one modeling study, for example, Rogers and Randolph (2000) employed five climate variables and obtained very different results. Briefly, they used the present-day distribution of malaria to determine the specific climatic constraints that best define that distribution, after which the multivariate relationship they derived from this exercise was applied to future climate scenarios derived from state-of-the-art climate models, in order to map potential future geographical distributions of the disease.

Their study revealed very little change: a 0.84% increase in potential malaria exposure under the "medium-high" scenario of global warming and a 0.92% decrease under the "high" scenario. Rogers and Randolph explicitly state their quantitative model "contradicts prevailing forecasts of global malaria expansion" and "highlights the use of multivariate rather than univariate constraints in such applications. They found "climate warming, expressed as a systematic temperature increase over the 85-year period, does not appear to be responsible for an increase in malaria suitability over any region in Africa." They conclude "research on the links between climate change and the recent resurgence of malaria across Africa would be best served through refinements in maps and models of precipitation patterns and through closer examination of the role of nonclimatic influences."

Kuhn et al. (2003) analyzed the determinants of temporal trends in malaria deaths within England and Wales in 1840–1910 and found "a 1°C increase or decrease was responsible for an increase in malaria deaths of 8.3% or a decrease of 6.5%, respectively," which explains "the malaria epidemics in the 'unusually hot summers' of 1848 and 1859." Nevertheless, the long- term near-linear temporal decline in malaria deaths over the period of study, the researchers write, "was probably driven by nonclimatic factors," among which they identify increasing livestock populations (which tend to divert mosquito biting from humans), decreasing acreages of marsh wetlands (where mosquitoes breed), as well as "improved housing, better access to health care and medication, and improved nutrition, sanitation, and hygiene." Kuhn et al. say "the projected increase in proportional risk is clearly insufficient to lead to the reestablishment of endemicity."

Childs et al. (2006) present a detailed analysis of malaria incidence in northern Thailand based on a quarter-century monthly time series (January 1977 through January 2002) of total malaria cases in the country's 13 Northern provinces. Over this time period, when IPCC claims the world warmed at a rate and to a level unprecedented over the prior one to two millennia, Childs et al. report there was an approximately constant rate of decline in total malaria incidence (from a mean monthly incidence in 1977 of 41.5 cases per hundred thousand people to 6.72 cases per hundred thousand people in 2001). Noting "there has been a steady reduction through time of total malaria incidence in northern Thailand, with an average decline of 6.45% per year," they say this result "reflects changing agronomic practices and patterns of immigration, as well as the success of interventions such as vector control programs, improved availability of treatment and changing drug policies."

Reiter (2008) came to similar conclusions, writing "simplistic reasoning on the future prevalence of malaria is ill-founded; malaria is not limited by climate in most temperate regions, nor in the tropics, and in nearly all cases, 'new' malaria at high altitudes is well below the maximum altitudinal limits for transmission." He further states, "Future changes in climate may alter the prevalence and incidence of the disease, but

obsessive emphasis on 'global warming' as a dominant parameter is indefensible; the principal determinants are linked to ecological and societal change, politics and economics."
Hulden and Hulden (2009) analyzed malaria statistics collected in Finland from 1750 to 2008 via correlation analyses between malaria frequency per million people and all variables that have been used in similar studies throughout other parts of Europe, including temperature data, animal husbandry, consolidation of land by redistribution, and household size. Over the entire period, "malaria frequency decreased from about 20,000–50,000 per 1,000,000 people to less than 1 per 1,000,000 people," they report. The two Finnish researchers conclude, "Indigenous malaria in Finland faded out evenly in the whole country during 200 years with limited or no counter measures or medication," making that situation "one of the very few opportunities where natural malaria dynamics can be studied in detail." Their study indicates "malaria in Finland basically was a sociological disease and that malaria trends were strongly linked to changes in the human household size and housing standard."

Effects of climate and socioeconomic factors on the projected future global distribution of malaria.

Source: Béguin et al. (2011).

The many findings described above make it clear a vast body of scientific examination and research contradict the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming.

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Dengue Fever

Concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever.

According to Ooi and Gubler (2009), "dengue/dengue hemorrhagic fever is the most important vector-borne viral disease globally," with more than half the world's population living in areas deemed to be at risk of infection. Kyle and Harris (2008) note "dengue is a spectrum of disease caused by four serotypes of the most

prevalent arthropod-borne virus affecting humans today," and "its incidence has increased dramatically in the past 50 years," to where "tens of millions of cases of dengue fever are estimated to occur annually, including up to 500,000 cases of the life- threatening dengue hemorrhagic fever/dengue shock syndrome." Some of the research papers summarized in previous sections address dengue fever as well as malaria. With a few worthy exceptions, we do not repeat those summaries in this section. The most important exceptions are papers written by or coauthored by Paul Reiter (2001, 2003, 2010a, 2010b), one of the world's premier authorities on the subject. Reiter analyzed the history of malaria and dengue fever in an attempt to determine whether the incidence and range of influence of these diseases would indeed increase in response to CO2-induced global warming.

His reviews established what is now widely accepted among experts in the field, that the natural history of these vector-borne diseases is highly complex, and the interplay of climate, ecology, vector biology, and a number of other factors defy definition by the simplistic analyses utilized in the computer models relied on by environmental activists and the IPCC.

That there has in fact been a resurgence of these diseases in parts of the world is true, but as Reiter (2001) notes; it is "facile to attribute this resurgence to climate change." This he shows via a number of independent analyses that clearly demonstrate factors associated with politics, economics, and human activity is the principal determinants of the spread of these diseases. He describes these factors as being "much more significant" than climate in promoting disease expansion. Two years later, Reiter took up the subject again, this time with 19 other scientists as coauthors (Reiter et al., 2003), and yet again in 2010. Reiter's work remains the most comprehensive critique of the claims of the Intergovernmental Panel on Climate Change.

Kyle and Harris (2008) wrote "there has been a great deal of debate on the implications of global warming for human health," but "at the moment, there is no consensus." However, "in the case of dengue," they report, "it is important to note that even if global warming does not cause the mosquito vectors to expand their geographic range, there could still be a significant impact on transmission in endemic regions," because "a 2°C increase in temperature would simultaneously lengthen the lifespan of the mosquito and shorten the extrinsic incubation period of the dengue virus, resulting in more infected mosquitoes for a longer period of time." Nevertheless, they state there are "infrastructure and socioeconomic differences that exist today and already prevent the transmission of vector-borne diseases, including dengue, even in the continued presence of their vectors," citing Reiter (2001).

Wilder-Smith and Gubler (2008) conducted a review of the scientific literature, noting "the past two decades saw an unprecedented geographic expansion of dengue" and "global climate change is commonly blamed for the resurgence of dengue," but they add, "There are no good scientific data to support this conclusion." The two researchers report, "Climate has rarely been the principal determinant of [their] prevalence or range," and "human activities and their impact on local ecology have generally been much more significant." They cite as contributing factors "urbanization, deforestation, new dams and irrigation systems, poor housing, sewage and waste management systems, and lack of reliable water systems that make it necessary to collect and store water," further noting "disruption of vector control programs, be it for reasons of political and social unrest or scientific reservations about the safety of DDT, has contributed to the resurgence of dengue around the world."

In addition, Wilder-Smith and Guble write "large populations in which viruses circulate may also allow more co-infection of mosquitoes and humans with more than one serotype of virus," which would appear to be borne out by the fact that "the number of dengue lineages has been increasing roughly in parallel with the size of the human population over the last two centuries." Most important, perhaps, is "the impact of international travel," of which they say "humans, whether troops, migrant workers, tourists, business travelers, refugees, or others, carry the virus into new geographic areas," and these movements "can lead to

epidemic waves." The two researchers conclude, "Population dynamics and viral evolution offer the most parsimonious explanation for the observed epidemic cycles of the disease, far more than climatic factors." Russell et al. (2009) showed the dengue vector (the Aedes Aegypti mosquito) "was previously common in parts of Queensland, the Northern Territory, Western Australia and New South Wales," and it had, "in the past, covered most of the climatic range theoretically available to it," adding "the distribution of local dengue transmission has [historically] nearly matched the geographic limits of the vector." This being the case, they conclude the vector's current absence from much of Australia "is not because of a lack of a favorable climate." Thus, they reason "a temperature rise of a few degrees is not alone likely to be responsible for substantial increases in the southern distribution of A. Aegypti or dengue, as has been recently proposed." Instead of futile attempts to limit dengue transmission by controlling the world's climate, therefore, the medical researchers recommend "well resourced and functioning surveillance programs, and effective public health intervention capabilities, are essential to counter threats from dengue and other mosquito-borne diseases."

Reiter (2010a) observed "the introduction and rapidly expanding range of Aedes Albopictus in Europe is an iconic example of the growing risk of the globalization of vectors and vector-borne diseases," and "the history of yellow fever and dengue in temperate regions confirms that transmission of both diseases could recur, particularly if Aedes Aegypti, a more effective vector, were to be re-introduced." He states "conditions are already suitable for transmission." Much more important than a rise or fall of a couple degrees of temperature, Reiter says, is "the quantum leap in the mobility of vectors and pathogens that has taken place in the past four decades, a direct result of the revolution of transport technologies and global travel."

Carbajo et al. (2012) evaluated the relative contributions of geographic, demographic, and climatic variables to the recent spread of dengue in Argentina. They found dengue spatial occurrence "was positively associated with days of possible transmission, human population number, population fall and distance to water bodies." When considered separately, the researchers write, "the classification performance of demographic variables was higher than that of climatic and geographic variables." Thus, although useful in estimating annual transmission risk, Carbajo et al. conclude temperature "does not fully describe the distribution of dengue occurrence at the country scale," and "when taken separately, climatic variables performed worse than geographic or demographic variables."

These several observations indicate concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever.

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Tick-borne Diseases

Climate change has not been the most significant factor driving the recent temporal patterns in the epidemiology of tick-borne diseases.

Sarah Randolph of the University of Oxford's Department of Zoology is a leading scholar on tick-borne diseases. She and fellow Oxford faculty member David Rogers observed in 2000 that tick-borne encephalitis (TBE) "is the most significant vector-borne disease in Europe and Eurasia," having "a case morbidity rate of 10–30% and a case mortality rate of typically 1–2% but as high as 24% in the Far East." The disease is

caused by a flavivirus (TBEV), which is maintained in natural rodent-tick cycles; humans may be infected with it if bitten by an infected tick or by drinking untreated milk from infected sheep or goats.

Early discussions on the relationship of TBE to global warming predicted the disease would expand its range and become more of a threat to humans in a warmer world. However, Randolph and Rogers (2000) note, "like many vector-borne pathogen cycles that depend on the interaction of so many biotic agents with each other and with their abiotic environment, enzootic cycles of TBEV have an inherent fragility," so "their continuing survival or expansion cannot be predicted from simple univariate correlations."

Randolph (2010) examined the roles played by various factors that may influence the spread of tick-borne diseases. After describing some of the outbreaks of tick-borne disease in Europe over the past couple of decades, Randolph states "the inescapable conclusion is that the observed climate change alone cannot explain the full heterogeneity in the epidemiological change, either within the Baltic States or amongst Central and Eastern European countries," citing Sumilo et al. (2007). Instead, she writes, "a nexus of interrelated causal factors—abiotic, biotic and human—has been identified," and "each factor appears to operate synergistically, but with differential force in space and time, which would inevitably generate the observed epidemiological heterogeneity."

Many of these factors, she continues, "were the unintended consequences of the fall of Soviet rule and the subsequent socio-economic transition (Sumilo et al., 2008b)," among which she cites "agricultural reforms resulting in changed land cover and land use, and an increased reliance on subsistence farming; reduction in the use of pesticides, and also in the emission of atmospheric pollution as industries collapsed; increased unemployment and poverty, but also wealth and leisure time in other sectors of the population as market forces took hold."

Randolph concludes "there is increasing evidence from detailed analyses that rapid changes in the incidence of tick-borne diseases are driven as much, if not more, by human behavior that determines exposure to infected ticks than by tick population biology that determines the abundance of infected ticks," as per Sumilo et al. (2008a) and Randolph et al. (2008). She ends her analysis by stating, "While nobody would deny the sensitivity of ticks and tick-borne disease systems to climatic factors that largely determine their geographical distributions, the evidence is that climate change has not been the most significant factor driving
the recent temporal patterns in the epidemiology of tick-borne diseases."

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Conclusion

IPCC fails to acknowledge the human health benefits of a warming world, claiming instead that the net effect of warming is a cost rather than a benefit.

Fossil fuels have benefited human health by making possible the dramatic increase in human prosperity since the first Industrial Revolution, making investments possible in goods and services that are essential to protecting human health and prolonging human life. Fossil fuels further improve human health by making environmental protection both valued and financially possible and by powering technologies and production of goods and services, transportation, communication that all improve quality of life, and protect human health and welfare, extend life spans.
If the combustion of fossil fuels leads to some amount of global warming, then the positive as well as negative health effects of that warming should be included in any cost-benefit analysis of fossil fuels.
Medical science explains why colder temperatures often cause diseases and sometimes fatalities whereas warmer temperatures are associated with health benefits.
Empirical research confirms that warmer temperatures lead to a net decrease in temperature- related mortality in virtually all parts of the world, even those with tropical climates. The evidence of this benefit comes from research conducted in nearly every major country of the world.
Global warming is reducing the incidence of fatal coronary events related to low temperatures and wintry weather by a much greater degree than it increases the incidence of heat related illness or death attributable to heat waves. Respiratory illness, strokes and myocardial infarction are less frequent during unseasonably warm periods than during unseasonably cold periods.
Global warming is reducing the incidence of death due to respiratory disease in many parts of the world, including Spain, Canada, Shanghai, and even on the subtropical island of Taiwan. Low minimum temperatures have been found to be a stronger risk factor than high temperatures for outpatient visits for respiratory diseases. Warm weather reduces the incidence of death due to stroke around the world.
A vast body of scientific examination and research contradicts and refutes the claim that malaria will expand across the globe or intensify in some regions as a result of any predicted CO2-induced warming. Concerns over large increases in mosquito-transmitted dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature.

While climatic factors largely determine the geographical distribution of ticks, temperature and climate change are not among the significant factors determining the incidence of tick-borne diseases.
In the face of this extensive evidence of the positive effects of fossil fuels on human health, IPCC continues to claim the net impact on human health of fossil fuels will be negative. Because virtually all cost-benefit analyses incorporate the IPCC's incorrect assumptions into their calculation of the social cost of fossil fuels, they are unreliable guides to policymakers.

12. Conclusion

This is not a complete expose of the misconduct of the US EPA sponsored researchers and in house science and policy staff in matters of epidemiology and toxicology and it focuses on the US EPA research/ policy /regulatory activities in air quality science and policy making—an equally scandalous case can be made for US EPA work in other areas of responsibility where toxicology and epidemiology are abused and misused to expand the EPA list of targets for regulation and opportunities for EPA to scaremonger.

I also cannot take the time or the space in this discussion to expose the US EPA new area of scientific misconduct and scaremongering—epigenetics and their claims of inheritable acquired toxin carcinogenic genetic mutations—revisiting Lamarck and Lysenko long ago discredited theories about acquired genetic changes. Such irresponsible scares about inherited toxic and cancer effects are ideal for irresponsible aggressive environmental fanatic wannabee regulators and their obedient research army.

US EPA researchers in epigenetics are their new breed of scaremongers with the target people who think exposure to some named toxin might effect their children or grandchildren. The lust of power and influence and cheating on science go hand in hand.

All of what I have exposed above combines to make an effective and urgent argument for the proposed US EPA policy change to promote integrity and transparency of US EPA science in matters of regulatory policy decision making. The time for cleaning up the US EPA scientific perfidy and misconduct, malfeasance is long past overdue.

I anticipate there will be institutions and scientists panicked and anxious about proving up their research assertions and conclusions—a very beneficial and healthy development. The polity will benefit from science and policy making that is based on reliable methods used by researchers with integrity who are subjected to impartial and thorough competent reviews by experts who are not conflicted by ideological, political, monetary or social/professional influences.

John Dale Dunn MD JD

Personal Matters / Ex. 6

https://www.regulations.gov.

Docket ID No. EPA-HQ-OA-2018-0259

Comments submitted on the Docket Subject titled

Strengthening Transparency in Regulatory Science
Comment on Strengthening Transparency in Regulatory Science, Environmental Protection Agency, 40 CFR Part 30, RIN 2080—AA14 [EPA-HQ-OA-2018-0259; FRL-9977-40-ORD].

Comments submitted by John Dale Dunn MD JD
Emergency Physician, inactive attorney
Lecturer, retired Clinical Instructor,
Emergency Medicine Residency
Carl R. Darnall Army Medical Center, Fort Hood, Texas.

Table of contents of elements of the submission

The Submitter's opinions are personal and not attributable to the US Army or Department of Defense.

This submitter has witnessed US EPA misconduct for a period of 3 decades on a scale that is stunning, or alarming, going back to the EPA decision to ban DDT in the early 1970s, resulting in the deaths of millions in the 3rd world, and a particularly horrific impact on children.

More recently in addition to serial misconduct with regards to toxicology and epidemiology research the EPA has compounded its scientific methodology misconduct with a systematic violation of domestic and international ethical and moral/legal norms in regards to human experimentation—promoting and funding, approving human experiments that resulted in uninformed subjects being involved in experiments at 10 domestic and 6 foreign medical research institutions where they were intentionally observed while inhaling small particle contaminated air while being observed for adverse effects. These experiments carried out by prominent Medical Schools, is in spite of US EPA public pronouncements and testimony before congress that small particles are toxic, lethal (Hundreds of thousands of deaths annually) and carcinogenic.

US domestic law prohibits human experiments that might harm and international medical ethical standards for human experiments prohibit human experiments with no exceptions except exigencies of great need if the researchers act as subjects. Any other human experiments with a risk of harm are prohibited, and no consent will remove that proscription.

In the past 3 decades US EPA air quality research has been an abomination, relying on junk toxicology/epidemiology and the precautionary principle. The submitter has actively tried to expose the misconduct.

The proposal by the US EPA, discussed here to force EPA scientific transparency and scientific integrity is salutary and significant in all its elements, and the submitter is grateful for the change from the formerly fraudulent toxicology and epidemiology of the EPA to impose a new form of integrity.

I will detail in this submission the nature of the EPA sponsored research fraud, the methods and data manipulation and management that have resulted in EPA fraud on the public about air quality health effects, toxicological claims in other areas of EPA responsibility and the EPA full blown commitment to the hoax of CO2 levels as a cause of catastrophic warming. In these three areas of EPA research and policy making it is easy to identify the frauds on the public that are supported by a well-paid band of hired researchers and an in house gang of committed environmental true believers. The result is a fraud and research and policy conduct that is so badly informed and poorly researched and developed that it includes systematic commission of civil and even criminal acts to further an EPA agenda of aggressive environmental regulations that have created tremendous economic burdens for no good reason other than a fanatic environmental ideological agenda.

I will elaborate with specific references and documents in the submission below—elaborate on the irresponsible and flagrantly unscientific research funded and promoted by the USEPA on all matters of toxicology and epidemiology and my admonition to any reader is that if we do not stop this junk science for politics and ideology, we will follow the path of fools for a cause—the path of true believers that is paved with confirmation biases and fallacious science and policy making that violates the law and cheats the taxpayer in two ways, scaremongering, and regulatory burdens that steal resources and assets for regulatory compliance that diminishes better use of those resources in the public and private sectors. My promise to the reader is I will show you how and how much the EPA disrespects and abuses the rules and methods of science.

1. Other commentaries I agree with highlighted

The Washington Post
By Robert Hahn
May 10, 2018

https://www.washingtonpost.com/opinions/many-mocked-this-scott-pruitt-proposal-they-should-have-read-it-first/2018/05/10/31baba9a-53c2-11e8-abd8-265bd07a9859_story.html?noredirect=on&utm_term=.f7bcbc0a1887

Robert Hahn is a visiting professor at Oxford University's Smith School of Enterprise and the Environment and a non-resident senior fellow at the Brookings Institution. He recently served as a commissioner on the U.S. Commission on Evidence-Based Policymaking.

When Environmental Protection Agency Administrator Scott Pruitt proposed a rule last month to improve transparency in science used to make policy decisions, he was roundly criticized by interest groups and academics. Several researchers asserted that the policy would be used to undermine a litany of existing environmental protections. Former Obama administration EPA officials co-wrote a New York Times op-ed in which they said the proposal "would undermine the nation's scientific credibility." The Economist derided the policy as "swamp science."

But there is a lot to cheer about in the rule that opponents have missed. A careful reading suggests it could promote precisely the kind of evidence-based policy most scientists and the public should support.

Critics typically argue that the proposed regulation would suppress research that contains confidential medical records and therefore scientists could not share underlying data publicly for privacy reasons. Such restrictions, these critics say, would have excluded landmark research, such as Harvard University's "Six Cities" study, which suggested that reducing fine particles in the air would dramatically improve human health and helped lead to more stringent regulation of fine particles in the United States.

...

But it appears that few defenders or opponents of the proposal have actually read the proposed EPA regulation, which is only seven pages long. Both sides distort the regulatory text.

Here's what the rule would actually do about the question of confidentiality of Personal Health Information under HIPAA or any other rule.

First, it would require the EPA to identify studies that are used in making regulatory decisions.

Second, it would encourage studies to be made publicly available "to the extent practicable."

Third, it would define "publicly available" by listing examples of information that could be used for validation, such as underlying data, models, computer code and protocols.

Fourth, the proposal recognizes not all data can be openly accessible in the public domain and that restricted access to some data may be necessary.

Fifth, it would direct the EPA to work with third parties, including universities and private firms, to make information available to the extent reasonable.

Sixth, it would encourage the use of efforts to de-identify data sets to create public-use data files that would simultaneously help protect privacy and promote transparency.

Seventh, the proposal outlines an exemption process when compliance is "impracticable." Finally, it would direct the EPA to clearly state and document assumptions made in regulatory analyses.

(It is this submitter's position that the privacy/confidentiality issues raised by EPA sponsored researchers are intended to be a distraction—there is nothing that prevents a release of the data used in the EPA studies of the 90s, and since, because data can be collected without identifiers that penetrate to reveal Personal Health Information or the identity of individuals. Most of the EPA Sponsored studies on small particle effects are death studies—there is nothing that is sacred and confidential about a death certificate. The Studies the on ozone effects can easily be done to redact personal health information.) Here's what the EPA's new proposed rule wouldn't do: nullify existing environmental regulations, disregard existing research, violate confidentiality protections, jeopardize privacy or undermine the peer-review process.

Taking steps to increase access to data, with strong privacy protections, is how society will continue to make scientific and economic progress and ensure that evidence in rule-making is sound. The EPA's proposed rule follows principles laid out in 2017 by the bipartisan Commission on Evidence-Based Policymaking — humility, transparency, privacy, capacity and rigor — and moves us toward providing greater access to scientific data while protecting individual privacy.

Instead of throwing stones, the scientific community should come together to offer practical suggestions to make the rule better. For example, the rule should recognize the incentives for scientists to produce new research. . . .

Done right, this could improve government policy not only in the United States but also around the world.
It's still hard to tell how this rule will affect EPA decisions, but one thing is clear: The rule will make the evidence by which we make policy decisions more transparent. The policy might not be perfect, but its benefits will likely far outweigh its costs.

Comment by the submitter—this is blowing smoke and making excuses for the "secret science" that has dominated EPA activities for decades—there is no privacy or confidentiality problem with gathering data on deaths in studies that do not depend on personal data or release that personal data. Death Certificates with accompanying information do not violate confidentiality or privacy rules and can be used to assess the validity of the studies submitted—period.

Michael Dourson is a prominent toxicologist in the private sector. Here, again below I provide bold highlighting for his essay on the matter of the transparency proposal:

From A Risk-Assessment Perspective, EPA Getting Rid Of 'Secret Science' Makes Sense

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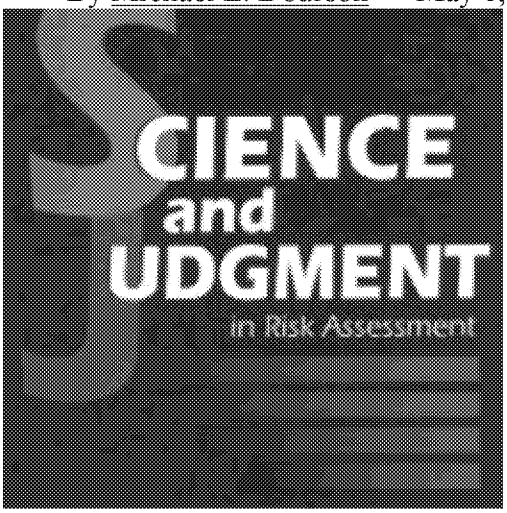
By Michael L. Dourson — May 8, 2018 Washington Examiner



Science and Judgment in Risk Assessment - the "Blue Book"

Environmental Protection Agency Administrator Scott Pruitt's recent announcement that EPA will not use "secret science" — that is science for which the underlying data is not available — is challenging. Whereas EPA is routinely in receipt of unpublished toxicity studies for chemicals designed for commerce, not all important scientific findings are publishable. Nor do scientific journals generally have sufficient space to include all data.

Much has been made in recent weeks of this new EPA policy, including an op-ed opposing it by former EPA Administrator Gina McCarthy and former acting Assistant Administrator Janet McCabe.

The media coverage has focused attention on how science is considered acceptable and useful in EPA's rulemaking. But missing from this is the perspective of risk scientists charged with protecting public health. In the case of EPA, it is often not enough for any one positive study to be published in a peer-reviewed journal. Such work often needs replication because a positive finding occurs, on average, in one out of every 20 studies due to chance.

If a study cannot be replicated, then it at least needs to make sense within the pattern of available data. For pesticides regulated by EPA, these data are often from hundreds of studies done according to federal guidelines.

Studies that are not replicated or that do not make sense in an overall pattern are still considered, however. Risk scientists will often contact the authors to obtain additional information in order to conduct their own analysis, a common practice within EPA.

When such data are forthcoming, without the need to break confidentiality or disclose confidential business information, independent analyses can be conducted and the public health is better served. But when such information is withheld by the authors, government risk scientists are often left with a dilemma.

For example, imagine that a series of studies come out on a single human group that is exposed to a commonly used insecticide, and they show an unexpected effect at extremely low exposures. This finding

has not been replicated and clashes with multiple animal and human studies that point to danger only at much higher exposures.

In this case, EPA scientists would ask the authors for the underlying data to confirm this unexpected low-dose effect. But let's say they can't get it. EPA is then left with neither confirmatory studies, nor information that makes sense in light of other studies, nor the ability to conduct its own analysis. Understandably, Pruitt has chosen a policy of not using such studies.

There is one sense in which McCarthy and McCabe are spot on. The judgment over which epidemiology and/or toxicology data to use for risk or safety assessment purposes should be left to risk scientists. But from my perspective as a risk scientist, Pruitt's decision is still correct. The public's interest is best served when science is replicable and consistent with other information. When studies cannot be replicated or are inconsistent with other information, access to their underlying data is vital to independent analysis. When the underlying data are not provided to a risk scientist, it is difficult to use this study to make a credible risk judgment, much less national rulemaking.

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a safety level. But the public's interest is best served by trusting in experts dedicated to public health protection, not by withholding scientific data from independent analysis.

This article is republished from the *Washington Examiner*. Read the original here.

By Michael L. Dourson

Michael L. Dourson, PhD, DABT, FATS, FSRA, is prominent and accomplished toxicologist.

2. Choices in Risk Assessment--Report for the DOE 1994 by Steve Milloy

Steve Milloy, the founder and main writer for JunkScience.com for 20 plus years wrote a major research Monograph on Toxicological Policy issues as a contractor for the US Department of Energy in the early 90s. He exposed the federal agency science and policy misconduct in a major report "Choices in Risk Assessment" completed in 1994 on EPA 'science policy' and 'default assumptions.'

What is science policy? From "Choices in Risk Assessment", below are 10 common science policy issues and default assumptions used in EPA risk assessment.

Click here for a PDF of "Choices in Risk Assessment." It is more than 200 pages that explain why the EPA has lost its way, had lost its way in the early 90s because of ideologically energized environmental nonsense science.

Following the end of the Cold War, the Department of Energy (DOE) faced clean-up costs for its nuclear weapons sites amounting to hundreds of billions of dollars. The high costs would largely have been incurred because of EPA standards that essentially would have required the former weapons sites be returned to "Garden of Eden" status.

At the time, the DOE took the EPA standards so seriously that it was actually developing essentially a giant vacuum cleaner to suck-up the top layer of sand at the Nevada Test Site (approximately 5,400 square miles in size), decontaminate it and replace the sand.

Overwhelmed by the magnitude of the clean-ups, the Bush administration DOE commissioned Milloy in 1992 to lead an investigation into whether EPA clean-up standards were based on science or politics. Milloy's team of science and policy experts (called the Regulatory Information Analysis Project) compiled a report titled, "Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process."

Completed in the fall of 1994, the report concluded that environmental policy was largely based on politics, not science. But when the report was completed and circulated for review within the Clinton administration-run DOE, the report was flagged as politically incorrect and Milloy was ordered by Clinton appointee Carol Henry (a former EPA staffer) to keep the report secret.

Sacrificing his business relationship with the Clinton DOE, Milloy disobeyed the order and released the report, which was subsequently featured in a Wall Street Journal editorial.

The attention that "Choices in Risk Assessment" garnered coincided with the Republican takeover of 104th Congress and congressional focus on regulatory reform, vaulting Milloy into the regulatory reform debate about to take place on Capitol Hill. Milloy testified before the U.S. Senate about risk assessment in the context of DOE clean-up on March 6, 1995. The DOE never wound up spending hundreds of billions of dollars to clean up its weapons sites. No word on what ever happened to the giant NTS vacuum cleaner.

Dunn comment:

The DOE report by Milloy

CHOICES IN RISK ASSESSMENT: THE ROLE OF SCIENCE POLICY IN THE

ENVIRONMENTAL RISK MANAGEMENT PROCESS

Prepared for Sandia National Laboratories

Sponsored by the U.S. Department of Energy

Office of Environmental Management and Office of Environment, Safety and Health (1994)

There are more than 200 pages, so I provide some pertinent sections emphasized by Milloy that pertain to scientific issues that hit on the big issues.

This is the link to the document:

https://junkscience.com/wp-content/uploads/2018/05/Choices-In-Risk-Asscssment-v-01-01Interior-With-Cover.pdf

Below is the table of contents, that will give one a sense of the magnitude of the report.

Hereunder I also feature sections of the summary and conclusions of the report—that are stunning. Consider—this is a report written by one man, essentially, a biostatistician and lawyer, and it exposes the problem of risk management in a politically charged atmosphere—the scaremonger environment of the US federal agencies committed to the environmental cause. Misconduct of the federal agencies and their paid researchers in matters of toxicology/epidemiology/risk management.

My question would be—why didn't this author get a National Award for exposing scientific malfeasance and scaremongering in Federal Agencies in the early 1990s? Well the answer is found in an analysis of what has gone on since—Deep State, totalitarian, junk science fraud that promotes the precautionary principle approach in all matters of public health research and science, the agenda of leftist environmentalist fanatics.

The proposal for scientific integrity and transparency is long overdue and the damage done by ideologues in the federal agencies will require a major overhaul in methods and internal review processes.

Much of the damage could have been avoided, had Milloy's report been respectfully considered and used as a guide for federal agency risk management. Instead it was suppressed and ignored by the Clinton Administration environmental fanatics.

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Many risks to human health and the environment are "unprovable."

Some risks to human health and the environment are provable. Provable risks can be measured or observed directly and include actuarial risks such as those associated with highway or air travel accidents. In contrast, other risks—such as those associated with low-doses of radiation or exposure

to chemicals in the environment—are often too small to be measured or observed directly with existing scientific methods and available resources. Additionally, specific health and environmental effects are often difficult to attribute to specific causes because other competing causes cannot be excluded with reasonable certainty. Such risks are unprovable. However, the fact that a risk is unprovable does not mean that it does not exist. Provable risks can be calculated, whereas unprovable risks can only be estimated through the risk assessment process. Although unprovable risks may be estimated and expressed in probabilistic terms, they are at best educated guesses and do not constitute knowledge or uncontroverted fact. In other words, the ability to produce a numerical estimate of an unprovable risk does not mean that the risk is proven.

Science policy issues are unavoidable in, and science policy decisions are essential to, the regulatory risk assessment process.

Risks are unprovable because of significant gaps and uncertainties in scientific knowledge, data, and method. When risk assessment is used to estimate unprovable risks, these gaps and uncertainties become science policy issues. Both risk assessors and risk managers make science policy decisions in order to bridge the gaps and uncertainties. Thus, science policy decisions enable the estimation of unprovable risks.

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CHOICES IN RISK ASSESSMENT

The existence and extent of science policy in risk assessment are rarely fully and fairly disclosed.

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The lack of disclosure causes risk assessment results to be communicated essentially as fact. Such communication is misleading. Lack of full and fair disclosure of the role of science policy in risk assessment is not the fault of regulators alone. Media communication of risk information tends to omit discussions of science policy because such discussions: (1) do not fit into sound bites; (2) tend to detract from the sensationalism of the risk information; or (3) are not simple to communicate, and subtleties are lost.

Science policy decisions are responsible for regulatory programs and regulatory impacts that are justified on the basis of risk assessment

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CONCLUSIONS AND RECOMMENDATIONS

As in the risk assessment process, science policy and other assumptions play a significant role in the estimation of benefits and costs associated with regulatory programs.

When risks can only be estimated, the benefits of regulatory programs to reduce those risks also can only be estimated, are not verifiable, and depend on science policy-based assumptions. Similarly, cost assessments often depend on assumptions, are uncertain, and cannot constitute uncontroverted fact. An important distinction between estimates of costs and benefits is in the certainty of their existence. Because it is not possible to prove with certainty the existence of unprovable risks, the existence of benefits from regulatory

programs also cannot be proven. In contrast, while there is uncertainty involved in cost assessments, such uncertainty is associated with the magnitude of the estimated costs, not their existence.

Science policy decisions can be made so as to result in desired regulatory outcomes.

The case studies of fluoride in drinking water, asbestos in consumer products, unleaded gasoline, and used oil are examples of decisions where science policy-based assumptions help to justify desired regulatory outcomes.

- In the case of fluoride in drinking water, the weight-of-evidence science policy decision that fluoride was not carcinogenic in humans supported the continued fluoridation of water, a highly valued and desirable public health measure. This science policy decision also helped maintain the credibility of the Public Health Service, which has been promoting the use of fluoride since the 1940s.

- In the case of asbestos in consumer products, the science policy decision to consider only the estimated cancer risk from asbestos brake products and not to consider the potentially offsetting safety risk from the use of non-asbestos brake product substitutes helped justify EPA's decision to promulgate a ban on commercial uses of asbestos.

- In the case of unleaded gasoline, the science policy decision that mechanisms of carcinogenicity varied between rodents and humans provided the basis for concluding that unleaded gasoline is not carcinogenic to humans. This science policy decision helped maintain the credibility of EPA's program to remove lead from gasoline.

- In the case of used oil, the science policy decision that used oil is not a hazardous waste facilitates used oil recycling. Labeling of used oil as a hazardous waste would have resulted in a burdensome cradle-to-grave regulatory scheme for used oil that might have undermined recycling efforts and increased pollution from illegal or improper disposal of used oil.

CHOICES IN RISK ASSESSMENT

For the foreseeable future, science policy will remain the key to all regulatory programs that rely on quantitative risk assessment.

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Recommendations

Policy makers, risk managers, the media, and the public should be made aware of the role of science policy in risk assessment and subsequent risk management decisions.

Although risk assessors are likely to be aware of science policy issues and decisions, the same cannot be said for policy makers, risk managers, the media, and the public. Risk assessors often fail to emphasize the existence and extent of science policy in risk assessment. Where the role of science policy is not explicitly explained, risk estimates may be erroneously communicated to policy makers, risk managers, the media, and the public as uncontroverted fact. Because these groups are unaware of the role of science policy, they often fail to inquire about its impact on risk assessment. Either failure may result in regulatory decisions that are made on an uninformed basis to an uninformed, misled, or unnecessarily alarmed public. Risk assessors

should ensure that such miscommunication does not occur. Policy makers, risk managers, and the media should inquire about the existence and extent of science policy.

The federal government should institute a mandatory training and continuing education program on regulatory risk assessment and risk management for policy makers, risk managers, risk assessors, and their staffs.

Communication of risk assessment results should emphasize the role of science policy.

Because risk assessments for unprovable risks are educated guesses, risk assessment results should never intentionally or inadvertently be presented as fact. Full disclosure of the role of science policy should accompany risk estimates wherever presented, including Federal Register notices, executive summaries of regulatory documents, press releases, and other public and media communications. Disclosure is ineffective if it is inaccessible, comprehensive, explicit, and understandable. Disclosure should attempt to address the following questions:

- **Is the risk of concern provable, and can it be calculated? If the risk is unprovable, is it because the risk is too small to be detected with current scientific methods or because competing risk factors cannot be sufficiently distinguished?**

- **If the risk is unprovable, or provable but incalculable, what are the gaps and uncertainties in scientific knowledge and data that preclude the calculation of risk?**

- **What science policy decisions have been made to bridge these gaps and uncertainties? For unprovable risks, what science policy decisions have been made that concern the existence of the risk?**

- **Could alternative science policy decisions have been considered? What would the impacts have been on the risk assessment of these alternative decisions?**

- **What are the implications for regulation of the science policy decisions made as well as the alternatives? Do alternative science policy decisions reduce or eliminate the basis for regulation? Does consideration of substitution risks or lifecycle risks affect the basis for regulation?**

Answers to these questions will facilitate understanding of the likelihood that a risk exists and its potential magnitude. Improved understanding will enable: (1) policy makers and risk managers to decide on a more fully informed basis whether and what resources should be expended to address the risk; and (2) the public and media to debate the issue on a more fully informed basis.

Risk assessment guidelines may help provide a framework for the use of science policy in risk assessment, but only if such guidelines are flexible and complied with in good faith.

Risk assessment guidelines can provide a framework within which regulators can make science policy decisions. Such a framework would provide the regulated community and the public with the "rules" for science policy decisions in regulatory risk assessment. . . . With respect to potential judicial review, although it will be difficult for a court to rule on the scientific merits of an agency science policy judgment, a court can rule whether that judgment has been explained adequately. Ultimately, the merits of the judgment will be evaluated, and the agency's credibility will be weighed in the court of public opinion as well as by the scientific community.

Precedent has been established, and agencies should be encouraged to give meaningful consideration to alternatives to the default assumptions used in risk assessment

Only when policy makers, risk managers, the public, and the media fully understand the role of science policy decisions in risk assessment can the "real" issue in environmental and public health protection be debated. We must determine what society is willing to pay to reduce or avoid risks to human health and the environment which have been identified and estimated using science policy rather than science alone. These risks may or may not actually exist. If they do exist, they are likely to be relatively small or indistinguishable from other risks. If risks are too small or indistinguishable, it likely will not be possible to know whether regulation produced any benefit. The open debate of the value and priority of regulating these types of risks will enable, but not guarantee, policy and regulatory decisions to be made on a fully informed basis.

3. Commentary on proposed new, more stringent EPA ambient air standards for 2006.

Submitted for consideration in the comment period to end April 17, 2006.

April 13, 2006

John Dale Dunn MD JD

Brownwood, Texas violations of epidemiological and toxicology scientific rules are a scandal that cannot be ignored. The Dockery 1993, Pope 1995, and Samet 2000 studies (see endnotes) and other studies of health effects of air pollution relied on by the EPA, all showed that large studies with adequate power could not demonstrate relative risk of any significance. The studies all showed effects less than ten percent, rather than the statistically and scientifically required 200 to 300 percent effect. It is astounding the EPA has the gall to announce an air pollution crisis and propose more stringent air quality standards when none of the studies the EPA relies on show and proof of health effects.

The EPA is obligated to educate the public on the clear evidence that air pollution may have aesthetic and cultural import, but that there is no air pollution health "crisis." The EPA and its sponsored and supported health effects researchers are now just raising their voice in this debate instead of trying to use science. The EPA air pollution health effects science is an emperor with no clothes, as discussed below.

This commentary challenges the EPA to show one study that proves that one person has died due to air pollution in America in this past 20 years. People die for various reasons, suddenly and not so suddenly, as will be discussed below. That reality eludes the work of numbers crunchers who slave at desks over death certificate information like Pope and Dockery. One doesn't die from an exposure to air pollution, one dies from failed medical therapy, arrhythmias caused by long term coronary disease, stroke, pulmonary embolism, which are not caused by air pollution. The Asthma problem is an increasing problem not related to air pollution, since the rate of asthma is increasing with decreasing air pollution. The deaths from asthma will be discussed below and have nothing to do with air pollution, it is a socioeconomic phenomenon. It is time to retire the air pollution health effects studies of crude death tallies and it's time for the EPA to stand down from this repeated use of crisis talk and aggressive pursuit of pure air—a religious campaign disguised as science in the public interest.

As a last and compelling consideration, this author is familiar with death in America. As an emergency physician, much more familiar with what kills people than economists and public health officials who don't know which is the business end of a ventilator and live in the world of death certificates and mortality data. People die for many reasons and under many circumstances in America, but air pollution doesn't kill them, even the worst levels of outdoor air pollution one might imagine in America don't create a toxic level, which reveals the other major flaw in the EPA crisis rhetoric, junk science toxicology that completely disregards any effort to define toxin or toxicity. That subject will also be dealt with herein below.

The scientific epidemiological and toxicological criticisms of the EPA health effects studies and policy making are:

1. The Dockery 1993 and Pope 1995 studies did not show valid evidence of death effects, since they showed a death effects relative risk below 1.1, a negligible relative risk that is 10 percent of the minimal relative risk all epidemiologists consider necessary for proof of causation. A 200% or 300% change in death effect is the lower limit. Some epidemiologists require relative risk of 4 or a 400% effect when evaluating poorly controlled cohort studies.

2. This relative risk problem cannot be overcome by EPA and health effects researchers emphasizing the misleading use of the term statistical significance, which is not a proof test, but a statistical reliability test. One can be statistically confident and reliable but absolutely wrong.

3. The EPA and its health effects researchers have consistently and persistently ignored the lack of proof of health effects in these studies, and have made public announcements and allowed media reports to proclaim that thousands are dying in America due to air pollution when the studies do not show any proof of death effect at all. Lying for justice or an environmental ideal does not make the lie any less dishonest.

4. The health effects research used by the EPA has consistently ignored the basic rules for toxicology and the well-known phenomenon of threshold for toxicity. Only at the EPA does straight line toxicology have any status, mostly because it avoids serious science. Main stream toxicology science is still committed to the idea of threshold of effect and the old saying—the dose makes the toxin. The EPA scientists in house know the truth, but again politics and a commitment to a policy/environmental ideal results in lies.

5. Under no valid scientific analysis retro or prospectively, can the EPA use the methodologies or the results of the Pope, Dockery, McDonnell, or Lipfert (see endnotes) studies to justify one more burdensome air pollution regulation, but there is strong evidence for rescinding the last round of Air Quality Standards.

6. The EPA has a mandate to act only on the basis of acceptable scientific evidence of health effects, and is obligated to abandon the precautionary principle approach to regulatory policy, a pathetic substitute for legitimate science and clearly a principle founded in politics, not science.

7. The EPA could never convince a Federal Court, operating under Federal Rules of Evidence 702 and the court dicta for expert and scientific testimony that the EPA air pollution health effects science is valid proof of anything. The Pope, Dockery and Lipfert or Samet studies cannot be massaged or misrepresented enough to create any proof of air pollution health effects. The studies show trends within an insignificant range and "associations," that are not evidence of proof of health effects.

8. Precautionary principles that are used by the EPA as stand-alone policy justification are nothing more than a dressed up version of anxiety, cannot pass muster for admissible scientific evidence in a Federal Court and ignore the reality of risk/benefit analysis.

9. Based on the information reviewed in this critique, the EPA must revisit old rigs, forgo new, more onerous and expensive regulatory interventions, and the EPA must suspend its rulemaking in air pollution until it can find valid and reliable science on health effects.

Toxic air pollution existed in the past, and still may occasionally occur in some places on the planet as a local phenomenon, as particulate and other noxious air pollution in industrial areas, from various sources. Certainly air in big cities, Pittsburg, Los Angeles, Houston, New York was fouled in the past by air pollutants and even when not toxic, was smelly and visible, but trends in air pollution in the past 30 years as reported and confirmed by the EPA, have all been positive, attributable to changes in industrial processes, regulatory efforts and cleaner petroleum and coal consumption. Any study or discussion of air pollution is focused on a moving, improving problem. However the public thinks the air is worse than ever and there is an air pollution health effects crisis, and that is the fault of the EPA, its favorite researchers, and the mass media, who love to scare the public, since EPA budgets and environmental organization budgets depend on the anxiety of the public.

The death and illness rates during smog and air pollution catastrophe periods in the past were affected by less effective medical management and heavier cigarette smoking but also significantly higher air pollution than exists anywhere in the United States today, for many reasons. Deaths from acute respiratory failure in the past were more common and less preventable, but that is an independent factor related to medical advances and not due to air pollution itself. Airway diseases, the main effect of any air pollution, were less treatable before the 1970s. Pulmonary Medicine has changed dramatically for the better since 1970. Many airway diseases were more dangerous in the past and medical therapies frequently failed to control disease and death. Medical expertise in respiratory illness and cardiovascular disease is changed, but Pope and Dockery still yearn for the good old days of killer air because it scares the public. Their research ignores the trends of the last 20 years and below I will discuss a conscious deception in the second half of the Pope research from NCI data. In addition the EPA air pollution researchers continue to ignore the weakness of their findings, hoping to keep alive the "deadly air" panic talk alive.

People die for lots of reasons in America, but not due to air pollution. Air pollution health effects researchers know that, but act as though nothing has changed. The EPA should carefully reevaluate the number of deaths that researchers claim are due to air pollution in the last 20 years, but the EPA has a conflict of interest. No air pollution crisis might mean reduced EPA funding. No air pollution crisis might mean no funding for the researchers and their support organizations.

The air pollution health effects studies are based on weak epidemiologic relationships and trends carelessly described without definition as "associations," or "trends." Well ice cream consumption and drowning or boating accidents are associated by season, but ice cream eating doesn't cause water accidents. Associations are not proof, they are observations of phenomena--clusters of events that may or may not mean something. Epidemiologists know these things and should be careful when describing data associations and trends within insignificant ranges like less than relative risk of 2, so that the reader or reporter won't mislead the public or a politician. However, the definitions are not forthcoming from the scientists and researchers because saying that there is no crisis of air pollution means no publications for air pollution researchers, no

invitations to swell events, no funding, no chance to pursue a political agenda and change the world, making your mother proud.

The uncertainties of the air pollution health effects studies, the weak relative risks and the methodological problems of the most influential of the health effects studies are so noticeable and remarkable that during this comment period the EPA should reassess what has gone wrong in air pollution health effects research. The EPA should assess how these weak studies have affected EPA policy and rule making. The EPA doesn't have the right to panic the public and political leaders with deceptive junk science in the service of religious and fanatic environmentalism.

DISCUSSION OF THE STATISTICAL AND METHODOLOGIC PROBLEMS OF THE SAMET, POPE, AND DOCKERY HEALTH EFFECT DEATH STUDIES.

Author's comments are in bold. Studies referenced are underlined and the cite is in the endnotes by name and year. Sorry to disappoint those who want numbered endnotes—not a formal paper.

J. Samet (Samet 2000) published in the New England Journal of Medicine, a study modeled after the studies of Pope (1995) and Dockery (1993). He compiled and studied deaths in twenty American cities over a period of years, and compared them with air pollution monitor reports for those cities.

Samet in this 2000 paper asserts the following:

--"the relative rate of death from all causes was 0.51 percent increase for each increase in the PM 10 (10 micron size particulates) of 10 micrograms per cubic meter." This effect is not proof of anything, and Dr. Samet knows it. Less than a 1-% death effect is a nonsense result in a big cohort study.

--"the relative rate of death from cardiovascular and respiratory diseases rises 0.68 percent for each increase of 10 micrograms per cubic meter" Trends of less than 1% inside of a meaningless range of relative risk less than 1.05? A serious epidemiologist would snicker?

--"we also analyzed the effects of levels of carbon monoxide, sulfur dioxide, and nitrogen dioxide in a fashion similar to that of the analysis of pm 10 levels. After adjustment for pm 10 and ozone levels we found little evidence that these pollutants had a significant effect on the relative rate of death." Hold it, hold it, Samet says that he can't find an effect, even itsy bitsy effects from ozone precursor and carbon monoxide, something the other EPA favorite researchers say are killing thousands? Samet is not helping the EPA here. What about those dastardly pollutants? We scientists and particularly toxicologists are smiling to see Samet make a fool of himself and by adoption of this weak and deceptive epidemiology, the EPA doesn't look too good either. This is the kind of research the EPA has been using in air pollution regulatory policy now for years.

--"We did not find an effect of ozone levels on the overall rate of death from all causes or from cardiovascular and respiratory causes during the full year periods. Ozone levels were positively associated with mortality rates during the summer months when ozone levels were highest, although the 95 percent posterior interval extended into the range indicating no effect of ozone levels on mortality." Might this non-Johns Hopkins man who owns no jacket with arm patches translate for the benighted—Samet says even ozone doesn't have a death effect in his study. Score so far on this paper—rational skeptics for people in search of truth 3, EPA and Samet 0.

--"We found no evidence that key socioeconomic factors such as low socioeconomic status affect the association between PM10 and the risk of death in linear regression models." Some might be surprised to know that Samet works at a School of Public Health and all Public Health research for the last 20 years has shown clearly that there is a socioeconomic effect that produces premature deaths. Skeptics now 4 and running away, EPA and Samet still 0. Socioeconomic noise cancels out air pollution effects; that's the way the epidemiologists put it.

--"Our analysis also did not address the extent to which life is shortened in association with daily exposure to the various pollutants." Well golly Dr. Samet, everyone dies, how can you talk about death effects if you don't measure whether deaths are premature? Skeptics 5, Samet and EPA still 0.

Additional comments by this author:

1. The rate of death changes in Samet's studies are less than 1%, which is epidemiologically meaningless and shows no respect for the relative risk of 2 (100%) or more, that all cohort studies have to show in order to be able to assert effect. Little effects, even in studies with good confidence intervals and lots of power, are still empty studies, make work exercises. Samet's study was a nothing, yet it got published in the New England Journal, so one must wonder about political and environmentalist agendas up in Boston. I suppose they are neutral on the environment and always demand valid research in support of political agendas. I suppose.

2. The study fails to age/sex adjust for the important analysis—premature death. How did Samet get published? Samet is asserting proof of effect at less than one two hundredth of what is required in epidemiology. Then he says he didn't bother with measuring whether air pollution caused premature deaths. This research is about acute death affects? At non-toxic pollution levels? There is no plausible biologic science to support the idea that non-toxic air pollution kills people. Samet is beyond redemption. He's in scientific denial, or he works for the EPA agenda and he will be funded until he is old and gray.

3. Low relative risks, below 1.2, are the results in Samet's studies and all the other EPA health effects studies. One study goes above 1.2, the Dockery 1993 smaller study at 1.26, since recalculated by Enstrom in his article, Enstrom 2005 to 1.13. Such weak and minimal findings are unacceptable for publication, much less serious EPA policy making. The EPA and the studies misuse the term statistical significance, trends or association if they mean proof. There is no proof in any of these studies of an air pollution health effect. These studies prove nothing in the relative risk ranges of less than 1.3, particularly in cohort studies of death certificates that are subject to serious confounding.

4. The failure by Samet to find any effect, even these minimal effects, from other air pollutants like nitrous and sulfur oxides (ozone precursors), ozone, and carbon monoxide should give the EPA cause to wonder about any further attempts to impose new ambient air standards. The EPA has noticeably ignored Samet conclusions about these pollutants, why?

5. Samet's assertion that socio economics do not effect death rates is a an extraordinarily faulty conclusion for a public health researcher, since his study only looked at average area incomes for the twenty cities; and there is a vast body of public health research that shows that socioeconomics independently are a significant factor in life expectancy. (Wong 2002, Fitzpatrick 2001, Lantz 1998).

6. Socioeconomics is a factor and would nullify the signal from air pollution effect, and could even be a cofactor in another way by causing poor indoor air quality from substandard housing and a higher rate of

smoking along with a higher rate of underreported smoking. For example the poor have outdoor jobs where they can smoke more, and culturally they may be much heavier smokers with more inhaling, a potential confounder. Such confounding might explain the Ohio and West Virginia data from Pope 1995. That's why relative risk has to be set high, to avoid the effect of confounders not seen or understood.

The Samet article includes cautionary notes on the limitations of the study's methodology. His caveats are applicable to the all the previously mentioned Pope and Dockery, favorite EPA studies on air pollution health effects:

1. "For the pollutants measured on an hourly basis we calculated the 24-hour average." Toxicologists cringe at that one.

2. "If the pollutants were measured at multiple locations in a metropolitan area, we averaged the data." Remember the basic principles of toxicology, if you're downwind from an air pollutant you're safe, how can he say these things with a straight face. You have to know the patient and the toxin and the dose to know anything much about the science. Population studies are very crude at non-toxic levels of exposure.

3. "Since the Environmental Protection Agency requires levels of PM 10 to be measured only every six days, data for ozone and other pollutants were generally more available on more days." Good grief, this is a sham, a toxicology study with exposures every so often in sub toxic ranges.

4. "We analyzed the effect of the day on which the pollution data were obtained (the current day, the day before, or two days before) on the association with mortality rates. The overall effect did not vary with the lag interval selected. We report data for a one day lag between pollution variables and mortality." This is the place where Dr. Samet shows he doesn't know anything about death. You could be sick to death in a hospital and I can keep you alive indefinitely until the family gives up—where do those cases fit in Dr. Samet's arbitrary lag time of one day? What about people who die in a bed at a nursing home and haven't been outside in two years? These public health wonks and economists who hate dirty air do research as if a death certificate signed by the local GP is a piece of reliable data on the health effects of air pollution. They are in dreamland.

Then Samet says they found a temporal-causal relationship -- astounding! He didn't find a causal relationship, but he can find a temporal relationship. Did he dredge and dredge until he found something to point at? What's he talking about? Who's to know when the blips in the data are differences of less than 1%? That's not about cause of death, that's about political agendas and a polemic dressed up as science that causes public anxiety.

The good Doctor continues.

5. "Data on levels of PM 2.5 (small particulates) are not yet available nationally, since a monitoring network for particles in this size range is currently being implemented." This writer believes that Dr. Samet is working the agenda for the "annuity." Small particulates are an annuity for the EPA and air pollution researchers because, along with ozone, dust will never go away. Those air pollution demons assure EPA power into the distant future and more regs and anxiety. Dust is bad. Dust is always going to be there. It's the perfect air pollutant for the EPA.

Samet and others in the air pollution junk science club just use the PM 10-micron data that is measured every six days as a surrogate for PM 2.5. The supportive press and academic colleagues forgive such a lapse since they are working on the agreed upon agenda.

6. "Our analyses also did not address the extent to which life is shortened in association with daily exposure to the various pollutants."

Extraordinary. If the endpoint is a death effect, then the study must analyze premature death in mortal man and assess acute events as a measure of effect and endpoint for acute and/or chronic disease. To determine premature death effect, age and sex adjusted death rates are the accepted methodology, but Samet is just doing death rates and he gets published in the New England Journal of Medicine? Politics and the right agenda trump science and peer review?

7. "The finding that the association between PM 10 levels and the risk of death was strongest for cardiovascular and respiratory causes of death is consistent with the hypothesis that persons made frail by advanced heart and lung disease are more susceptible to the adverse effects of air pollution."

Again they didn't show that at all, they showed less than a 1% effect on death rates. I thought these people were dying of air pollution caused illness, not acute effects of air pollution, which at current levels couldn't kill a canary. What gives? What gives is that Dr. Samet is clueless because he's a numbers cruncher for the EPA in cahoots with his friends in the spic and span air society. I know why people die and it isn't from air in America, or even from Air America. Air pollution comes in many forms but we are obligated to live with toxicology science, not anxiety. Living organisms don't die for the thought of a smoggy day or from a bad smell. Dr. Samet and his cottage clack of air pollution hand wringers should go to a hospital and see how and why people die before they do these desk analyses of death certificates.

Despite these caveats the Samet research group asserts in the conclusion of their paper:

"Our analyses provide evidence that particulate air pollution continues to have an adverse effect on the public's health and strengthen the rationale for limiting levels of respirable particles in outdoor air." Samet says nothing about the significance of their research showing no death effect from ozone, carbon monoxide, sulfur and nitrous oxides. That would certainly disrupt current EPA policy, and he avoids an admission that the relative risks and death rate changes he found do not reach epidemiologic significance.

This study by Samet is sham epidemiology/science, junk science with lipstick, and the deception and "newspeak" harkens back to junk science in the service of the King or the current tyrant. Pope, Dockery and Samet are the officials/magicians/astrologers/conjurers in the EPA court, providing the EPA regent with needed "expertise" to justify the latest edict.

Briefly we will discuss below Dr. Samet's mentors, the EPA's favorite air pollution haters, Drs Dockery and Pope, who work together and change places on the authors lists of their papers.

The Six City and Pope Studies?

Dockery (1993) and Pope (1995) did studies that were the model for the Samet study discussed above. The studies did do better than Samet, in that they measured relative risk of premature death by studying death rate with age sex adjusting. Both Dockery and Pope were unable to show significant relative risk of health effect. The Pope and Dockery studies were used in the mid 1990s to justify EPA Director Browner's "emergency" new ambient air quality standards on ozone and other pollutants. The resulting cost was

estimated by the Center for Study of American Business at Washington University, St. Louis, at more than 100 billion. The Browner action was taken unilaterally, in spite of protests from many agencies within the government and without the approval or support of EPA internal experts. This action was taken without proof of a health effect, since Pope and Dockery never showed an acceptable relative risk. They were limited again to Samet's "associations" and trends within meaningless ranges below a relative risk of 1.3.

There is a greater relative risk of whole milk causing lung cancer than the relative risk that the EPA has shown for air pollution. One might say that's because of some confounder—well duuuh, that's why relative risk has to be above a threshold of 2 and some say 3, so confounders don't make the epidemiologist look confounded. Samet, Pope, Dockery don't care, they're on a roll and have the support of the environmentalist zealots, and the EPA (whoops, that's redundant). Call public relations, the research shows air pollution is killing thousands. It causes CANCER.

This paper points out that the EPA and the researchers are cheatin', and Dr. K. Popper, famous philosopher of science favorably cited by the Supreme Court in the Daubert decision, says that science must be more serious and reliable than politics. Popper asserts that science must be based on proofs that are reliable. Popper even talks about what the air pollution research by Pope, Dockery and Samet and the spic and span society is—Popper says some "science" is so bad it can't be falsified. How does one falsify something that means nothing? Associations at the edge of or in the midst of nothingness is what Pope's and the other health effects studies assert should be the basis for society wide regulatory regimes. Breathtaking—no pun intended.

The EPA says that air pollution kills thousands, because air pollution kills thousands. That is a tautalogy, a common tool for junk scientists. IT IS BECAUSE IT IS. I write here to tell the EPA that their anxious pursuit of clean air is more about politics and power and anger with modern industrial society that is already cleaning up the air, more about the religion of environmentalism. That's why the crisis, without the deaths or the science is a political or a polemic tool, not science. Not nice to fool with science that way, particularly when there is a Federal mandate that the EPA insist on scientific integrity for policy making. The EPA should not be in the business of ginning up false crises and scaring mothers that their kids are going to suffer from the air just so that the bureaucracy will thrive at the Federal and State level.

The EPA cannot claim to be unaware of the failure to prove health effects by the insignificant level of relative risk in the Pope and Dockery studies. These are the most basic of epidemiologic rules. And no subsequent studies have rehabilitated the failures of the Pope and Dockery studies. Samet, as described above, just repeated the same mistakes and came to up with the same lack of proof of health effect, unjustified conclusions and excessive and activist recommendations.

The barriers to a good study on health effects of air pollution for Dockery and Pope were the same as for Samet,

1. mobile populations,

2. unreliable, non-continuous and fixed monitor information,

3. no monitor information on some pollutants all the time (2.5 micron particles for example) or part of the time (10 micron and others),

4. an attempt to assess long term chronic health effects of air pollution by death studies, an acute phenomenon,

5. death certificates and raw death data used without autopsies,

6. inside air quality ignored for populations living indoors, particularly during old age, advanced medical illness, and terminal illness,

7. But most of all, no biological plausibility because the deaths are in the setting of non-toxic levels of air pollution (the inane straight line effect toxicology of the EPA cannot continue to get a pass—it is advocacy at the expense of science).

The EPA in assessing the air pollution effects studies must revive Bradford-Hill Criteria for toxicology.

The Bradford Hill (BH) criteria for toxicology are elementary, and establish biological plausibility for toxin effects. They require the toxicologist to establish plausibility, dose effect, reproducibility, time relationship, and a pattern of predictable and observable effects. Sounds like good science, but that's only part of it. Karl Popper was referenced above as the guru of the philosophy of science, and master or curator of scientific principles. The Popper legacy of science rules are referred to reverently in the Supreme Court opinion in the Daubert v. Merrill Dow Case [509 U.S. 579 (1993)] on admissibility of scientific testimony. Falsifiability is the key. To be true science one must submit to the test of being proven wrong. Pope and Dockery study results can't be falsified because they don't even allow a legitimate assertion of proof. They are tools in the game of politics, not in the game of toxicology. The EPA is required by common sense and federal statute to apply the BH criteria in air pollution studies, and all other toxicology work, but instead this wildly deceptive use of small changes within insignificant ranges of effect is souped-up to become the reason the EPA must act, now, immediately, to save lives. The EPA is saving itself, but the air pollution regulations are not saving any lives because the research would show the lives lost with valid epidemiology, and it doesn't.

The only reason that the EPA can create a crisis from the Pope or Dockery studies if it holds its nose and just projects to the whole population of the United States, then relative risk of less than 5% becomes thousands of deaths, even though it fails to show proof of one death caused by the toxicity of air pollution. Not one death.

If the biological plausibility of air pollution causing disease and death consistent with the BH criteria was established or could be established, then EPA and air pollution health effects researchers like Pope, Dockery and Samet could rest with their laurels. If air really were a killer or a toxin, we wouldn't see these weak cohort studies from the EPA with itsy-bitsy relative risks, and the argument would be over.

The EPA is not the national agency or institute for the arts, culture, pleasantness and good smells, it has a serious public health responsibility and a federal mandate to find toxins with legitimate science, promulgate appropriate solutions for the public benefit and then assess the effectiveness of what it has done. None of those steps are being taken in the air pollution policy making of the EPA.

The air pollution health effects studies in America will never be able to show the required relative risk of 2 or 3. What was the EPA role in such deception?

The idea that seems to control the EPA policy making on air pollution in the past 15 years is--ignore methodology and statistical problems, science be damned, move on to the grand program of air purification.

Find the ultimate terrible pollutant that will never go away, even with all our regulations. That is why small particulates are so promising for the EPA, enough so that these health effects studies talk about small particulates without measuring them, or measuring them in only one part of the study and not everywhere. The project of demonizing small particulates is reflected in the Samet study. He makes strong assertions with extraordinarily weak evidence, but he goes to the meetings, he knows what the EPA is concerned about. With EPA leading and frequently funding the crusade—science and truth casualties are acceptable. Small particulates are the worst crisis in the history of air pollution, they might cause CANCER.

I grew up and still live on a farm. I consider dust a reality that cannot be regulated away, just like ozone is part of the Smoky Mountains. There is a form of air pollution that is now being generated by the EPA in its ozone and small particulates crisis project—it is composed of dust, water, methane, and biological particulates.

Joseph Shumpeter said that the first casualty of a commitment to an ideal is the truth. The second casualty, this author asserts, is the unwary taxpayer and public that depends on responsible government. Solzhenitsyn said "The simple step of a courageous individual is not to take part in the lie. One word of truth outweighs the world." The EPA has become a slave to the lie of junk science in health effects research because the agency is devoted to its own importance and the importance of its religious and political agendas. EPA dredges up and makes icons of the precautionary principle, the small numbers/large projections lie, small trends within meaningless relative risks in populations studies, the refusal to recognize basic toxicology concepts. The EPA is a rogue agency in need of a stand down and close internal inspection with regards to bad policy making on the basis of bad science.

The Killer Smog

In The New England Journal of Medicine, Dr. C. Arden Pope, clean air activist, and one of the EPA's all time favorite air pollution health effects researchers, describes killer air in Belgium in 1930, Pennsylvania in 1948, and London in 1952 -- and uses those incidents as examples of why he thinks there is good reason to pay attention to a study in that issue of the Journal that claims to show a causal relationship between non-toxic air pollution and children's pulmonary functions. Again the study he is supportive of shows no epidemiological proof, just "associations," which are nothing more than statistical cluster puffs in population studies subject, as pointed out above, to bias and confounders. But the key is the study includes two important things for environmentalist zealots, children, and air pollution. Most importantly this study, like all the air pollution health effect studies, is working in insignificant causation ranges of effects so Pope and the EPA can talk about little bitsy trends and associations and urge that something be done before children die on playgrounds. They talk of these numbers exercises like they foretell an apocalypse. Gather the elderly and children and go seek shelter from the air, says Dr. Pope, an economist who got in the air pollution health effects business because he hated the air in Utah—imagine if he had lived in New Jersey. Dr. Pope advises---Stop breathing, if you must.

People do not go out into the streets of America, choke and die. The days of the people of London and Pittsburgh wearing dark clothes to mask the effect of soot and smoke are gone. The public health hanky battalion wants Americans to think air is killing their children and old folks, but in America ambient air pollution did not kill anyone, last week, last year, or in the last ten years. The panicky talk has to stop and the EPA must stop being the sponsor of the lie. The medical journals have to put their scientist hats back on and stop wringing their hands about nonsense environmental crises. The EPA is so busy these days frightening people about their rat studies and the imagined effects of so many things. Hardly enough time in

the day to pursue air pollution, except the EPA has lots of staff and lots of money and much energy and religious devotion to the cause.

EPA Policy and Regulation Activity

Fredrick Bastiat is known for his "law of unintended consequences," best exemplified as the analysis of the Paris shopkeeper's broken window. Bastiat made a common sense observation that when government or individuals choose to spend money or act, it produces desired and undesired effects, always making a ripple within the society and economy.

Let us propose to the EPA that if asthma deaths are predominately in young adult black males in America because of poor compliance (McFadden 1997), due to cost and availability of asthma treatment for disadvantaged adult black males or some other socio-economic or political problem, the EPA would be foolish to work on parsing senseless air quality regulations in preference to better asthma health care. The EPA would not be a party to such nonsense, would it, to relieve the anxiety of anxious environmentalists or satisfy the EPA staff's need for power and control?

There are no free regulatory actions. Every choice has multiple consequences, and government interventions have effects unforeseen. The EPA takes taxpayer dollars for every jot and tittle, every phone call, every new grand idea of every zealous bureaucrat. Every dollar spent for the EPA's ideal of pure air comes from somewhere and is taken from somewhere else.

The EPA is charged with responsible health effects research and policy making. The questions raised in the mid 1990s and now are the same:

1. If relative risk is a well known measure of cause and effect in epidemiology, why does the EPA allow relative risk below acceptable levels of proof to influence policy making?

2. Considering that EPA regulatory activity is tremendous burden to the economy, and the air regulations have a cost effect measured in billions per year taken from the taxpayer. If socioeconomic factors are an undeniable influence on quality of life and life expectancy, then can weak and unacceptable health effects epidemiology as described above, be excused for some abstract ideal of pure air?

3. Can studies that measure acute events in any way be considered studies of cumulative health effects? Are these death studies that Pope and the other air pollution researchers insist on basically flawed and deceptive. The answer is yes.

4. If some of the studies can't eliminate confounders, does the EPA have the authority to impose an onerous regulatory regime on the American society on the theory that cleaner air is a worthwhile, even if it doesn't have any effect on health?

Enstrom Particulate Air pollution Health Effects Study of 50,000 elderly Californians. 2005

Dr. James Enstrom, in the attached article found in appendix A, studied deaths in elderly Californians in 25 counties. He found that the relationship between fine particulates and mortality was very weak during the 1973-2002, particularly after 1982. He also reviewed the cohort studies on health effects of fine particulates and mortality by Pope, Dockery, McDonnell, and Lipfert, and found that their results were fairly similar to his, with the weakest health effects being present during the most recent years.

Enstrom finds:

1. The relative risks, age and sex adjusted and homogenized, are close to 1.00 in his and the other death studies (Pope, Dockery, McDonnell, Lipfert) he reviews in Table 10—there is no proof of health effect shown from particulate air pollution in his or the other studies.

2. Pope's year 2000 16 year follow up to the earlier (Pope 1995) study of the same cohort (Pope 2002) shows a declining cumulative risk from 1.07 to 1.04, first half to second That means to all but the innumerate that the relative risk in the second decade is well below 1.04. Hello Dr. Pope, Helloooo EPA.

3. Enstrom points out there are substantial geographic variation between the California populations of his study and Pope's Ohio, Kentucky and West Virginia data. The potential for confounders should be considered. I know something about that, and people in those states aren't the same as people in Enstrom's study. They might live different lives from their fellow citizens in Lala land. That's what homogenizing and sampling in epidemiology is all about. Without the data from those three states, Pope's studies would be more epidemiologically insignificant than they are, if that were possible. So much for avoiding cherry picking and the admonition to chip off the edges of the data to norm a cohort analysis.

The important points of the Enstrom study: .

1. Deaths and air pollution relative risks were assessed for 25 California counties, a cohort of 50,000 elderly Californians, and 39,000 dead before the end of the study in 2002. The relative risks were measured with proper confidence and homogeneity.

2. Relative risk found was extremely small and insignificant, 1.04 in the first part of the study (1973-1982), then relative risk of death from air pollution disappeared altogether in the second part of the study (1983-2002). Which will it be EPA, a crisis or salvation from killer air.

3. For the entire period the relative risk was 1.01 Pulleeez, 1-% risk? That's a relative risk of 1.01. I am closer than that to being rich and good looking, like Michael Jordan. The results would have to be 2.00 to be proof of any health effect, 1.00 is no effect.)

4. This Enstrom study, like all the other studies that the EPA uses to analyze health effects, and supposedly to study small particulate effects, is limited by the lack of PM 2.5 micron monitors before 1979 and only limited monitors after.

5. No increased death effects of any kind were shown in the counties with higher levels of air pollution, eliminating any dose response effect (a favorite rhetorical tool of the EPA researcher group), that, some of the higher pollution counties had lower relative risks. So is air pollution good for you if you live in California? In this range of relative risk absence of trend is meaningless but Dr. Enstrom does the

prescribed exercise, since the air pollution cabal likes to do trending and associations. The idea of a trend within an insignificance is interesting to consider, for fun, but not for science.)

6. Table 10 in Enstrom's paper shows a comprehensive review of comparable relative risks from large (Pope, Enstrom) and small (Dockery, McDonnell, Lipfert) studies, showing that only the Dockery study published in 1993 in a small cohort shows a relative risk above 1.1 at 1.15. All the other studies show relative risk similar to Enstrom, in the range of 1.07 or less.

7. In table 10 a number of the confidence intervals cross 1.0, the cumulative relative risk of the Pope study for the second half is lost in the failure to separate out the second half, indicating there is a reason to believe that in the second half of his study 1990-98, Pope had a relative risk approaching an insignificant 1.01. I worry, sort of, about Pope hiding this bad trend downward of an already weak relative risk. Could one suppose he has revealed this problem to his friends at the EPA?

Suresh Moolgavkar comments

It would not be practical here to cover all the writings of Suresh Moolgavkar on the epidemiologic and methodology problems he identifies in the EPA air pollution health effects research and policy making, and this writer does not understand some of the subtleties. Dr. M's brain and pen are too capable for an adequate treatment here, by a mere emergency physician. Dr. Moolgavkar's recent in depth review and critique of EPA particulate and air pollution research and policy making is in Appendix B.

Moolgavkar 2005 wrote a commentary on Enstrom's paper for Inhalation Toxicology discussed above (see second part of App. A). He asked the rhetorical question "Can contemporary epidemiological and statistical tools reliably detect miniscule risks, particularly with strong risk factors as potential confounders?" (Dr. Moolgavkar is too kind. He politely avoids exposing the junk science, the obvious, that miniscule risks in a cohort study like the results in the Pope, Dockery and other studies show no health effects at all and talking about trends in those ranges is silly.)

Moolgavkar objects to the methodology of proportional hazards modeling because "it is highly unlikely that proportionality of hazards would hold over the entire period of time covered by these studies." (The long term air pollution health affects studies). He asserts that it can be argued that "the SO 2 effect wipes out the PM signal in joint pollutant models." He does not even address the Samet study showing no SO 2 effect, so even that problem may ignore the more basic one that is so apparent—there is no detectable causal effect between air pollution and death. Dr. M is operating with the assumption that SO2 still is on the top of the list of bad pollutants. No doubt it is more toxic than others, but again, we must repeat the toxicology commandment—the dose makes the toxin. The air pollution health effect studies relied on by the EPA are ridiculously weak and are used as silly substitutes for a lack of laboratory proof that the current air conditions cause disease. The health effects research of Pope Dockery and Samet is just an exercise in the traditional deception of the "data dredge," the tool of crisismongers.

What is the point of quibbling about miniscule, below threshold of proof, differences in a cohort death study, some slavish devotion to arithmetic? I benefit, I suppose from not liking higher math, in this circumstances, that's why I focus on the medicine and the proper analysis of death studies and why people die.

Moolgavkar (2005 See App. B) wrote a lengthy review and criticism of EPA policy in Regulatory Toxicology and Pharmacology that exposes the epidemiologic and toxicological problems of the EPA air pollution health effects research discussed above.

Moolgavkar asserts: "evidence fell far short of supporting a causal association between particle mass concentration and human health." He goes on "the results of observational epidemiology studies can be seriously biased, particularly when estimated risks are small, as is the case with studies of air pollution. The Agency (EPA) has largely ignored these issues." "I conclude that a particle mass standard is not defensible on the basis of a causal association between ambient particle mass and adverse effects on human health."

Although Moolgavkar allows that the EPA may be bending the science in an attempt to pursue the precautionary principle on particulates, the precautionary principle under a mandate of good science in the public interest is not good policy. It is the default position for making concerns, feelings and aesthetics into the basis for regulatory actions that cost society billions for compliance. However no sandal-footed environmentalist gang of enviro-religious concerned citizens can allow the EPA to reject science.

The EPA is prohibited by federal mandate from ignoring science in the pursuit of the precautionary principle. The precautionary principle is anti-science and irrational by definition. Health effects not showed scientifically trumps feeling, concern and governmental overreach. The EPA is mandated by federal law to halt the overreach of the air pollution crisis crusade until it can resuscitate science in the public interest.

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App. A

Abstract only with one table added.

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Fine Particulate Air Pollution and Total Mortality Among Elderly Californians, 1973–2002

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Fine particulate air pollution has been associated with increases in long-term mortality in selected cohort studies, and this association has been influential in the establishment of air quality regulations for fine particles (PM2.5).However, this epidemiologic evidence has been questioned because of methodological issues, conflicting findings, and lack of an accepted causal mechanism. To further evaluate this association, the long-term relation between fine particulate air pollution and total mortality was examined in a cohort of 49,975 elderly Californians, with a mean age of 65 yr as of 1973. These subjects, who resided in 25 California counties, were enrolled in 1959, recontacted in 1972, and followed from 1973 through 2002; 39,846 deaths were identified. Proportional hazards regression models were used to determine their relative risk of death (RR) and 95% confidence interval (CI) during 1973–2002 by county of residence. The models adjusted for age, sex, cigarette smoking, race, education, marital status, body mass index, occupational exposure, exercise, and a dietary factor. For the 35,789 subjects residing in 11 of these counties, county-wide exposure to fine particles was estimated from outdoor ambient concentrations measured during 1979–1983 and RRs were calculated as a function of these PM2.5 levels (mean of 23.4 μg/m 3). For the initial period, 1973–1982, a small positive risk was found: RR was 1.04 (1.01–1.07) for a 10-μg/m 3 increase in PM2.5.For the subsequent period, 1983–2002, this risk was no longer present: RR was 1.00 (0.98–1.02). For the entire follow-up period, RR was 1.01 (0.99–1.03). The RRs varied somewhat among major subgroups defined by sex, age, education level, smoking status, and health status. None of the subgroups that had significantly elevated RRs during 1973–1982 had significantly elevated RRs during 1983–2002. The RRs showed no substantial variation by county of residence during any of the three follow-up periods. Subjects in the two counties with the highest PM2.5 levels (mean of 36.1 μg/m 3) had no greater risk of death than those in the two counties with the lowest PM2.5 levels (mean of 13.1 μg/m 3). These epidemiologic results do not support a current relationship between fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly before 1983.

Table ten is present as originally published in a pdf file of the article. Attached.

TABLE 10 Relative risk (RR) and 95% confidence interval (CI) for long- term all- cause mortality per 10- μ g/ m 3 increase in PM 2 . 5 for U. S. cohort studies based on PM 2 . 5

data, circa 1980

PM 2 . 5 Study characteristics

Study (author, year)

Data period/ Mean (range)/ (μ g/ m 3)/ Cohort geographic definition/ Follow- up period/

Mean entry age for period/ Number entered in cohort/ Deaths in follow-up period/ RR (95% CI)

Males

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 3671 a 830 a 1.15 (1.02– 1.30) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 130,310 a _ 12,400 a 1.07 (1.03– 1.11) b

McDonnell et al., 2000 1973– 1977 32 (17– 45) 9 CA airsheds 1976– 1992 58 _ 1347 _ 375 1.09 (0.98– 1.21) b

Lipfert et al., 2000 1979– 1981 24 (6– 42) 42 U. S. counties 1975– 1981 51 26,067 _ 4600 c 0.95 (0.89– 1.01) c

1982– 1984 22 (8– 41) 1982– 1988 57 _ 21,467 _ 6100 c 0.94 (0.90– 0.98) c

1982– 1984 22 (8– 41) 1989– 1996 63 _ 15,367 _ 5765 c 0.89 (0.85– 0.95) c

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 159,000 a _ 36,000 a 1.05 (1.01– 1.10)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 66 15,573 4701 1.03 (0.99– 1.07)

1979– 1983 24 (11– 42) 1983– 2002 74 10,872 8831 0.97 (0.95– 1.00)

Females

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 4440 a 599 a 1.12 (0.96– 1.30) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 164,913 a _ 8365 a 1.06 (1.01– 1.12) b

McDonnell et al., 2000 1973– 1977 32 (17– 45) 9 CA airsheds 1976– 1992 58 _ 2422 _ 568 _ 1.00 (assumed)

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 200,000 a _ 24,000 a 1.02 (0.98– 1.06)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 65 20,210 4094 1.05 (1.01– 1.10)

1979– 1983 24 (11– 42) 1983– 2002 73 16,116 10,815 1.02 (0.99– 1.04)

Both Sexes

Dockery et al., 1993 1979– 1985 19 (11– 30) 6 U. S. cities 1975– 1989 _ 50 8111 1430 1.13 (1.04– 1.23) b

Pope et al., 1995 1979– 1981 18 (9– 34) 50 U. S. SMSAs 1982– 1989 57 295,223 20,765 1.07 (1.04– 1.10) b

Pope et al., 2002 1979– 1983 21 (10– 30) 61 U. S. SMSAs 1982– 1998 57 _ 359,000 _ 60,000 1.04 (1.01– 1.08)

Enstrom, 2005 1979– 1983 24 (11– 42) 11 CA counties 1973– 1982 65 35,783 8795 1.04 (1.01– 1.07)

1979– 1983 24 (11– 42) 1983– 2002 73 26,988 19,646 1.00 (0.98– 1.02)

a Obtained from supplementary data (Krewski et al., 2000).b Recalculated from published data (US EPA, 2004).c Obtained from the author.

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Commentary

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Fine Particles and Mortality

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In an interesting paper in a recent issue (vol 17, issue 14)

of the journal, Enstrom examined the association between fine particulate matter (PM) pollution and mortality in a cohort of elderly Californians. The analyses used proportional hazards

regression and after adjusting for age, sex, cigarette smoking, and other potential confounders, Enstrom concluded, "These epidemiologic results do not support a current relationship between

fine particulate pollution and total mortality in elderly Californians, but they do not rule out a small effect, particularly

before 1983." Enstrom's analyses were based on a sub-cohort of individuals enrolled in the first Cancer Prevention

Study (CPS I) conducted by the American Cancer Society (ACS). Enstrom's conclusion is consistent with the conclusions of a cohort study among veterans conducted by Lipfert et al.

(2000), but is at odds with the results from analyses of the second ACS cohort (CPS II) by Pope and others (Pope et al., 1995, 2002; Krewski et al., 2000), which reported statistically

significant associations between fine particulate pollution and mortality.

Every epidemiological study has weaknesses and limitations and, undoubtedly, both proponents and skeptics of the 'fine par-ticles cause death' thesis will find much to criticize in the studies

that do not support their conclusions. These discrepant results raise an important question, however. Can contemporary epidemiological

and statistical tools reliably detect miniscule risks, particularly with strong risk factors as potential confounders? All the cohort studies referred to above use proportional haz-ards modeling for data analyses. But is proportional hazards really the appropriate tool for these analyses? First, it is highly unlikely that proportionality of hazards would hold over the en-tire period of time covered by these studies. Statistical tests for departures from proportionality of hazards have low power. En-strom states that, in his analyses, these tests failed to reject pro-portionality of hazards. However, his finding of a higher relative risk associated with fine particles over the period 1973–1982 is inconsistent with proportionality of hazards over the entire

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I have discussed the original CPS II study (Pope et al., 1995)

and reanalyses (Krewski et al., 2000; Pope et al., 2002) in de-tail

elsewhere (Moolgavkar, 2005). I note here, however, that

the reanalysis by Krewski et al. (2000) of the original (Pope

et al., 1995) study (which considered no pollutant other than

PM), showed quite clearly that the pollutant most strongly as-sociated

with mortality was not PM but SO2.In fact, when SO2

was considered along with PM in the model for all-cause mor-tality, the coefficient for sulfates was reduced to less than a third of its original value, that for fine particles was reduced to a sixth of its original value, and both became statistically insignif-icant. It is also of interest to note that consideration of spatial correlations attenuated the PM coefficients to a much greater extent than the coefficients for SO2.Given the much stronger and more robust association of SO2 with mortality in the CPS II reanalyses, I find it surprising that this study continues to be taken as providing strong support for the PM mortality asso-ciation. It can be plausibly argued on biological grounds that SO2 could not be causally associated with mortality. But that still does not explain why SO2 wipes out the PM signal in joint pollutant models. This awkward fact has simply been dismissed as being irrelevant. In a more recent study of the CPS II cohort that doubles the follow-up time and triples the number of deaths, Pope et al (2002) reported significant associations between fine particles and oxides of sulfur with all-cause, cardiovascular and lung cancer mortality. Surprisingly, despite the findings in the Krewski analyses that SO2 was the pollutant most strongly as-sociated with mortality, no joint pollutant analyses were carried

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App. B

Abstract only

A review and critique of the EPA's rationale for a fine particle standard

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Abstract I review the rationale for the Environmental Protection Agency_s 1996 fine particle standard, which was based almost entirely on the epidemiological data with neither support from Toxicology nor understanding of mechanism. While many epidemiological papers available in 1996 reported associations between ambient particles and adverse effects on human health, many others did not and the evidence fell far short of supporting a causal association between particle mass concentration and human health.

The literature appearing after 1996 further complicates the picture. The large studies that have appeared after 1996, such as National Mortality Morbidity and Air Pollution Study, and the reanalyses of the American Cancer Society II study, report risks that are substantially smaller than the risks reported in the 1996 Criteria Document and Staff Paper. Moreover, concerns about confounding by weather, temporal trends and co-pollutants remain unresolved. Other issues having to do with model choice have resurfaced as a result of reanalyses of critical data to address a glitch in a widely used software package for time-series epidemiology studies of air pollution. Finally, contemporary examples show that the results of observational epidemiology studies can be seriously biased, par-ticularly when estimated risks are small, as is the case with studies of air pollution. The Agency has largely ignored these issues. I conclude that a particle mass standard is not defensible on the basis of a causal association between ambient particle mass and adverse effects on human health. Such a standard may be justifiable on the basis of the precautionary principle, however. The Agency could argue that the Science raises concerns about current levels of air pollution, and that reduction of ambient fine par-ticulate matter mass, if it could be achieved without an increase in the level of the ultrafines, could have positive effects on human health. If the Agency justifies a particulate matter mass standard on these grounds then the debate over the form and level of the standard will, for all practical purposes, belong strictly in the Policy arena.

Keywords: Air Pollution; Particulate matter; Criteria document; Staff paper

4. Dunn submission on Ozone October 8, 2007

Subject: Comments on Ozone Standards 2007

Submitted via the a-and-r-docket@EPA.gov 10-9-07

Docket ID No. EPA-HQ-OAR-2005-0172

Comments by John Dale Dunn, MD, JD, Civilian Emergency Medicine Faculty, Carl R. Darnall Army Medical Center, Fort Hood, Texas, Policy Advisor, Heartland Institute, Chicago, IL. Member, Board of Scientific and Policy Advisers, American Council on Science and Health, New York, NY.

Corrected and revised final draft submitted 0915 CDT 10-9-07.

1. The EPA ozone science does not justify continued aggressive ozone regulation and a new lower 8-hour standard.

2. The observational air pollution studies and the weak exercise/ozone inhalation studies cited by the EPA show weak associations and relative risk less than 1.5, as well as lab results best described as non adverse. The study evidence cited by the EPA would not be admissible in a Federal Court because it violates basic epidemiology and toxicology scientific rules.

3. The EPA's own Clean Air Scientific Advisory Committee advised in the past that ozone effects research did not show adverse effects and the ozone standard should be left as is.

4. There is no EPA research that shows any benefits from the air quality improvements of the past 20 years. Is it that the EPA doesn't want to report any improvement, for fear it will jeopardize agency funding? Is it evidence that the air pollution wars of the past 20 years were against a PHANTOM MENACE? Are the weak population studies on air pollution weak for a reason--there was no killer air in America?

DISCUSSION

The EPA cited health effects studies are weak on adverse ozone health effects and weak generally on air pollution adverse effects.

The Scientific studies discussed in the proposal document are reviewed below. Although the studies are cited by the EPA to justify the ozone standard, they are not what the EPA commentary says they are. They do not excuse the old standard, or justify the new proposed ozone standards because they are a combination of weak observational studies and no-effect intense exercise/high ozone studies.

Commentary on some of the prominent studies:

1 Dockery DW, Pope CA 3d, Xu X, et. al. An association between air pollution and mortality in six U.S. cities. N Engl J Med 1993;329:1753-9.

Weak observational study that mentions, but does not control confounders. The results are small effects with relative risks of an insignificant magnitude that is proof of nothing.

2 Pope CA, Thun MJ, Namboodiri MM, et.al. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am J Respir Crit Care Med 1995;151:669-74.

Like the Dockery study above, one of the EPA's most important studies for justifying air pollution regulations. This study is another example of weak epidemiology with weak relative risks and no correction for confounders.

Even after the congress passed a law sponsored by Senator Shelby, requiring Pope and Dockery to produce their data sets, they still dodge and feint, and have not complied. Pope and Dockery are still in the inside clique of EPA favored and sponsored epidemiologists. They continue unhindered and well funded by the EPA and other governmental grant sources friendly to an aggressive regulatory agenda.

3 Hrostman DH Ozone concentration and pulmonary response relationships for 6.6 hour exposures with five hours of moderate exercise to 0.9, 0.10, and 0.12 PPM. American Review of Resp Dis Nov, 1990; 142: 1158-63.

Even heavy exercise with ozone inspired above current limits shows little ozone effect and no disease. The effect shown was mostly subjective respiratory mechanical effect. Ozone makes air heavy and increases its suspended/solute load.

4 Samet JM, Dominici F, Curriero FC, et.al. Fine particulate air pollution and mortality in 20 U.S. cities, 1987-1994. NEJM 2000; 343:1742-9.

Study of cities that claims to know how many days it takes for air pollution to kill someone, then proceeds to find no kill effect from all the air pollution factors, including ozone and ozone precursors, except small particulates, but then admits that the small particle monitor information is not available for the study and that big particles were used as a surrogate. Breathtaking, but published by Dr. Samet's friends in Boston. Incidentally the EPA on its air web site now has announced that large particles are no longer monitored or controlled because they do not cause adverse effects, but the old studies that concluded the dangers of small particles admit they used large particle monitor data as a surrogate for the small particles, since small particle monitors only became available in the late 1990s.

5 Wong JD, Shapiro MF, Boscardin WJ, et. al. Contribution of major diseases to disparities in mortality. N Engl J Med 2002;347:1585-92.

Discussion of confounders in death studies. Apparently has not been read by EPA sponsored and in-house epidemiologists, since the proposal documentation of the EPA makes little mention of he problem of the studies that are relied on—they make assertions without caveats like they were environmental gurus.

6 Fitzpatrick R. Ed. Social status and mortality. Ann Intern Med 2001 134;10:1001-2.

Lantz 1998 Lantz PM, Lepkowski JM et. al. Low income was an independent risk factor for premature death after controlling for health behaviors. JAMA 1998; 279:1703-8.

None of the studies used by the EPA for air pollution regulatory strategies control well for socio-economic status. Some of the studies do nothing more than mention that average income and education were used over large areas. Very similar to the casual use of wide-area, even regional monitors as measures of exposure to pollution.

7 McFadden ER jr., Warren EL. Observations on asthma mortality. Ann Intern Med 1997;127:142-7.

Shows that asthma mortality is in a select group of patients and caused by under-treatment and socioeconomic factors.

8 Mcconnell R, Berhane KT Gilliland F, "Asthma in exercising children exposed to ozone: a cohort study, Lancet 359 (2002) 386-91.

Selective reporting of this study ignored the protective effect of ozone, (yes, protective) in the whole cohort while making much of a minimal evidence of detrimental effects in one group--kids who were in three sports. McConnell is part of the Gauderman group that specializes in studying air in Southern California and always finds detrimental effects, even though many times the methodology and the evidence of risk are questionable and weak.

9 Gauderman WJ, Vora H, McConnell R, et al. Effect of exposure to traffic on lung development from 10 to 18 years of age: a cohort study. Lancet (on line) Jan 26, 2007. www.thelancet.com.

This study by the Southern California group had two major problems--1. Very small pulmonary function differences, less than 5%, which is insignificant, and no real negative trend, since the trend line only existed because of one outlier. There was also a high drop out rate. 2. The study measured differences in groups up to 1500 meters, dividing by 500 meters except for a group within 300 meters. Research shows that air quality from roadways is at background by 300 meters. The air quality on Southern California roadways was reported by H. Zhu in Atmospheric Environment 2002; 36: 4325-35 and in Environmental Science and Technology 2006; 40: 2531-36. Gauderman's group is well sponsored by a division of the California EPA. Imagine their funding stream if they reported no roadway effects?

Studies and analysis ignored by the EPA

The EPA also refuses to recognize the research and analysis that contradicts the EPA air regulation proposals.

Lipfert FW, Perry HM, Miller JP, et.al. The Washington University—EPRI veteran's cohort mortality study: preliminary results. Inhal. Toxicol. 2000, 12 S4:41-73. (Insignificant air pollution health effects.)

Enstrom J. Fine particulate air pollution and total mortality among elderly Californians, 1973-2002. Inhalation Toxicology 2005; 17:803-16. (Very large and long term study shows no air pollution death effect, in fact a counter intuitive protective effect of air pollution in many California cities. This study essentially nullifies the weak studies of Pope and Dockery as well as other death studies that are used by the EPA to push tighter NAAQS)

Moolgavkar S. Let. Fine particles and mortality. Inhalation Toxicology 2006;18:93-4. (Refutes the EPA air pollution project dogma. Discussion of EPA overreach and excessive regulatory zeal.)

Moolgavkar S. A review and critique of the EPA's rationale for a fine particle standard. Reg Tox Pharm 2005; 42:123-44. (Expose' of the EPA's failure to use good science to justify its agenda to make current ambient air pollution appear to be a serious health risk for Americans.)

Schwartz, J. No Way Back: Why Air Pollution Will Continue to Decline, (Washington: American Enterprise Institute, 2003). (Discussion of declining air pollution and improving air quality.)

The situation is so bad that the EPA and its sponsored epidemiologists and public health toxicologists control the literature and the journals. Journal editors now ignore toxicology and relative risk rule breaking. A recent poll by the National Institute for Statistical Science indicates that epidemiology journal editors no longer require data set production, p value calculation adjustments for multiple testing, and compliance with the rule on relative risk. The epidemiology journals have become political commentary on the hot environmental and social issues of the day—a mirror on the mental state of the academy.

Federal Rules of Evidence

The persistent failure of research on ozone and other air pollution observational studies to meet the requirement for relative risk of 2 and the p valued calculations without adjustment for multiple testing are examples of pseudo-science. The measure of scientific integrity, however, goes outside the academic and journal community. The Federal Courts have a stake in reliable evidence and the Federal Trial Court Judge makes the call on admissible scientific evidence.

The Federal Judicial Center's *Reference Manual on Scientific Evidence*, 2nd Edition (2000, West Group), also free on line at http://www.fjc.gov) Chapter on Epidemiology, written by highly esteemed experts, including Leon Gordis, the former Chair of epidemiology at Johns Hopkins School of Public Health deals with various matters of admissibility. The Manual states, at page 384:

> The threshold for concluding that an agent was more likely than not the
>
> cause of an individual's disease is a relative risk greater than 2.0. Recall that a
>
> relative risk of 1.0 means that the agent has no effect on the incidence of disease. When the relative risk reaches 2.0, that implies that the agent is responsible (with certain qualifications noted below) and implies a 50% likelihood that an exposed individual's disease was caused by the agent.
>
> A relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. Thus, a relative risk of 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent.

There are no major studies of ozone health effects relied on by the EPA that show a relative risk 2 or more. In fact there is not, at this time, a way to design a study on ozone that will show evidence of any relative risk, because there is no end point to measure. Ozone is a benign molecule, and doesn't cause death or disease. Exercise studies with excess exposure are a house of scientific cards for any EPA effort to build a toxicology argument against ozone.

The only reason the EPA can use these studies with relative risk of 1.5 or less, and not blush or apologize, is a political climate of panic about the environment and collusion in the academic and journal community collecting around the non-scientific social science concept of the precautionary principle. Discarding the relative risk rule is necessary to the survival of the precautionary principle, since the scientific evidence on ozone and most other pollutants cannot be shown to reach the relative risk of 2.

Expanding the effect of the EPA with "susceptibility."

The EPA also misuses the concept of sensitive or susceptible groups to make any exposure a concern for regulation. Susceptibility allows the EPA extraordinary latitude. There is always someone who is really, really sensitive—therefore the EPA plans to play the sensitive game and will make the society pay, eliminating any target toxin, regardless of the cost of the ablution. The rational regulatory regime does not adopt such a nonsensical approach, but the EPA embraces the concept as an excuse to overdo.

Reviewing the EPA United States air quality map, there are presently very few unsafe air quality areas, but that map will deceptively and dramatically change if the new ozone standard is implemented, along with the nonsense of the susceptibility. It will make no difference whether the standard is 0.06 ppm or .07 ppm, the non-compliance expansion guarantees that the EPA will exist into eternity.

The EPA is no longer in the business of protecting the public health and preserving the environment, the new range of ozone standards is an example of an EPA attempt to redefine what the environment should be and assure itself agency immortality. The EPA wants the world to be a scrubbed down bubble with no dust and no ozone for its own purposes, with no consideration of the rules of scientific integrity or even the mission of the agency to protect the environment and the public. Next the EPA will be regulating nitrogen, which is toxic if found at too high a percentage in the air. Really toxic.

The EPA is consciously and intentionally pushing the limits of scientific concepts of toxicity and epidemiology and cheating on the margins with the help of aggressive and flexible toxicology and epidemiology research. At this point a responsible Federal Judge, properly informed by the Federal Judicial Center Reference Manual on Scientific Evidence, chapters on toxicology and epidemiology, would throw out the "evidence" the EPA is using for this round of ozone standards.

The EPA refuses to study the health effects of the air quality improvements of the past 20 years. Why?

The EPA, like most government agencies or political advocacy groups, lives or dies by the old H.L. Mencken maxim about practical politics, that the public must be frightened, and anxious to be led to safety. False ozone fears and air pollution anxiety prop up the EPA. The EPA and its allies in the environmental movement feed the irrational and uninformed concern that the public has about a declining air quality, in the face of contrary evidence of improving air.

Why is there no research from the EPA that shows a public health benefit from the 20-year improvement in the quality of the air in the United States? Is the health benefit there and not shown or is it possible that the ambient air of 20 years ago, including the ozone levels, was not toxic? Generally even a blind toxicologist can prove a toxic effect by showing that the removal of a toxin caused a benefit. If there are air quality improvements that the EPA documents in its monitor information, then there should be a corresponding improvement in the health of the public.

Los Angeles and Houston air have improved—why no research to show the benefits? Is the EPA a one trick pony—they can only talk panic and crisis and bad air. Good air is not in the lexicon, only bad air and assertions of people dying from bad air? The proof of benefit would be the logical scientific inquiry to show the value of EPA activity and tighter air standards. Where are those studies of benefit?

If there is no real change in life expectancy or quality of life from air quality improvements, what will the EPA do, more importantly what should the country and the society do? Fire the EPA for lying or malpractice? The EPA and its allies in state and local government agencies, and in the non-governmental

environmental advocacy sector would be decimated by reports that there is no crisis in the environment, never was. They would also be, incidentally, unemployed and unemployable as pollution sheriffs.

Air Pollution Trends and Policy

Some places in America will be naturally dusty; some places will have natural background ozone levels that create haze. West Texas exemplifies the first, the Smoky Mountains the second. Trends in air pollution, control of ozone and ozone precursors in the past 30 years have all been positive, yet the EPA does not and will not report any benefit or improvement and continues to aggressively and energetically pursue every opportunity to increase its regulatory empire and authority. The EPA even sponsors and funds non-governmental entities like the American Lung Association and other rabid environmental groups that sue the EPA to push more environmental intrusions. That raises a question about conflicts and influence peddling, and contaminates the very important debate about EPA responsibilities to protect health and preserve the environment and maintain a high level of integrity in its science and research.

The blow back on the latest round of EPA overreach in ramming down the ozone standard is the protest of reasonable people confronting a new regulatory burden based on weak science. Ten years ago the EPA Clean Air Scientific Advisory Committee advised the EPA that ozone could not be shown to produce adverse health effects at the standard then, 0.12 PPM. Even then the CASAC, which is inclined to favor EPA policy proposals as a creature of the agency, was reluctant to support the ozone standard reduction from 0.120 ppm to a lower number. Chairman George Wolff said " although the panel member's opinions differed, none supported the lower end of EPA staff's recommendations, and a majority of members stated a position which included . . . the present standard."

EPA Clean Air Scientific Advisory Committee

The EPA Clean Air Scientific Advisory Committee (CASAC) in the late 1980s pointed out that ozone respiratory effects were not "adverse" health effects, and the CASAC in the 1990s refused to support using the Pope and Dockery studies to justify new NAAQS in 1997, but now the EPA is less scientific or objective in its analyses. The CASAC of today has become an advocacy committee committed to EPA agendas, even advocating more aggressive EPA activity. The CASAC of today has not and cannot be objective about ozone issues, and the current CASAC commentaries are not objective science but advocacy for aggressive environmentalism, now and forever.

There is no explanation for the CASAC conduct of the past few years other than political commitment to the environmental movement and the precautionary principle. In the past the CASAC and other agencies were the only chance that fanatic EPA officials would be brought under control, but now the CASAC has gone to the political side and cannot be trusted to show objectivity. Any argument for more regulation is supported. They represent the politicization of environmental science. CASAC commentary on small particulates last year was over the top.

Only 6 of 21 CASAC members supported the small particulate standards in 1996, the CASAC in 1996 advised in favor of the standard for ozone remaining at 0.120 ppm. Times have changed, the CASAC is now no restraint on junk science, and the CASAC of today is predictably in favor of any new and more stringent standard.

There are many in America who believe that the air quality is worse now than ever. That is because they get no reliable information from the EPA. The EPA is no longer a public agency that protects the public, but a

political propaganda mill, intent on panicking the public and working an environmentalist agenda. Informing the public of the improvements in air quality would reduce public anxiety and EPA and environmental group funding. Environmentalism would suffer a setback as a movement. The EPA is intentionally giving the public incorrect information about the current air quality, creating more anxiety, pollution warnings and claims about deaths.

This proposed new ozone standard is part of the deception, since the day the standard goes into place the American Lung Association, the EPA and the usual environmentalist organizations like Sierra Club will announce a new dirty air crisis. This latest round for ozone standard setting appears to be an effort by an EPA and its allies to reinvigorate their position as protecting the innocent public from killer air. They offer the naïve members of he public the proposal to create a pristine environment, more pristine than even Mother Nature could produce.

Consider, instead the reality as described by an environmental regulation expert:

> The United States has made tremendous progress in reducing air pollution during the last forty years. Air pollution has declined dramatically since the 1960s and 1970s, and virtually the entire nation now meets federal health standards for carbon monoxide (CO), sulfur dioxide (SO2), and nitrogen dioxide (NO2). Many areas of the country still exceed health standards for ground-level ozone ("smog") and airborne particulate matter (PM), but both of these pollutants continue to decline as well. Half of the nation's ozone-monitoring locations exceeded the federal one-hour ozone standard in the early 1980s, but only 13 percent exceeded the standard by the end of 2002. PM measurement methods have changed a number of times during the last forty years, but all trend data show PM levels dropping. Average levels of PM2.5—the form of PM now of greatest regulatory concern—have declined by a third during the last twenty years. (Joel Schwartz, 2003)

A good example of irrational panic mongering is in the September 9, 2004 issue of New England Journal of Medicine, in which C. Arden Pope, an economist cum environmentalist, describes as a companion piece to another children are victims of bad air article, describes killer air in Belgium in 1930, Pennsylvania in 1948, and London in 1952 and proposes those incidents as examples of why he thinks there is good reason to be worried. Pope is always worried, although he can't show me one person in his studies who really died from air pollution. They died as members of the cohort and he counted them as dead from air pollution after he looked at their death certificates. That's not a proper toxicologic analysis, that's an association. People don't die on epidemiologist's desks from associations.

In America ambient air pollution did not kill anyone, last week, last year, or in the last ten years. The crisis of bad air is long past, and the real health effects from air are non existent, but won't go away because the EPA is too big and too influential and too aggressive to go silent.

I agree with the Chairman of the Texas Commission on Environmental Quality, Buddy Garcia, who said in his letter of September 25, 2007 to EPA Administrator Johnson that ozone non-compliance will be the rule rather than the current exception, if the new standard is put in place. Mr. Garcia points out that 0.06 is well

known to the EPA as a background level in many environments—and that such a standard is irrational and cannot be complied with in places like the Gulf Coastal Plain.

Chairman Garcia also points out a little problem that the EPA ignores, that ozone precursors are mostly a product of mobile sources, not point/stationary sources, so the penalties and costs will be imposed on cities and communities for things they can't fix. Why is it that the EPA appears to care little about Mr. Garcia's concerns and his appeals for sensible science and policy making?

Summary

The research used to justify the proposed new ozone standard does not demonstrate results that meet the basic rule for proof of detrimental health effects. In fact the consistent findings of the EPA ozone research is insignificant ambient ozone pollution relative risk and laboratory evidence of fleeting effects if humans or animals are forced to breath high levels of ozone and exercise.

Research studies have shown that low relative risk results and pervasive confounders make it very unlikely that the proposed new ozone rules will have measurable beneficial or protective health effects. The EPA has failed to show the previous reduction in ozone levels has produced any benefits.

The EPA should abandon this precautionary-principle driven and junk science justified new standard, and retreat from continued aggressive tightening of ozone and other air quality standards.

Conclusion and recommendation.

There is no health effects science that justifies the current ozone standard of 0.08 ppm, so I urge the EPA to reset the ozone standard at the more reasonable 0.12 ppm, pending evaluation of the ozone control program for termination. Ozone should go the way of large particles, no longer on the list of EPA targets.

Imagine a government control program that has an end.

Economic and political effects of adoption of the recommendation.

I project that billions of taxpayer dollars and compliance costs could be returned to the citizens as soon as the EPA gives up chasing ozone, a benign component of the natural world.

I also project that a chastened and re-dedicated EPA might,fter the end of the ozone campaign, eschew future goose chases, and focus on serious, non-political, scientific inquiries in the public interest.

11-15-07

5. Dunn Presentation to the Health Risk Assessment Subcommittee of the and Executive Committee of the US EPA Board of Scientific Counselors 2007, 2008

John Dale Dunn MD JD

November 15, 2007 in person Bethesda, Maryland

Committee members and staff,

My name is John Dale Dunn. I am an inactive attorney. I teach emergency medicine at the Carl R. Darnall Army Medical Center, Fort Hood, Texas.

I asked for more time to present in early October, but I will do the best I can with the 3 minutes allotted. Dr. Stan Young from the National Institute for Statistical Science, and Dr. James Enstrom, epidemiologist from UCLA, will follow my presentation on the phone. We are not professionally or financially affiliated, but we share a concern about EPA scientific activity and integrity. In the future we will ask for more time to discuss our concerns with the BOSC.

H.L. Mencken made the prescient observation that the goal of practical politics is to create a hobgoblin, and make the public clamorous to be led to safety.

1. The Federal Judicial Center's Reference Manual on Scientific Evidence, published in 2000, and provided to the committee, was written by experts like Leon Gordis and Bernard Goldstein.

2. The scientific advice and rules provided to judges in the Manual are generally held and well known to the committee.

3. My concern is that EPA research repeatedly violates the Reference Manual rules on observational study relative risk as proof of causation and the rules on toxicology. I think well established and reliable scientific rules should govern EPA research.

4. The Manual insists on Relative Risk of at least 2 for proof of causation in observational studies. The EPA sponsored and funded research repeatedly and flagrantly violates that rule and claims small effects are reliable.

5. The Manual recites the traditional rules of toxicology, including the concept of threshold. The EPA violates those rules by arguing for high-dose toxin experiments on hybrid homogeneous rats and mice, combined with linear modeling as proof of toxicity.

EPA Administrator Browner had the chutzpah to claim that the adoption of ambient air standards proposed in 1995, that were based on Pope and Dockery small effects results, would prevent 20,000 deaths.

The quality of air and the environment is better now, but Americans think the environment is worse due to EPA public relations and research activities.

The BOSC is charged with assuring reliable and credible EPA research and policy making. EPA science should not risk a sensible judge applying the rules and finding EPA research inadmissible. It should be research and that does not panic the public with weak and incredible claims, like those made by Ms. Browner.

The BOSC should prevent the EPA shouting "consensus," intimidating the academic and journal community into breaking the rules and creating unjustified public anxiety.

Respectfully,

John Dale Dunn MD JD

Previous submissions:

Dunn Comments on small particle standards--2006.

Dunn Comments on ozone standards--2007.

Reference Manual on Scientific Evidence 2nd Ed. (2000)

Submission with this email:

2001 Editorial by Drs. Samet and Burke in American Journal of Public Health defending use of small effects studies.

Amicus brief submitted on behalf of Drs. Wogan, Eaton and 29 other distinguished Scientists criticizing EPA Linear Modeling on dioxin.

DUNN PUBLIC COMMENT SUBMISSION

MEETING OF THE EXECUTIVE COMMITTEE

Board of Scientific Counselors (BOSC) OF THE EPA

JANUARY 24-25, 2008 by phone with written submission emailed.

In the recent months I have provided materials and commentary on scientific integrity issues that fall within the BOSC Mission. The submissions and commentary were to the HHRA meeting and NERL meetings.

I renew for the Executive committee, my concerns about the following:

1. EPA sponsored scientists have repeatedly used relative risk in the negligible range as proof of health effects causation, in spite of epidemiology rules to the contrary, as recited in the Reference Manual on Scientific Evidence, published by the Federal Judicial Center.

2. The same is true of EPA sponsored science on the issue of hi dose rodent toxicology combined with linear modelling with no threshold. Again, I submitted the Reference Manual chapter on toxicology.

3. In addition to the Reference Manual materials, I submitted the brief filed on behalf of the American Council on Science and Health and many distinguished scientists criticizing EPA linear modelling and no threshold toxicology.

I will not resubmit these materials today, since they are already available to the Executive Committee, in addition to submissions by Dr. Stan Young on multiple testing unreliability and Dr. James Enstrom's submissions on his concerns about conduct in the scientific community that stifles inquiry and penalizes legitimate scientists.

The Executive Committee is composed of members much more expert than in the problems of data dredging in small effects science. The EPA is also embarked on a new series of toxicology projects that will increase the chance for problems, the genomic effects toxicology and small effects chemical toxicology research projects that increases the risk of more uncertain and unreliable research in health effects.

I ask the Executive Committee to begin to make more inquiries in these areas, and hold the EPA to a higher standard of reliability. The BOSC represents the interests of the public in assuring EPA science does not just promote interests and agendas of the EPA, but a balanced and reliable effort on behalf of the public interest and deserving of the public's trust.

Thank you for your consideration.

6. Essay by John Dale Dunn for congressional Aides of the Space, Science and Technology Committee of the House, on matter of Science and the Law

10-10-11

Introduction to fallacious and erroneous science and the law.

In addition to reviewing the Reference Manual on Scientific Evidence of the Federal Judicial Center, txt and links in this folder, there are also some excerpts from a book by Peter Huber, PhD and attorney, and Ken Foster PhD on the meaning of the new rules of admissibility for scientific evidence and testimony.

The section of the book excerpted focuses on fallacies in science and the intellectual, epistemological, political, social and psychological aspects of bad science.

First, however, anyone attempting to understand the current state of affairs should read the folder file on Angelo Codevilla, the essay on scientific pretense, along with the farewell speech by Dwight D Eisenhower in 1960 that discussed after the military-industrial complex, the government-research complex and in that section Ike warns of the danger of big government funding research programs and how such developments might corrupt the scientific process, which is not about authority and consensus, but skepticism and humility, the self-questioning that is essential for good science.

After reviewing the essay by Codevilla, one might expand on the problem of oligarchies in the other essay by Angelo Codevilla on the Ruling Class in America, that discusses the problem of elitist oligarchy dominated government tainted by group think and statist agendas. That is critical to the development of science in the service of politics.

Peter Huber, Kenneth Foster *Judging Science* (1997 MIT Press)

The chapters of importance in this book discuss the judicial articulation of what is good science, then essays and discussion on '

Testability and Falsification—Chapter 3

Errors in Science—Chapter 4

Reliability—Chapter 5

Scientific Validity—Chapter 6

That's enough for this folder material and will be summarized with the excerpts from the book including in the materials of the folder.

The materials are valuable, because they include original essays by many of the important figures in the philosophy of science. This summary is by John Dunn, but the original writers are better in their original discussion for more in depth inquiry.

1. Karl Popper is quoted and his teaching on good science is adhered to in the Blackmun Daubert opinion. Popper, a philosopher, emphasizes the importance of the deductive method of development of scientific concept and solutions, which is heavily focused on evidence and testing theories developed for evidence that might falsify the theory. Falsifiable is essential to a good scientific theory, otherwise Popper considers the theory non science. Pp. 35- 55

2. Weinberg proposes a concept of trans-science that is not practically verifiable or it may exceed the sensitivity of the instruments and methodology. Pp 55, 56.

3. An example of trans-science is epidemiology in the range below proof of effect, for example uncertain methodology or Relative Risk of less than 2. P 57.

4. Another concept of trans-science that is rhetorically in widespread use is to prove no risk, to prove the negative. P 58.

5. Reliability and validity are not the same, for example a reproducible and reliable measure may be invalidated because of a poor instrument or methods or bad underlying science. The first error is easier to identify and correct than the second, which looks valid. P 69-71.

6. Confounders produce validity errors and are the reason observational studies require effects of 100 percent—there are many confounders, listed at p 71, migrations or maturation of the study group, attrition, selection, regression to the mean, sequence of effects, experimenter and subject biases and behavior, even simple things like recall bias and overreliance on recall.

7. Confidence interval is another form of measure of reliability of the data, providing a range of accuracy or reliability around a result. P 79, 81. But some say that confidence interval is too loose. One important consideration is that if a confidence interval includes 1.0, there is no basis to argue for an effect. STUDIES RELIED ON BY US EPA THAT INCLUDE 1.0 IN THE CONFIDENCE INTERVAL (CI) ARE NOT RELAIBLE TO SUPPORT AN ASSERTION OF TOXICITY. A CONFIDENCE INTERVAL THAT INCLUDES 1.0 SHOWS A NULL EFFECT.

8. When the signal (results) is in the range of the noise (background natural variability) the reliability of the research is compromised by the signal to noise confusion. In studies with small effects like the US EPA air pollution premature death studies, confirmation bias (also called tunnel vision) energized by intellectual passion and commitment to a political agenda produce studies that do not justify the policies proposed and pursued or the regulatory regimes imposed. P 84.

9. Fallacies and fallacious thinking and research derive from reliance on authority, consensus, acceptance of a vote of those present, obfuscation or cover and selection bias in the service of intellectual passion or ambition, or the "gold effect" which is another form of intellectual passion combined with social

pressure consensus bias. All these biases and prejudices and fallacies of thinking are in contravention to the gold standard for scientific inquiry—skeptical experimentation by researchers who are the most strict judge of the nature and reliability of their research and disciplined in analyzing whether their evidence is proof of a theory. P 85.

10. Intellectual passion and ego of the researcher are sources of bad science and one of the most important conflicts of interest. Ego produces a failure to test one's theory adequately and produces confirmation bias—gathering supportive evidence and rejecting dissent or disagreement and evidence that falsifies the theory in favor. All researchers tend to mythologize themselves and their research, and lack the humility to recognize their own fallibility or see the limits or weakness of their research. Their investment in their career and stature make them rigid and uncritical in their assertions of theory or positing of solutions or answers. P 86

11. Sick science is characterized by:

a. The maximum effect is produced by a phenomenon of barely detectable intensity.

b. Observations are made near the threshold of visibility of the eyes or instruments.

c. There are claims of great accuracy (and significance).

d. Ad hoc excuses are used to nullify any dissent or criticism.

e. The supporters rise and then fall.

12. Another characteristic of sick science is the cargo cult syndrome—pretense of scientific methodology that has no substance. P 89.

13. Another characteristic of sick science is the reports of effects that are considered ominous are in the range of background. E.g. EMG that was proposed to cause terrible carcinogenic effects in the range of the earth's magnetic fields.

14. The pattern of error that goes to policy making, for example ignoring opportunity benefits, fear of introducing new technologies on the precautionary principle, ignoring safety risks associated with a proposed regulatory regime or remedy, ignoring large existing benefits in favor of fear of risk or the precautionary principle, or MOST IMPORTANT, IGNORING THE UNINTENDED CONSEQUENCES OF PROPOSED SOLUTIONS, EITHER IN TERMS OF COMPLIANCE COSTS OR DIRECT AND KNOWN RISKS AND DETRIMENTS.

15. Procrustean data torturing is not different from opportunistic data torturing, and certainly no less pernicious and deceitful. P 99.

16. The seven deadly sins of knowledge or the cognitive illusions that are nefarious;

a. overconfidence

b. magical thinking

c. predictability in hindsight

d. anchoring or tunnel vision

e. ease of deception

f. probability blindness or chance ignorance

g. the game of conjuring of linkages and ignoring the weak links in a chain P 118, 119

17. Reliability refers to the reproducibility of the data. Reliability is measured in terms of sensitivity and specificity. Bayes' theorem measures positive and negative predictive values that are both dependent on sensitivity and specificity. P 113-115.

18. Back to Popper, the soundness of a theory depends on

a. the conclusions must be internally consistent

b. avoid tautological statements that prove nothing but just reference the assertion

c. look for scientific advances in a theory

d. test a theory with experiments

19. The theory must be logically consistent, falsifiable, must assert something new, or novel, and it must be verified by experimental evidence (p 138, 139).

20. There are a fistful of fallacies

a. indirect cause asserted

b. necessary causes are not always sufficient cause

c. temporal or post hoc causation is not real causation

d. ecological fallacy transfers observations about populations to individuals

e. the faggot fallacy piles small and suspect items of proof or evidence and attempts to validate by the bundle or the height of the pile

f. weight of evidence fallacy is similar to e. and relies on the pile

g. bellman's fallacy is another form of the pile fallacy

h. fallacy of risk is the confusion of absolute and relative risk and using one or the other to deceive

i. inappropriate extrapolation is the assumption that one knows the trends and can project

j. new syndrome fallacy is novelty to an extreme

k. insignificant significance—overemphasizing the importance of statically significance in proof of a theory

l. Fallacy of ignoring large effects in small studies because hey fail a statistical significance test.

m. Positive results are fallaciously given more significance

n. Denial of medical mistakes (all these are on P 143)

21. There are good rules for reading and evaluating a paper as a reviewer. P 149-150

22. Feinstein dissects fallacious and alarming medical reports on reserpine causing breast cancer, coffee causing pancreatic cancer, and alcohol and breast cancer. Feinstein reviews how the studies on these reports were flawed. P 156.

It is important to note that the book Judging Science is an exceptional effort by extraordinary authors and this writer cannot do them justice. The books sections are excerpted by necessity.

Buying the book will be the best choice for anyone compelled to learn the intricacies of legal management of scientific evidence and the theories of science that underlie any reasonable discussion of scientific reliability and veracity.

7. An abbreviated story of the effort by John D. Dunn MD JD to expose the misconduct of the US EPA in matters of toxicology and epidemiology.

The Environmental Protection Agency's Particulate Matter Rules: One Physician's Crusade against Cargo Cult Science (JPANDS Spring 2014)

John Dale Dunn, M.D., J.D.

http://www.jpands.org/vol19no1/dunn.pdf

The U.S. Environmental Protection Agency has an annual budget of almost $10 billion, and influence and power far beyond that, with U.S. industry and society always subject to EPA orders, regulations, guidelines, fines, and edicts on environmental compliance.

My effort to expose EPA's bad science and policy making began in the early 1990s, and has culminated in the past 2 years in EPA's admissions, in declarations under penalty of perjury, that inadequate and unreliable, even unethical science underlies EPA regulatory regimes under the Clean Air Act (CAA).

In the infamous Tuskegee syphilis experiment, innocent black Americans suffered the depredations of advanced syphilis as federal public health agents denied them treatment. Now EPA-sponsored studies deliberately expose human subjects to pollutants that the EPA claims to be toxic, lethal, and carcinogenic. The Tuskegee experiment was unnecessary—the effects of advanced syphilis had been known for centuries. The EPA claims it already knows how dangerous fine-particulate air pollution is, but the agency is funding human exposure experiments with what EPA-published air quality standards say are toxic levels of fine-particulate air pollution.

Environmental Law Course

I was a small-town emergency physician and inactive attorney when the dean of sciences at the local Howard Payne University asked me to teach environmental law for the new undergraduate major in environmental science. I obtained the federal and state statute books and put the course on the curriculum to

include adult education for community people interested in compliance issues, as well as the environmental science students.

My study of the economics and politics of environmental regulation led to the conclusion that it involved a **form of cargo cult science** (fake science that looks like science), as described by Nobel Prize winner Richard Feynman,1 that develops when government money is lavishly given to people in the academy to support a political agenda built on a false threat of public harm. EPA's cargo cult science was in the area of epidemiology (population studies) and toxicology (study of poisons and harmful substances). It allowed EPA to beat the panic drum and scare people about killer environmental poisons that were not harming anyone in the ambient environment. This coincided with the growth of the radical environmentalist movement, which I would describe as a cult built on pantheism and a commitment to statist control of society.

One of my guest lecturers, an engineer responsible for compliance for Phillips 66 and an alumnus of Howard Payne, said that EPA would eventually take as much as five percent out of the gross domestic product. His predictions didn't seem so exaggerated when, in the mid-1990s, ozone air standards proposed by EPA Administrator Carol Browner under President Clinton were estimated by economists to cost the economy more than $100 billion. Browner pushed ahead in spite of objections and opposition by EPA's in-house Clean Air Scientific Advisory Committee, and all the Democrat administration-controlled executive agency divisions and offices.

Many aspects of junk science in the public health sector promoted by agencies like EPA are explained by biostatistician and lawyer Steve Milloy in his books *Science Without Sense* (Cato, 1995), *Silencing Science* (with Michael Gough, Cato, 1998), and *Junk Science Judo* (Cato, 2001). Other valuable books on bad science are by Peter Huber: *Galileo's Revenge* (Basic Books, 1991); *Phantom Risk: Scientific Inference and the Law* (MIT Press, 1993); and the most extraordinary study of junk science I have read, *Judging Science: Scientific Knowledge and the Federal Courts* (with Kenneth Foster, MIT Press 1997). The last focuses on the question of science as evidence and how rules of evidence should be used to determine admissibility of scientific testimony and evidence in court proceedings.

"Clean" Air vs. Safe Air: Justifying Regulatory Overreach

The cottage industry of air pollution research is committed to the proposition that air pollution panic is justifiable if it allows regulatory reach by the EPA that would satisfy an aesthetic demand for "clean" air. In my opinion, the research community is distorting the intent of the Clean Air Act (CAA), which should have been named the Safe Air Act since it is impossible to make the air"clean" of pollutants (such as dust, for example). The statutory language of the CAA required the EPA to identify harmful air pollution and mitigate the effects, not make the air "clean."

One of the most prominent EPA-sponsored researchers in air pollution is Jonathan Samet, M.D., chair of epidemiology at Johns Hopkins Bloomberg School of Public Health and chair of the EPA Clean Air Scientific Advisory Committee (CASAC). In a 2000 paper in New England Journal of Medicine, 2 he claimed that fine particles were causing deaths. This claim was based on an inadequately small association of fine particulates and deaths in a study of 20 cities. Small associations are not proof of causation and could easily be a random effect or result from data mining and dredging. By the year 2000 EPA had used its junk science to stack up a well-funded and sponsored pile of papers using the same bad methodology and claims

as the Samet paper, going all the way back to the Pope 3 and Dockery 4 foundational air pollution studies that created the EPA air pollution research and regulation crusade of the 1990s.

Samet and his fellow air pollution researchers, who had become advocates, would mine the data to find a small association and then announce a threat and crisis. In his 2000 paper, 2 however, Samet made an admission that I thought very important: he could not find a toxic effect from the other EPA criteria air pollutants, carbon monoxide, sulfur oxides, ozone, or ozone precursors such as nitrogen oxides and volatile organics. Today, however, Samet campaigns against ozone as if he had never written that paper.

After a two-part science and legal critique that I wrote on Samet's 2000 New England Journal of Medicine 20-city study of effects of air pollution at the website of the American Council on Science and Health, 5,6 James Enstrom, Ph.D., research professor at the University of California at Los Angeles, contacted me and asked for assistance with his efforts to stop California government efforts to create more air pollution regulations that would harm business and industry. I submitted public comments opposing proposed EPA particulate and ozone regulations in 20067 and 2007, 8 with no effect on EPA policy or attitude. EPA continued to make absurd claims that this or that air pollution regulation would save lives.

During that same period, I benefited from the statistics expertise of S. Stanley Young, Ph.D., of the National Institute for Statistical Science in Research Triangle Park, North Carolina.

U.S. EPA Board of Scientific Counselors

In 2007 Enstrom, Young, and I decided to approach EPA's Board of Scientific Counselors (BOSC), an outside independent scientific advisory group that was supposed to monitor and critique EPA science and policy making to encourage research compliance with basic scientific rules. BOSC was composed of members of high professional standing who were in private or state activities, and not EPA employees.

We articulated our positions, based on our areas of concern for BOSC subcommittee meetings in late 2007, and then the executive committee in early 2008. Our pleas and arguments were:

1) Irresponsible and false epidemiology and toxicology by EPA researchers claimed an effect that clearly fell well below any threshold needed to show a toxic effect in observational epidemiological population studies. Evidence for claimed air pollution death effects was inadequate to prove any causation and was asserted without a plausible toxicological mechanism.

2) Studies with multiple inquiries exaggerate the chance of false positives. The EPA was misusing the concept of statistical significance by failing to adjust for the multiple inquiries.

3) The EPA and its sponsored researchers and reviewers ignored studies that disproved their theories and suffered from tunnel vision and confirmation bias. Moreover they persecuted researchers like Enstrom who found results that didn't support the EPA agenda.9

I traveled to Maryland to present my concerns in person to the BOSC subcommittee of the Human Health Risk Assessment Committee, and Enstrom and Young presented by telephone. After waiting through hours of presentations by insider EPA officials and researchers before the scheduled public comment period, each of us was allowed only three minutes. Considering the inhospitable reception we received, it was not surprising we were the only outside commenters. Many lectures of an hour or more had been followed by laudatory comments from other EPA employees and officials present. I also noted that the roster of

committee members was clearly made up of people who had previously, or would in the future, want to be grantees of EPA largesse. It was definitely a home game, with home umpires.

I reviewed the Board of Counselors minutes for the previous five years and found there were no public comments at Board of Counselors meetings in those years. Even highly placed people in private industry, who were severely affected by its regulations, had no taste for criticizing EPA or its sponsored researchers. Favoritism and influence peddling are constant factors in governmental programs. Enstrom, Young, and I decided that appeals to the supposedly independent BOSC were worthless. Nonetheless, we made presentations to another subcommittee and then the BOSC executive committee.

The CARB Toxic Air Machine Project of 2007-2008

The battle was over at EPA, since it was a fixed game, but at the same time there was a battle going on in California led by Enstrom, which heated up in 2008 because of a new set of diesel engine rules focused on fine-particulate air pollution. These regulations were proposed and supported by research sponsored by EPA and the California Air Resources Board (CARB), a subdivision of the California EPA.

In 2005 Enstrom published his results of a robust and current study on the effects of fine-particulate air pollution in California. The study (10) involved 50,000 people in the years 1973-2002. It showed no premature death effect in California from fine- particulate air pollution. Moreover, California's air pollution of the 1950s and 1960s had declined for 30 years. Nonetheless, the increasing rate of asthma was misrepresented as a sign of an air pollution crisis justifying more air pollution regulations for no discernible benefit. Enstrom was also concerned that economic hardships would prove to be important causes of deprivation and decreased human life expectancy, as demonstrated in reliable population studies.11

In 2007, the CARB "solicitation" and review process was set up for a document entitled "Methodology for Estimating Premature Deaths Associated with Long-term Exposure to Fine Airborne Particulate Matter in California." The process included three scientific advisors and six "independent" but paid reviewers well known to, and allies of, CARB. Then CARB staff in May of 2008 released a draft report and proposed regulatory regime, claiming that air pollution caused premature deaths in California. A public comment period began, and the CARB business-as-usual process ran into vigorous critiques 12 submitted by Enstrom and other distinguished public health scientists and engineers in July 2008.

Public criticisms of the CARB draft report included:

1) Panel reviewers were reviewing their own or their close colleagues' air pollution studies.

2) CARB had discarded the Enstrom study and ignored geographic and time trend evidence available in the reviewed research that argued against their conclusions of air pollution death effects in California and the need for more regulations.

3) CARB had failed to adjust for changes in engines and emissions that also made older studies invalid.

4) Basic rules of the sciences of epidemiology and toxicology were violated in the CARB research that made claims based on small associations that were inadequate to claim a premature death effect.

My critique 10, pp 129-135 of the comments document discusses basic principles of scientific evidence that the EPA violates in its overreach. According to the Federal Judicial Center's Reference Manual on Scientific Evidence, 13, 14 which discusses the magnitude of toxic effect required in observational studies that are

used in public health toxicology research, an agent was more likely than not the cause of an individual's disease when the relative risk (RR) is 2.0, that is, a 100 percent increase in the disease or effect (e.g. premature death) in the exposed population. For example, the research on effects of cigarette smoking showed the RR of lung cancer in cigarette smokers is 10.

An RR greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. None of the cited foundational and supportive studies EPA or CARB use to justify air pollution regulatory regimes have the minimum RR of 2 needed to assert evidence in associations of causation.

While epidemiologists study population effects, toxicologists study adverse effects. In the early 1950s, Sir Austin Bradford Hill, British icon of public health research, originated nine criteria referred to by the Federal Judicial Center in the Reference Manual for proving toxicity. Hill's first and most important criterion was evidence of a measurable and significant toxic effect. Other criteria include that the toxic effect proposed has to be plausible, has to make temporal and dosage exposure sense, and should be evaluated to make sure some other factor is not in play.15

EPA has consistently disregarded the Bradford Hill criteria, in particular using small associations that fail the test of adequate evidence of effect. There is no real knowledge of actual exposure of individuals alleged to be affected or dead, and certainly no assurance that outside air quality is the exposure that is appropriate to measure, since people spend the majority of their time indoors. A final and important consideration is that EPA research shows no evidence of a current understanding of a plausible mechanism for fine-particle toxicity or lethality.

CARB staff in October 2008 issued a final report that was the same as the preliminary draft report of May 2008. CARB staff admitted that they didn't show the public scientific critiques to the expert panel or request an expert response to those criticisms of CARB research conclusions or policy proposals.

In December 2008, Enstrom and three other prominent California air pollution experts directly contacted CARB board members to urge rejection of the 2008 report. The four also wrote a public letter to CARB to recommend that CARB reassess the report and delay any decision on air pollution and diesel regulations.16

Enstrom and Young checked the credentials of Hien Tran, lead author of the CARB Report on Fine Particles and Premature Death in California, and found that he had a fake Ph.D., purchased for $1,000 from a drop box, Thornhill University.17 Enstrom and others also pursued another scandal—that CARB executive Mary Nichols knew of the Tran fraud and had not reported it to the CARB Board before Dec 12, 2008, when it voted to approve the Truck and Bus Regulation. Enstrom's research into the enabling legislation for CARB also found that most members of the Scientific Review Panel on Toxic Air Contaminants had served in their positions longer than the specified term of 3 years without following the nomination and appointment process of members required by the 1983 enabling statute. Pacific Legal Foundation filed a lawsuit in June 2009 to force compliance with the nomination and appointment process, resulting in the removal of five of the nine members.

A taxpayers' protest was held with speeches and demonstrations at the State Capitol on Aug 28, 2009, reinforced by the sound of a 220-truck convoy sponsored by the California Dump Truck Owners Association (now the California Construction Trucking Association). The convoy circled the Capitol building and, on

cue, sounded truck horns for one minute. The convoy and the Capitol steps rally on California agency overreach were not covered by the press, but the legislators were there.

Business leaders and industry sectors that use diesel engines raised their voices. Dr.Bill Wattenberg, an engineer and influential talk show host from San Francisco's KGO, railed against CARB. Bloggers and other radio hosts joined in. Bryan Bloom, Lee Brown, and Betty Plowman and other trucking industry people were eloquent in public meetings. Jay McKeenan for the California Independent Oil Marketers Association, representatives of the logging industry organizations, Bill Davis with the Southern California Contractors Association, and Shelly Sullivan of the California Manufacturers and Technology Association, all pressed for a CARB suspension of the new diesel rules and a sensible agency retreat from its aggressive stance. Skip Brown, construction executive, was a steady and important participant as a speaker and writer.

California Assemblyman Roger Niello (R-5th Assembly District) presented a bipartisan letter with 52 signers demanding that CARB suspend the new diesel rules. Senator Robert Dutton (R-31st Senate District) and Assemblyman Dan Logue (R-3rd Assembly District) introduced bills to slow down CARB implementation plans on greenhouse gas and global warming regulations. Gov. Arnold Schwarzenegger weighed in to advocate a suspension of any new fine particulate/diesel regulations until the California economy could recover.

As a result of this 2-year campaign, CARB attempted to repair its damaged reputation for reliable research with a full-day scientific discussion and "cage match" debate on Feb 26, 2010 at the California EPA hearing room in Sacramento.

CARB designated three experts from the original scientific review panel: Daniel Krewski, Ph.D., Michael Jerrett, Ph.D., and Arden Pope, Ph.D., well-credentialed and also longtime friends and beneficiaries of CARB and EPA grants, members of the insider air pollution club with senior status. CARB paid for them to appear just as they had paid for previous research and review work.

Krewski has headed a large group that did a national study.18 A close look at the results showed that they found no air pollution "associations" that would support a claim of human health effects in California, but they ignored their own results, which would argue against their basic premise. During the symposium, Jerrett admitted that he couldn't find an air pollution health effect in California, but a year later he manipulated the data to show a minor association in one of his models19 created by a trick in methodology and geographic gerrymandering that he called "conurbation."20 As noted above, the Pope and Dockery group 3,4 have been prolific and always predictably produced studies with very weak associations that they claim support their position that air pollution kills.

For the opposing public critics, James Enstrom, Ph.D., Fred Lipfert, Ph.D., Robert Phalen, Ph.D., Roger McClellan, D.V.M., Suresh Moolgavkar, M.D., Ph.D, and Tom Hesterberg, Ph.D., M.B.A., appeared. These well-qualified researchers urged no more regulations and no more exaggeration of the science on air pollution health effects.

The webcast is seven hours long. 21 The net effect was that the public commenters exposed the nature of the CARB malfeasance on human health effects science, and demonstrated that the CARB research project was a setup that involved conflicts of interest and a failure to objectively evaluate competing data and evidence on the question of California air quality and its effect on health.

No regulatory relief came from the debate and the proof of CARB malfeasance, and CARB proceeded with the originally planned air pollution regulations.

Washington Politics

The Space Science and Technology Committee of the House of Representatives contacted me in 2010, and I provided information from the CARB wars and the previous challenges of EPA air pollution research claims and policy making. Congress had hearings in the fall of 2010 and through 2011 on EPA air pollution research and regulations. In 2011 and 2012, the House Energy and Commerce Committee also had activities and an interest, and in February 2012 former chairman Rep. Joe Barton (R-Texas) gave a speech outlining the perfidy of the EPA on many aspects of science and policy, as well as legal aspects of EPA misconduct.

Barton condemned:

- EPA's refusal to assess risk and benefit on regulations;
- EPA's burdensome and nonsensical power plant regulations;
- EPA's failure to cooperate with congressional oversight;
- Persistent and flagrant conflicts of interest among EPA researchers and advisers who receive tens of millions of dollars in research grants from the agency while serving as reviewers of EPA research;22
- EPA researchers' refusal to comply with basic rules of public health research in toxicology and epidemiology;
- Inappropriate reliance on the precautionary principle;
- Circumvention of congressional oversight; and
- Grant-giving to non-governmental advocacy groups that then enter into collusive lawsuits and aggressive regulatory requests that promote the agency's agenda and expand its regulatory and political power.

As Barton pointed out, "I believe that the American public and taxpayers should not be paying for an agency that manipulates data and funds researchers in the form of exterior grants, who in turn serve on the internal committees within the EPA to create policy and work in an oversight capacity. This is an incredible conflict of interest to the American public."23

Rep. Barton's dressing-down of EPA and its administrator was a first step in the right direction. But now Rep. Barton and his colleagues need to follow through by implementing real solutions that will stop EPA's regulatory excesses.

EPA and the Admissibility of Scientific Evidence

EPA research on human health effects of air pollution consistently violates the rules of science and is not admissible in a federal court under the rules of Daubert v. Merrell Dow, 509 U.S. 579 (1993). The Daubert majority opinion, written by Justice Harry Blackmun, discarded the old rule of "generally accepted" for scientific testimony and evidence, from the 1923 case of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) and adopted new, more rigorous tests for admissibility of science testimony and evidence, under Federal

Rules of Evidence (1975), particularly Rule of Evidence 702 on Testimony by Experts. The rule provides that if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue (Rule 104 test), a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In his written opinion, Justice Blackmun provided an erudite discussion on the philosophy of science, with a strong dose of the theories of a respected philosopher of science, Karl Popper.

Justice Blackmun's major points were as follows:

1) Trial judges were the gate keepers to assure that reliable science was admitted as evidence.

2) Scientific testimony and other scientific evidence had to be consistent with everyday good scientific practice.

3) The science would be assessed generally as follows:

a. The general acceptance rule of Frye did not survive the new Federal Rules of Evidence.

b. Knowledge is more than subjective belief or unsupported speculation; it must be supported by evidence and proven methods.

c. An expert witness is permitted wide latitude under the federal rules of evidence to offer opinions, including those that are not based on firsthand knowledge or observation.

d. Under Federal Rule of Evidence 104, a federal trial judge must determine the threshold question of whether the evidence is relevant and material to the case and will assist the trier of fact.

Justice Blackmun continued that if the threshold test of Rule 104 is satisfied (3d above), then the judge, in applying the rules of Daubert, must assess the admissibility of the scientific evidence and testimony on the basis of four tests under Federal Rule of Evidence 702 on Testimony of Experts:

1) Whether the theory or technique can be and has been tested;

2) Whether the theory or technique has been subjected to peer review and publication (this test is not dispositive, only additive);

3) Whether the technique or method has a known or potential rate of error; and

4) Acceptance of the theory or technique within a relevant scientific community of scholars.

Professor Michael Fenner of Creighton Law School wrote a helpful, in-depth review of the Daubert opinion. 24 In *Judging Science*, 25 Kenneth Foster and Peter Huber (MIT Press 1995) also review and analyze Daubert, providing much background analysis on the problems of junk science and fallacious science and also on the methods that produce reliable evidence and avoid scientific negligence and misconduct.

The Federal Rules of Evidence provide a means to challenge EPA-sponsored research, claims, conduct, actions, and policy-making. The burden of the challenge to an action, or ruling or fine or penalty, is to prove that the agency was arbitrary and capricious in its analysis of the pertinent science and research on human health effects and detriment. A common-sense understanding of those words entails actions taken without good justification or rationale. The courts have been inclined to be excessively deferential and allow agency

hegemony, even refusing to hear arguments on the arbitrary and capricious standard for agency acceptance of scientific research assertions.

Jurisprudence allows for judicial deference to agency discretion in matters of ambiguous statutory provisions, described by Justice Antonin Scalia in *Whitman v. American Trucking Association*. 26 What the erudite Justice Scalia fails to constrain is the inordinate and inappropriate expansion of the deference allowed EPA in reference to interpretation of ambiguous statutory language to include arbitrary and capricious agency acceptance of what would be arguably inadmissible scientific testimony and evidence.

Judges are, however, and always have been, the ones to decide what's admissible as evidence. Agency discretion under the jurisprudence of the Chevron decision 27 should not allow unreliable scientific evidence into the record under the rules of *Daubert*, whether it's a hearing or a trial. The evidence must be admissible for purposes of proving that the agency is or is not being arbitrary or capricious, which makes the decision on evidentiary admissibility and reliability separate from whatever idea the court might have about agency authority and discretion.

Unreliable scientific evidence is inadmissible and therefore cannot be used to justify agency actions. The admissibility rulings on evidence trump some arcane idea about agency discretion that is all tied up in the jurisprudence on congressional delegation. There is no law that Congress has passed that permits agencies to use and promote junk science.

In the excessive support of congressional delegation to agencies under the statutes, and the general deference for agency discretion under Chevron, Scalia allows EPA research to cheat and avoid a challenge under the "arbitrary and capricious" standard. Justice Scalia just plain ignores the commonly and legally understood meaning of "arbitrary and capricious." Proposing inadmissible scientific evidence and testimony on critical research assertions that are foundations for policy and regulatory action would certainly cross the threshold of "arbitrary and capricious" under the Administrative Procedure Act.

The Role of the Administrative Procedure Act (APA)

The Administrative Procedure Act (APA) allows a successful challenge of agency conduct when that action is arbitrary (without good reason) and capricious (on a whim and without a good reason). Violating scientific rules, like the ones that are clearly outlined in the *Reference Manual on Scientific Evidence* 11, 12 to educate judges on science, would certainly raise the question of irrationality that is the fundamental issue for claiming that an agency has acted in an arbitrary and capricious manner.

The courts have, however, been very lenient with the EPA on the violations of scientific rules and provided many opportunities for agencies to violate the rules of science, so legislative actions may be necessary to force better science and policymaking at EPA. The alternative is to find a judge with integrity and an appellate court that doesn't undermine a judgment of inadmissibility, or will entertain and find valid an appeal to reverse an improper judgment on Daubert admissibility.

Legislative Remedies

In the political sphere, Congress can modify standards of administrative and judicial review to demand good science and a better standard for agency conduct, with more reasonable rules on challenges to EPA actions. This is similar to the rules for challenges to actions by the Occupational Safety and Health Administration, which carry a preponderance-of-evidence burden.

The pertinent legislative act is the Congressional Review Act (CRA), found at 5 U.S.C. 801, which allows Congress to jump in when the agencies are involved in misconduct. CRA was enacted as section 251 of the Contract with America

Advancement Act of 1996, also known as the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The law allows Congress to review, by means of an expedited legislative process, new federal regulations and, by passage of a joint resolution, to overrule a regulation.

Another legislative effort to bring the pressure to bear on the federal agency and their sponsored researchers is the **Data Quality Act**, which requires agency-sponsored research to hold to good scientific principles or be subject to review and possible modification or recision.

Even without legislation, responsible, competent, and serious legislators can find reasons to question EPA conduct, and lawyers can frame evidentiary challenges so that the courts and administrative hearings will be required to make clear rulings on admissibility of scientific evidence with an accompanying rationale for appellate review.

A bad evidentiary ruling is a reversible error; a good ruling will nurture good science in the courtroom. No lawyer but a pettifogger would admit to arguing for bad science that violates the public trust.

At present EPA, following Samet, 28 asserts the theory of "no threshold" for a toxic effect of air pollution, allowing EPA to pursue any pollutant to the last molecule. This impossible goal allows for unlimited expansion of EPA power. Chemical toxicology still is based on thresholds. **"No threshold" chemical air pollutant toxicology turns the Clean Air Act (42 USC 7401. 1963, amended 1970, 1990) on its head and nullifies and abandons the strategy Congress intended.**

Human Experimentation Scandal

As previously described in this journal, 29 EPA has been sponsoring research in which human subjects are exposed to air pollutants at levels far exceeding those EPA declares to be toxic or lethal. It is illegal, unethical, and immoral to expose experimental subjects to harmful or lethal toxins.30 The Reference Manual on Scientific Evidence, 3rd ed. (2011), [12, p 555] declares that exposing human subjects to toxic substances is "proscribed" by law, and cites case law. The editor of Environmental Health Perspectives (EHP) refused a request by Steve Milloy of JunkScience.com to withdraw a paper based on one such study and conduct an investigation.31

According to information obtained by Milloy from a Freedom of Information Act (FOIA) request, a University of North Carolina research study exposed 42 people to what EPA says are harmful or lethal levels of fine particles, with some receiving 10 times EPA's declared safe level of 35 micrograms per cubic meter of air. The EPA human experiments described were conducted from January 2010 to June 2011, and ended three months before then-EPA Director Lisa Jackson's congressional testimony, during which she still asserted dramatic claims of the lethality of small particulates less than 2.5 microns in diameter (PM2.5), claiming thousands of deaths and hundreds of billions of dollars in economic consequences from the deaths and disabilities caused by fine particles.

There have been no publications of toxic effects as declared by the authors of the paper, other than the one case report of a cardiac arrhythmia described earlier; 29 the researchers failed to report that none of the other

subjects had any adverse effects, despite the obligation of researchers to report results both for and against their hypothesis.

Did EPA risk the deaths of 42 subjects? Or are EPA officials lying in their testimony about the dangers of small-particle air pollution and deliberately misleading Congress and the public?

After filing complaints with EPA officials and the editor of EHP, Milloy and I filed complaints with the North Carolina Board of Medicine and the University of North Carolina (UNC) School of Medicine. The North Carolina medical board found no violation of the Medical Practice Act by the physicians, and no action was taken by the UNC School of Medicine.

A lawsuit was filed in Federal District Court in Arlington, Va., to ask for injunctive relief or a remedy that would stop the human experiments. The Court said it didn't have the authority or jurisdiction to stop the human experiments, but declarations under penalty of perjury obtained from officials of the EPA research team at UNC Chapel Hill School of Medicine were revealing.

Eugene Cascio, M.D., a lead EPA physician in the research team, declared that 10 domestic medical schools and six foreign medical schools were doing human exposure experiments. They included some of the most prominent medical schools in the United States—Rutgers, Rochester, Ohio State, University of Michigan, Michigan State, University of Washington, University of California at Los Angeles, University of Southern California, and Lovelace Clinic affiliated with the University of New Mexico. The foreign medical schools included three in Europe, one in Canada, and two in the UK.32

Two other declarations produced by EPA officials in the lawsuit were critical to understanding EPA misconduct. Martin Case, program administrator, declared that he told the subjects they could die from the exposures, but he did not write that warning in the consents obtained.33 Milloy has obtained the consent forms from UNC and other medical schools involved in the project for human experimentation, and none of programs warned subjects of EPA's position that fine particles were toxic, lethal, and carcinogenic, and that the subjects might suffer the consequences.34

Robert Devlin, Ph.D., senior research official for EPA and part of the UNC team, stated in his declaration under penalty of perjury that the EPA was sponsoring the human experimentation because the results of epidemiological studies are not reliable enough and do not establish a strong enough case for toxicity of air pollution.35

In paragraph 8, Devlin states:

> Controlled human exposure studies conducted by EPA scientists and EPA-funded scientists at multiple U.S. universities fill an information gap that cannot be filled by large population studies. In 1998 the Committee on Research Priorities for Airborne Particulate Matter was established by the National Research Council in response to a request from Congress. The committee was charged with producing four reports over a five- year period which describe a conceptual framework for an integrated national program of particulate-matter research, and identified the most critical research needs linked to key policy-related scientific uncertainties.

The committee states on page 36 of its report:

> Controlled human exposure studies offer the opportunity to study small numbers of human subjects under carefully controlled exposure conditions and gain valuable insights into both the relative deposition of inhaled particles and the resulting health effects. Individuals studied can range from healthy people to individuals with cardiac or respiratory diseases of varying degrees of severity. In all cases, the specific protocols defining the subjects, the exposure conditions, and the evaluation procedures must be reviewed and approved by institutional review boards providing oversight for human experimentation. The exposure atmospheres studied vary, ranging from well-defined, single- component aerosols (such as black carbon or sulfuric acid) to atmospheres produced by recently developed particle concentrators, which concentrate the particles present in ambient air. The concentrations of particles studied are limited by ethical considerations and by concern for the range of concentrations, from the experimental setting to typical ambient concentration, over which findings need to be extrapolated.

Controlled human exposures studies have been conducted for decades on important pollutants such as ozone, particulate matter, nitrogen dioxide (NO2), sulfur dioxide (SO2), VOCs [volatile organic compounds] emitted [in] new homes, and carbon monoxide (CO).

In paragraph 9 of his Declaration, Devlin states: "Controlled human exposure studies assess the biological plausibility of the associations observed in the large-population epidemiological studies."

So we have come full circle. For 20 years I have argued that EPA is involved in corrupted, invalid, unreliable epidemiology. Now, under pressure from a lawsuit for unethical conduct, it admits what we knew already, that epidemiology is being misused as a false portfolio of evidence of air pollution toxicity. The most astounding aspect of this human experiments scandal is the refusal of state boards of medicine, institutional review boards (IRBs), deans of medical schools, and EPA officials to investigate and stop the misconduct. This is in spite of the well-known and remembered Tuskegee and horrific wartime

Nazi/Japanese medical experiments on prisoners.

What we have discovered with EPA misconduct and that of the grantees at numerous medical schools is very sobering. These are not trivial violations of the ethical rules on human experimentation with which the IRBs are familiar. The rule is that one cannot perform harmful human exposure experiments— period. In only a very few circumstances where significant benefit is anticipated could subjects be exposed to harmful substances, after they are informed of the risks.

Conclusion

For 20 years or more EPA has promulgated bad epidemiology and bad toxicology that eventually evolved into research with unethical human exposure experiments. There is no easy way to excuse unethical human experiments to substantiate claims made in congressional hearings, despite lack of evidence, that air pollution or other forms of pollution are toxic and lethal.

If EPA is lying about the toxicity, the regulations fall. If it isn't, a federal agency is committing battery and unethical research that is criminal, unethical, and violates agency rules on human research. Either way, innocent experimental subjects are victimized.

Daubert and the *Reference Manual* guidelines could be used to restore sanity and objectivity to EPA regulatory activities so that they would improve public health policy-making rather than serving a political agenda.

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7. Dunn and Milloy on EPA sponsored Human Experiments using small particles emissions.

Environmental Protection Agency's Air Pollution Research: Unethical and Illegal?

Steve Milloy, M.H.S., J.D., L.L.M., John Dale Dunn, M.D., J.D (JPANDS Winter 2012)

- www.jpands.org/vol17no4/dunn.pdf

"First, do no harm"is a fundamental precept of medical ethics. So how do U.S. Environmental Protection Agency physicians explain their non-therapeutic experiments in which they exposed health-impaired people to high levels of concentrated diesel exhaust and other air pollutants?

A federal court may soon help clarify this dilemma.

Since at least 2004, EPA physicians have been intentionally exposing human beings to various forms of concentrated airborne particulate matter (PM), including diesel exhaust, at an EPA laboratory at the University of North Carolina School of Medicine (UNC). The diesel exhaust is generated by idling a diesel truck with its exhaust pipe located right under the air intake for the exposure chamber.

The university not only houses the EPA facility, but also provides on a contract basis the mandatory institutional review board (IRB) intended to serve as the last line of defense for human study subjects.

Although these experiments materially violate every law, regulation, and standard developed since World War II for the protection of human subjects, there are two primary violations.1

First, these experiments should never have been approved by UNC or conducted by EPA given the allegedly lethal nature of PM as determined by EPA.

Since 1997, the agency has regulated PM on the basis that it kills people. In 2004, EPA clarified its views of PM's lethality by concluding that any inhalation of PM could result in death within hours of exposure.2 The EPA reiterated this view in its 2009 scientific assessment of PM.3

In July 2011, Dr. Jon Samet, chairman of EPA's Clean Air Scientific Advisory Committee, wrote in the New England Journal of Medicine that there is no safe exposure to PM.4 This view was repeatedly echoed by EPA air chief Gina McCarthy in a February 2012 letter to House Energy and Commerce Chairman Fred Upton (R-Mich.).5

EPA Administrator Lisa Jackson testified before Congress in September 2011: "Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should. She added,"If we could reduce particulate matter to levels that are healthy we would have an identical impact to finding a cure for cancer."6 Cancer kills about 570,000 in the U.S. annually, according to the American Cancer Society.

In addition to the EPA-determined lethal nature of PM, EPA also says there is strong evidence that PM is carcinogenic.7

These characterizations of PM essentially portray it as one of the most toxic substances known to man—at least according to EPA. Though every poison has a lethal dose, any exposure to PM can kill, and kill quickly (within hours), EPA claims. Although exposure to carcinogens like asbestos, benzene, and vinyl chloride may cause cancers decades after exposure, or after decades of exposure, these risks obviously pale in comparison to that of PM in the view of EPA.

EPA, then, is experimenting on human beings with what it views as one of the most toxic substances known to man for the simple (and illegal) purpose of evaluating what would happen, apparently in an effort to bolster its epidemiological (i.e. statistical) claims.8,9 Worse, many of the study subjects are health-impaired, suffering from metabolic syndrome, asthma, old age, or combinations thereof.

The idea of a government agency deliberately exposing sick people to what it portrays as an extremely toxic substance is shocking. This is, however, only part of the story.

Second, informed consent is the cornerstone of medical practice and human testing protocols. Failure to obtain informed consent, among other misconduct, resulted in the execution of 16 of 23 Nazi doctors at the Nuremberg tribunal. The so-called "Common Rule" has been adopted by American medical researchers, including EPA, as a standard for conducting human experiments, and it prohibits harmful human experiments.10

Although EPA went through the motions of having its study subjects read and sign consent forms, the forms never mentioned that any exposure to PM could result in death within hours of the experiment. Study subjects were instead told, for example, "You may experience some minor degree of airway irritation, cough or shortness of breath or wheezing. These symptoms typically disappear two to four hours after exposure, but may last longer for particularly sensitive people."10

At least hundreds, and possibly thousands of human subjects have been so experimented upon by EPA physicians or EPA- grantee physicians at universities around the country. These experiments continue even as these concerns have been pointed out to EPA in recent months.

Has anyone been harmed? At least one 58-year-old obese woman with a personal and family history of heart problems had her experiment terminated early when she developed atrial fibrillation/flutter. The case was reported, 11 and it was said to be "the first case report of cardiovascular disease after exposure to elevated concentrations of any air pollutant." The rhythm resolved spontaneously about 2 hours after termination of the exposure. The authors concluded: "The resolution of the arrhythmia with termination of the particle exposure further supports a causal relationship between the two."They made this strong inference even while acknowledging evidence of a high frequency of supraventricular ectopy prior to exposure, numerous preexisting risk factors, and the fact that an

electrophysiologic study 6 weeks later revealed a re-entrant circuit, which was ablated. The authors suggested a potential mechanism of "disruption of the normal cardiac autonomic control," without

acknowledging the confounding factor of a potential emotional reaction to being in a setting resembling a gas chamber and being the subject of an exposure to an inhaled air mixture in a lab.

Although EPA physicians attributed the subject's arrhythmia to her PM exposure, they nevertheless did not modify the consent forms for subsequent human test subjects to reflect this risk.

As a result, the American Tradition Institute, a nonprofit public policy group, has filed suit in federal court against the EPA seeking an end to this illegal experimentation (American Tradition Institute Environmental Law Center v. U.S. EPA, Case 1:12- cv-01066-AJT-TCB, U.S. District Court for the Eastern District of Virginia—Alexandria Division).

Complaints have been filed with the North Carolina Medical Board concerning three of the North Carolina-licensed EPA physicians involved in the illegal experimentation. This investigation continues. The University of North Carolina School of Medicine has announced an internal review.

Congress has gotten involved, too. Sen. Jim Inhofe (R-Okla.) has requested that the Senate Environment and Public Works Committee, the committee responsible for overseeing EPA, schedule hearings on the scandal. Spearheaded by Rep. Paul Broun,

M.D. (R-Ga.-10), the House Science Committee has requested that the EPA Office of Inspector General conduct an investigation.

The lawsuit has already produced a notable admission of sorts from an EPA employee. In his declaration,12 EPA Clinical Studies Coordinator Martin W. Case asserted that he verbally informs human subjects in an ongoing trial that, "There is the possibility you may die from this." In addition to the shocking nature of this"warning,"even if it were acceptable to risk the lives of human study subjects for the sake of science—and it's not—such a warning would need to be in writing, according to federal regulations.

It's clear that "first, do no harm" was not a high priority concern of EPA physicians involved in this shocking experimentation. EPA and UNC are now in defensive postures, and the medical community needs to hold them accountable. Given past outrages of medical science, like the Nazi experiments and the Tuskegee syphilis experiments to name just two, what will the medical, political, and legal communities do to stop this ongoing research sponsored by a United States federal agency and funded with taxpayer dollars?

Another possibility is that the EPA does not believe its own testimony to Congress, and that oppressive, costly regulations have been imposed on American industry on the basis of flawed epidemiologic studies, unwarranted extrapolations, and contrived estimates of benefits. The experiments may be designed to find a potential mechanism of harm, like the one suggested in the case report by Ghio et al.11 If so, the very purpose of the experiments is to cause harm to human beings in an effort to justify false testimony.

[Editor's Note: In a letter from the Environmental Protection Agency Office of Inspector General, dated October 22, 2012, Assistant Inspector General for Program Evaluation, Carolyn Copper, indicated the agency "plans to begin an evaluation of the Environmental Protection Agency's (EPA's) Research on Human Subjects...to determine whether EPA: 1) Obtained sufficient approval to expose subjects to specific levels of diesel exhaust emissions or concentrated airborne particles; 2) Obtained adequate informed consent from human study subjects before exposing them to diesel exhaust emissions or concentrated airborne particles; 3) Adequately addressed any adverse events that occurred, including notifying the University of

North Carolina at Chapel Hill's Institutional Review Board (IRB), the Human Studies Review Board, and the Human Subjects Research Review Official, revising consent forms as needed, and providing clinical follow- up in accordance with the approved protocol." See http://junksciencecom. files.wordpress.com/2012/11/new-assignment-memorandum-on-oig- evaluation-on-epas-research-onhuman-subjects.pdf] .

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8. ESSAYS and ARTICLES THAT EMPHASIZE THE NATURE OF US EPA SCIENTIFIC MISCONDUCT

Hyperlinks to essays on correcting EPA science Abuses

- Science and the Toxic Scare Machine
- The EPA's Faulty Science Can Be Stopped
- A Strategy to Stop EPA Science Abuse

Hyperlinks to essays on the EPA human experiments scandal and legal and administrative review of the conduct of EPA

- http://www.americanthinker.com/articles/2012/06/epas_unethical_air_pollution_experiments.html
- The EPA Uses Children (and Adults) as Guinea Pigs
- http://www.americanthinker.com/articles/2016/08/epa_whitewashes_illegal_human_experiments.html
- http://www.americanthinker.com/articles/2017/04/swamp_diving_the_epas_secret_human_experiment_regime.html

  National Research Council Human Experiments investigation panel
- EPA Whitewashes Illegal Human Experiments

Arnett review of EPA misconduct on air quality research 2012

Politicized science, Enstrom v. environmental activists – 17(4):118-119, 2012

http://www.jpands.org/vol17no4/arnett.pdf

Enstrom study on small particles in Dose Response

https://junkscience.com/2017/04/epidemiologist-accuses-prominent-epa-funded-researchers-of-deliberate-misrepresentation-on-key-air-pollution-studies/

Dunn letter on Enstrom paper.

http://journals.sagepub.com/doi/full/10.1177/1559325817749414

CA study of small particles and ozone effects in 2017 by Young, Smith, Lopiano

Young S, Smith R, Lopiano K. Air quality and acute deaths in California, 2000-2012.
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JAMA DI small particles article 2017

https://junkscience.com/2018/02/dr-john-dunn-blasts-jama-over-harvard-pm2-5-fraud/

http://www.americanthinker.com/articles/2017/12/medical_journal_perpetrates_the_noble_lie_that_american_air_quality_kills_.html

9. 2018 Enstrom reviews and exposes EPA air quality epidemiological misconduct 2017

https://junkscience.com/2018/05/pope-fails-to-find-error-in-enstroms-2017-reanalysis-of-pope-1995-pm2-5-study/

The study below is a reanalysis of earlier studies relied on by the US EPA.

Dr. Enstrom shows that the studies not only show small associations that are proof of nothing, but in some cases reanalyzing the data shows Confidence Intervals that include Relative Risk of 1.0 so the studies failed in every way to show an effect. Dr. Enstrom also provides information on a systematic effort by journals to suppress his expose'.

James E. Enstrom, Original Article Fine Particulate Matter and Total Mortality in Cancer Prevention Study Cohort Reanalysis

Enstrom J. Fine particulate matter and total mortality in cancer prevention study cohort reanalysis. Dose-Response: January-March 2017 1-12 DOI: 10.1177/1559325817693345
https://www.ncbi.nlm.nih.gov/pubmed/28473741

Abstract

Background: In 1997 the US Environmental Protection Agency (EPA) established the National Ambient Air Quality Standard (NAAQS) for fine particulate matter ($PM_{2.5}$), largely because of its positive relationship to total mortality in the 1982 American Cancer Society Cancer Prevention Study (CPS II) cohort. Subsequently, EPA has used this relationship as the primary justification for many costly regulations, most recently the Clean Power Plan. An independent analysis of the CPS II data was conducted in order to test the validity of this relationship.

Methods: The original CPS II questionnaire data, including 1982 to 1988 mortality follow-up, were analyzed using Cox proportional hazards regression. Results were obtained for 292 277 participants in 85 counties with 1979-1983 EPA Inhalable Particulate Network $PM_{2.5}$ measurements, as well as for 212 370 participants in the 50 counties used in the original 1995 analysis.

Results: The 1982 to 1988 relative risk (RR) of death from all causes and 95% confidence interval adjusted for age, sex, race, education, and smoking status was 1.023 (0.997-1.049) for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ in 85 counties and 1.025 (0.990-1.061) in the 50 original counties. The fully adjusted RR was null in the western and eastern portions of the United States, including in areas with somewhat higher $PM_{2.5}$ levels, particularly 5 Ohio Valley states and California.

Conclusion: No significant relationship between $PM_{2.5}$ and total mortality in the CPS II cohort was found when the best available $PM_{2.5}$ data were used. The original 1995 analysis found a positive relationship by selective use of CPS II and $PM_{2.5}$ data. This independent analysis of underlying data raises serious doubts about the CPS II epidemiologic evidence supporting the $PM_{2.5}$ NAAQS. These findings provide strong justification for further independent analysis of the CPS II data.

James E. Enstrom

Here is another article in 2018 that describes Enstrom's efforts to expose US EPA air quality effects research misconduct.

http://www.jpands.org/vol23no1/enstrom.pdf

Scientific Distortions in Fine Particulate Matter Epidemiology
James E. Enstrom, Ph.D., M.P.H.

ABSTRACT
The theoretical prevention of premature deaths from the inhalation of fine particulate matter is being used by the U.S. Environmental Protection Agency (EPA) to justify the National Ambient Air Quality Standard (NAAQS) and multibillion dollar regulations across the U.S., including the EPA Clean Power Plan and the California Air Resources Board (CARB) Truck and Bus Regulation. The epidemiology is severely flawed. Fine particulates probably make no significant contribution to premature mortality in the U.S. The publication of null findings has been blocked or marginalized and studies claiming excess mortality need to be reassessed.

Basics of Fine Particulate Matter

Fine particulate matter (PM2.5) is defined by its size (≤2.5 μm diameter), not its composition. Major sources in the U.S. are forest fires, commercial and residential burning, and diesel engines. In California, a major source is China; on some days up to 30% of fine particulates had crossed the Pacific Ocean.
Of these invisible particles, the average adult in the U.S., based on actual 2015 exposure levels, would inhale about 1 gram in an 80-year lifespan, assuming that he breathes about 10,000 liters of air a day at rest. For comparison, the amount inhaled while smoking 100 cigarettes is about 4 grams.1

In 1997, the EPA established the NAAQS for PM2.5 as 15 μg/ m3. This was lowered to 12 μg/m3 in 2012. This standard has been largely justified on the basis of secret science epidemiology. These regulations are very powerful and impose huge costs on American businesses. The PM2.5 NAAQS, has been used to justify several multi-billion-dollar rules, such as the EPA Clean Power Plan and the CARB Truck and Bus Regulation.

Although a significant effect from such extremely low levels is on its face highly implausible, the stringent EPA regulations are justified primarily by a claim of preventing premature deaths, assuming a value of $10 million per statistical life saved. The controversy over the issue was brought to general attention in 2002 by Professor Robert Phalen.2

Epidemiology of Fine Particulate Matter

The EPA claim that PM2.5 causes "premature deaths" is based on epidemiologic cohort studies purporting to show that the relative risk (RR) for total mortality is slightly greater than 1.0 in U.S. populations exposed to higher levels of PM2.5. No etiologic mechanism has been established, and there is no experimental evidence that inhalation of 1 g or 5 g of PM2.5 can cause death. Weakly positive RRs do not prove causality. Major difficulties include: (1) geographic and temporal variation in PM2.5 mortality risk; (2) exaggeration of actual human exposure by PM2.5 monitors, which measure ambient outdoor levels

far from the subjects; and (3) confounding variables such as co-pollutants. Moreover, the key study relied on by EPA, the American Cancer Society (ACS) 1982 Cancer Prevention Study (CPS II)3 is seriously flawed.

Reanalysis of the American Cancer Society Cancer Prevention Study II (ACS CPS II)

CPS II began in 1982 and is similar to the original CPS I, which began in 1959. The seminal paper published by Pope et al. in 19953 was so controversial that the Health Effects Institute (HEI) sought applications from teams consisting of two to four epidemiologists, statisticians, and airpollution exposure experts to conduct a reanalysis, including "sensitivity analyses to test the robustness of the original findings and interpretations to alternative analytic approaches."4 The HEI Reanalysis published in 2000 did not complete the mandated sensitivity analysis to assess the effect of alternate data.5 HEI published a report in 2009,6 which extended the mortality follow-up of the study from 1989 to 2000, but it did not incorporate the EPA Inhalable Particulate Network (IPN) PM2.5 data7,8 that I had called to the authors' attention in my 2005 paper.9

In 2016 I was able to obtain access to data in an original 1982-1988 version of CPS II. The data had been previously inaccessible since 1995 despite a congressional subpoena and repeated requests by different agencies. I am the only independent scientist who has gained access to the individual level data in both CPS I and CPS II. I was able to reproduce the same key results as Pope et al. by doing exactly what the authors did in 1995.3 However, their results were sensitive to the PM2.5 data that they used and to their particular analysis.

HEI did not follow its own mandate to conduct a comprehensive reanalysis. In particular, their sensitivity analysis was not done properly. Of the 13 teams that submitted reanalysis applications, HEI selected a 31-member team based in Canada, headed by statistician Daniel Krewski. It included a geographer, Michael Jerrett, and another statistician, Richard Burnett, but only had one epidemiologist, Yue Chen. Chen's degree was from Shanghai Medical University, and he was not a coauthor on either the 2000 HEI report5 or the 2009 HEI report.6 Thus, to reanalyze a major U.S. epidemiological study, HEI used a Canadian team that had essentially no epidemiologist.

An early clue to the existence of problems is seen in Figure 21 in the 2000 HEI Reanalysis Report.5 (Figure 1 in this article.) This map shows that in 50 cities across the U.S. the level of PM2.5 mortality risk varies. Higher risks were found mainly in the Rust Belt or the Ohio Valley, and levels were actually reasonably low

in California and throughout most of the western part of the U.S. Beginning in 2002, I asked the head of HEI, Daniel Greenbaum, and its principal scientist, Aaron Cohen, to send me the underlying data for that map. For 16 years, they have consistently refused to reveal this data to me.

Fine Particles and Mortality Risk
Figure 1. PM2.5 Levels and Mortality Risk in the U.S. [Reprinted from 2000 HEI Reanalysis Report,5 with permission.]

Thus, using the HEI PM2.5 data of Pope et al., 3 there is a statistically significant slight increase in RR of 1.082. That means that if the PM2.5 level increases by 10 μg/m3, the risk of dying goes up by about 8%. But, using the IPN PM2.5 data, the effect is nonsignificant, RR = 1.025 (95% CI, 0.990-1.061). Note that if one divides the U.S. into the Ohio Valley (Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia) and the rest of the country, the RR is indistinguishable from 1.0, no matter what PM2.5 data is used. Only by combining the Ohio Valley, which has both a higher mortality risk and a higher level of PM2.5, with the rest of the country can HEI show a statistically significant effect.

My reanalysis10 has been published online since Mar 28, 2017, and so far its validity has not been challenged. The selection of data by HEI was also very interesting, as seen in Table 2. There were actually 11 counties in California that were part of the IPN network, and the HEI analyses omitted 7 of the 11 counties for reasons the authors have not explained. HEI had data from 50 different cities, and the only ones they included from California were Fresno, Los Angeles, San Francisco, and San Jose (in Santa Clara County). Two other counties that represent the extremes in PM2.5 levels are highlighted in the table. The Pope 1995 paper3 was based primarily on these extremes. HEI had Albuquerque, N.M., at 9 μg/

My analysis of the CPS II data revealed that the county of residence of subjects could be approximated based on the ACS Division and Unit numbers. The CPS II data were collected by about 70,000 researchers, including myself, who enrolled 1.2 million subjects in Fall 1982. I performed an analysis comparable to the HEI Reanalysis, as shown in Table 1. The PM2.5 data labeled IPN in the table was published in EPA reports from the Inhalable Particulate Network (IPN) by David Hinton et al. in 19847 and 1986.8 Because of the evasions that I have experienced in attempting to obtain information from HEI, I took a closer look at the 2000 HEI Reanalysis Report and found it actually contains the data that I used, although in a mislabeled and somewhat altered form. I have designated that data as HEIDC, which is labeled PM2.5 DC in the 2000 Report. This data was indirectly referred to in a couple of places in the 2000 HEI report, although it was not analyzed.

m3, as the lowest value, and Huntington, W.V., at 34.4 μg/m3, as the highest value. This is curious because the data that comes from the IPN network actually shows different high and low values. In fact, there is no measurement in the IPN for Huntington, W.V., but rather for Wheeling, W.V., listed in the IPN column. From the table, both the low and the high values are in California, both of which omitted from the HEI analysis. The low value is 10.6 μg/m3 in Santa Barbara County, and the high value is 42.0 μg/m3 in Riverside County. The PM2.5 DC data that I found in the 2000 HEI Report appendix table, labeled HEIDC by me, had more than 50 cities, but only five of the 63 total cities were from California. The IPN network as a whole has about 85 cities. These major inconsistencies need to be addressed by these investigators. And so far, there is nothing but silence. This is only one of the issues that must be addressed if the investigators want to maintain any credibility.

Table 1. Enstrom Analyses of ACS CPS II Data Using Three Sources of PM2.5 Data

Table 2. Comparison of Data on PM2.5 and Mortality from Enstrom and HEI9

Relationship between PM2.5 and Mortality in California

Because of the Feb 26, 2010, conference in Sacramento, which I attended along with Professor Robert Phalen, other prominent scientists, and impacted business groups, we were able to get an analysis done by HEI that dealt with the California portion of the national CPS II results. The California data was partitioned out from the national analysis in the 2009 HEI Report.6 Based on the four HEI California counties shown in Table 2, the RR is about 0.9, significantly below 1.0, as shown in Table 3. This inverse relationship was reproduced using either the HEI data or the IPN data. Of course, this relationship cannot be etiologically correct, but it shows what can result from data omission and manipulation.

Table 3. Relative Risk for PM2.5 and Mortality in California Based on Four Counties

Table 4. PM2.5 and Total Mortality in Six California Cohorts Both my analysis and that by Thurston et al. on the NIH
AARP cohort,14 summarized in Table 5, show no effect nation- wide or in California.

There are actually six California cohorts that have been used to analyze the relationship between PM2.5 and total mortality, as shown in Table 4. The cohort that I initially used is labeled CA CPS I;9 the cohort used by Jerrett et al.11 is labeled CA CPS II. The Adventist Health Study of Smog (AHSMOG) was the original cohort study in California.12 There are also the California Teachers Cohort,10 the "West" portion of the Medicare Cohort Air Pollution Study (MCAPS),13 and the National Institutes of Health-American Association of Retired Persons (NIH AARP) cohort, which was published in 2016 by Thurston et al.14 The NIH AARP cohort is supposed to be an open access database, but is apparently currently controlled by Thurston. I have been able to get access to only the California portion of the data, and my analysis shows no effect in California. Averaging all six cohorts gives an RR of exactly 1.00, which means no relationship between PM2.5 and total mortality.
The lack of an effect in California might explain why Pope et al.3 omitted seven California cities from the national analysis. As Figure 1 shows, there is tremendous variation across the country. Yet the most severe regulations are in California, despite the clear absence of mortality risk there!

Table 5. Comparison of Enstrom and Thurston Analyses for
U.S. and California

An International Perspective on PM2.5

Despite the null effect shown by their own data and analyses, prominent advocates of drastic measures to reduce PM2.5 levels state in a major paper in the May 13, 2017, Lancet that ambient PM2.5 was the fifth-ranking mortality risk factor worldwide in 2015. Aaron J. Cohen, until recently HEI Principal Scientist, is the lead author, and Pope is a coauthor. The study is part of the World Health Organization (WHO) Global Burden of Disease (GBD) Project and was largely funded by HEI. The article claims that PM2.5 causes 4.2 million deaths annually worldwide, with 88,000 deaths in the U.S. (see Table 6). The mean PM2.5 level is

8.4 μg/m3 in the U.S. and 58.4 μg/m3 in China. Clearly, the PM2.5 level and premature deaths are low in the U.S. and high in China, India, and Africa.

Table 6. Global Deaths Attributed to PM 15

Agenda-driven Science

Since publishing my 2005 critique of the relationship between PM2.5 and total mortality9 and my 2017 critique,10 I have sent numerous requests to Pope, ACS, HEI, and others, inviting a rebuttal. I have received no response that confirms or refutes any of my analyses. It has, however, been incorrectly asserted that, "The study by Enstrom does not contribute to the larger body of evidence on the health effects of PM2.5." ACS has criticized me for having CPS II data that they have deliberately tried to keep secret. My invitations to authors and ACS officials to attend meetings, teleconferences, and symposia have simply been ignored. They even ignored an August 1, 2013, subpoena from the U.S. House Science, Space, and Technology Committee.

The control over air pollution research and assessments that is recognized by EPA is not based on special expertise in epidemiology. Pope, the self-proclaimed "world's leading expert on the effects of air pollution on health," is a professor of economics at Brigham Young University and holds a 1981 Ph.D. in agricultural economics from Iowa State University, where he studied the dynamics of crop yields. Michael Jerrett, who is one of the most prolific publishers and a member of the HEI reanalysis team, has a 1996 Ph.D. in geography from the University of Toronto, and no formal training in epidemiology. Aaron J. Cohen, until recently HEI's Principal Scientist, does hold a 1991 D.Sc. degree in epidemiology from Boston University, but he has badly misused the principles and standards of epidemiology. Although he supervised the 1998-2000 HEI Reanalysis Project, he has refused to clarify findings from this project and has refused to confirm or refute the findings in my 2017 CPS II reanalysis. It is very disturbing that ACS has allowed CPS II data to be used for more than 20 years for research that misuses the principles and standards of epidemiology and that has nothing significant to do with cancer.

The principal qualification for admission to the elite circle of influence appears to be dedication to the agenda of global controls on economic activity via air pollution regulations. The conclusion reached by researchers is apparently predetermined, as stated in the last paragraph of the GBD study on ambient air pollution: "As the experience in the U.S. suggests, changes in ambient PM2.5 associated with aggressive air quality management programmes, focused on major sources of air pollution including coal combustion, household burning of solid fuels, and road transport, can lead to increased life expectancy over short timeframes."15

What is the state of scientific integrity? It is very dangerous to one's career to criticize views backed by powerful interests, and I do it only because I believe current trends are anti- science and dangerous to our country. Simply being a passive observer is no longer acceptable.

To disclose my own background, I obtained a Ph.D. in physics in 1970, but I became an epidemiologist starting in 1973 in order to apply the rigorous principles of physics to observational epidemiology. I had a long career as a research professor and researcher at the UCLA School of Public Health. My research has examined the influence of environmental and lifestyle factors on mortality, and has on occasion reached politically incorrect conclusions. My research in air pollution epidemiology has been strongly influenced by Dr. Frederick Lipfert and Professor Robert Phalen. In February 2010 I was terminated from UCLA without warning and told that my "research is not aligned with the academic mission of the Department." In

February 2015 I settled a three-year federal whistleblower retaliation lawsuit against UCLA and my termination was reversed. My case and some of the issues related to my air pollution epidemiology research have been discussed in this journal.16

My background and publications, including rejections of my research, often without peer review, are documented on my website, www.scientificintegrityinstitute.org. I believe that major journals simply will not accept articles that challenge the established view. Moreover, authors of the papers promoting PM2.5 premature deaths omit null results, even their own. For example, Jerrett is the lead author of a 2007 study that shows no increased mortality associated with PM2.5 in the CPS II cohort if the results are divided into five time periods.17 Although researchers are paid millions of dollars, they're not under any obligation to address any of the concerns about their work. Those who disagree with the agenda are denied research funding.

We must prevent American science from following historical examples like that of Trofim Denisovich Lysenko. He was a phony plant geneticist, who gained the favor of Joseph Stalin because he didn't believe in Mendelian genetics. Lysenko's views controlled much of Soviet agriculture in the 1930s, 1940s, and 1950s, with devastating effect. False crop statistics were published, and dissenting scientists were purged. Nikolai Vavilov, a renowned plant geneticist, was imprisoned by Stalin and died of malnutrition.
Concerns about integrity in Western science are being raised. Richard Horton, editor of The Lancet, writes: "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness."18

A U.S. House of Representatives bill called the Secret Science Reform Act was passed in 2014 and 2015 in order "to prohibit the Environmental Protection Agency from proposing, finalizing, and disseminating regulations or assessments based upon science that is not transparent or reproducible." The bill was revived in 2017 as the Honest and Open New EPA Science Treatment (HONEST) Act, labeled H.R. 1430, and was passed by the U.S. House of Representatives.
American science needs to guard against the heirs of Sinclair Lewis's protagonist in his 1927 novel Elmer Gantry, an itinerant preacher who is able to sell false religion to gullible people. We have prominent scientists who have successfully sold the notion that inhaling 1 g of invisible particles over an 80-year lifetime can cause premature death.

Conclusions

There is strong evidence from two large national cohorts that PM2.5 does not cause premature deaths in the US. There is strong evidence that this relationship has been falsified by EPA, the Health Effects Institute, and leading researchers for more than 20 years. Better oversight to assure scientific integrity, such as access to data, transparency, and consideration of opposing views, is imperative.

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10. Dunn on US EPA Linear No Threshold Misconduct 2018.

This is a paper by the submitter Dunn that is intended to be an abstract as a presentation to a conference of the American Nuclear Society and the Health Physics Society on the problem of Linear No Threshold toxicology. The Conference is scheduled for early October 2018.

AN ENVIRONMENTAL NOBLE LIE,
LINEAR NO-THRESHOLD Radiation Biophysics Toxicology,
IT NEEDS TO GO

John Dale Dunn MD JD
American Nuclear Society/Health Physics Society Conference
Sept 30-Oct 3, 2018
Pasco, Washington

Abstract
The United States Environmental Protection Agency (USEPA) is charged with identifying and mitigating environmental risks. This article will discuss US EPA misguided decision to use Linear No Threshold as the template for Radiation Biophysics and Toxicology.
The Health Physics Society (HPS) has stated that reliance on the LNT model "...tends to foment the public's fear of all types of radiation . . . reliance on the LNT model, especially at very low doses and dose rates, is inappropriate and can exaggerate the risk." (Kirner 2017) (Ring et al. 2017). The HPS also condemns "collective" (cumulative) dose as a measure of biological radiation risk.
One hit or linear no threshold (LNT) radiation biophysics makes no sense as a theory for carcinogenesis. Most cancer cell types are hyper/multiploid due to telomeric mitotic dysfunction, not mutations of genetic code. Carcinogenesis is also enabled by immune system failure to eliminate malignant cell lines. Both phenomena are associated with aging.

The US EPA acceptance of the assertions on LNT of Biological Effects of Atomic Radiation (BEAR), Biological Effects of Ionizing Radiation (BEIR) and National Academy of Science (NAS) committees, has been so irrational as to assume there is no safe level of ionizing radiation. Nonsense.
The LNT cancer theorists ignore protective biological processes, even hormetic, certainly no effect evidence of low level radiation. (Ulsh 2010; Sacks and Siegel 2017; Welsh et al. 2017), Scott 2017), acknowledged by the National Council on Radiation Protection and Measurements (NCRP) over 15 years ago (NCRP 2001). "These experimental observations are not compatible with a single hit mechanism. . . hypothesis." (Trott and Rosemann 2000)
The fruit fly research by Hermann Muller and Curt Stern founded the LNT model, but the research actually showed a threshold, misrepresented by Muller, a committed advocate of LNT (Siegel et al. 2015; Calabrese 2017a, 2017b). Muller was a deceitful, relentless advocate of LNT, and, as a Nobel Laureate, very influential. (Calabrese 2017c)
The American Association of Physicists in Medicine (AAPM) strongly objects to the LNT approach as creating harm from adverse attitudes about imaging procedures. They consider the risks at or below 50 mSv [5 rem] for single procedures or 100 mSv [10 rem] for multiple procedures not detectable.
The USEPA use of LNT causes harm with no evidence of worthwhile benefit. US EPA claims that LNT is "conservative" and "cautious," translated as adoption of the misbegotten precautionary principle. The Fukishima mitigation, for example, was excessive, harmful and expensive, applied at doses far below the range of any negative public health consequences (Siegel et al. 2017c; Welsh et al. 2017).

Conclusions
The US EPA has been irresponsible and unscientific in its application of the Linear No Threshold template for radiation biophysics and toxicology. US EPA risk management is unscientific, unreliable and unjustified, wrongly derived from high dose rate environments and bench experimentation. Rat and mouse studies with exposures at lethal levels have created a long list of "carcinogens" that are then part of the LNT toxicology deception. (Calabrese 2018)
Society has become so fearful of radiation and chemicals that unnecessary steps are taken, and other risks are accepted, compliance costs are tolerated and are pursued energetically and expensively in a risk management environment of zero tolerance.
From the 1979 Three Mile Island to Fukishima in 2011, radiation incidents impacting large areas repeatedly show potential, variable risk for the immediate plant area, but, for example, even the terrible Chernobyl explosion, a stunningly limited harm from radiation beyond that.
The Fukishima event caused no radiation-related deaths (UNSCEAR 2013b), however the scare and the evacuation increased mortality, particularly in the elderly (Nomura et al. 2013; Yasumura et al. 2013; Uchimura et al. 2014, Ichiseki 2013) and the evacuations were scientifically unethical as a risk management strategy (Akabayashi and Hayashi 2012).
Changes, long overdue, on the matter of LDDR radiation risk management must go forward with the knowledge that adverse health effects are not detectable and that radiation exposures have a no effect, a harmful threshold of effect and even a sweet spot where radiation produces hormetic beneficial effects. (Calabrese 2013, Scott, 2017)
The USEPA Scientific Advisory Board (SAB) properly recommended a "change in the agency culture, change in how the agency works, and increased support for scientists and managers in programs and regional offices responsible for science integration." (Swackhamer and Burke 2012)
The radiation biophysics and toxicological precautionary principle needs a retirement in favor of rational risk assessment and mitigation.

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Below is my abstract/monograph for a presentation to the Gulf Coast Geophysical Societies conference scheduled for late September of 2018. Here I summarize much of the research on human health impacts from warmer temperatures—that shows the benefits of warming. That debunks the catastrophic and ominous claims of the US EPA. There are certainly other reasons to object to US EPA clams that CO 2 is a pollutant and dangerous, but underlying those claims is their fraudulent and unsupported claim that warming would be deleterious to human health—when the opposite is true.

This if offered as just one exhibit that shows the US EPA has been irresponsible in its claims about the impact of CO2 rise and warming—there are other scientific research studies that show the claims about

11. Dunn on Global Warming and Climate Change EPA misconduct—the scam of making Carbon Dioxide a pollutant.

Warming is a Benefit to Humans and the Biosphere

John Dale Dunn MD JD

The Intergovernmental Panel on Climate Change (IPCC) predicts a global temperature increase of 3C or more by 2100, but other experts believe the best guess is 1C or less. We assert that increases in average temperature of the planet from the current 60 degrees F. will be beneficial to human health and the biosphere.

IPCC's alarms have led to widespread fear of the health effects of global warming (Schulte, 2008) and even political attack ads claiming people are dying of "carbon pollution" (WMC, 2015). These statements have no basis in scientific research and in fact and based on the evidence, warming will be a benefit to all living things. Carbon Dioxide that increases to even 1000 PPM will be beneficial to the biosphere and make the planet more hospitable and arable.

In fact, the litany of climate extremes postulated by the IPCC has been falsified by the actual record of climate measurements and observations. None of the environmental disasters, human displacements and disruptions predicted have come to pass during the past ten years, even as atmospheric carbon dioxide has continued to increase. We all know of the temperature "pause" that has accompanied an increase in atmospheric Carbon Dioxide.

In this document the benefits of fossil fuel use, and even warming, if it did occur, are explained in greater detail.

A warmer planet is beneficial to humanity as warmer temperatures lead to decreases in temperature-related mortality, premature deaths due to cardiovascular and respiratory disease, and stroke occurrences, and has little if any influence on vector-borne diseases such as malaria and dengue fever since vectors generally are not respectful of the definition of "tropical diseases.

Cool and colder temperatures kill while warmer temperatures are beneficial. It is troubling that, in the face of this evidence, environmentalists and politicians continue to frighten people with predictions of "killer heat waves" in a slightly warmer world. And yet, such claims are made. Severe heat waves are a weather phenomenon, not causally linked to average global temperature. Deaths from heat waves are most dramatic in areas with lack of adaptation—or general medical care for the disabled—who suffer from poor housing and medical problems that make them more susceptible.

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Global Warming and Mortality Rates

- Medical research confirms and explains why cooler, colder temperatures cause increased disease and death rates. Warmer temperatures are associated with health benefits and decreased deaths.

- Population studies around the world show that warmer temperatures lead to a net decrease in mortality worldwide, even in those areas described as tropical.

- Carbon dioxide (CO2) is invisible, odorless, nontoxic, and does not seriously affect human health until the CO2 content of the air reaches approximately 15,000 ppm, more than 37 times greater than the current concentration of atmospheric CO2 (Luft et al., 1974). There is no reason to be concerned about any direct adverse human health consequences of the ongoing rise in the air's CO2 content now or in the future,

currently at about 400 parts per million (0.04%) since even extreme model predictions by warming advocates are for less than 2000 parts per million (2%).

The Intergovernmental Panel on Climate Change (IPCC), however, sees looming health threats. The Summary for Policymakers of IPCC's Working Group II's report for the Fifth Assessment Report (AR5) identified eight "key risk factors" regarding the effect of climate change on human wellbeing, all of them allegedly "identified with high confidence" (IPCC, 2014, emphasis in original). They are:

i) Risk of death, injury, ill-health, or disrupted livelihoods in low-lying coastal zones and small island developing states and other small islands, due to storm surges, coastal flooding, and sea level rise. 37[RFC1-5]

ii) Risk of severe ill-health and disrupted livelihoods for large urban populations due to inland flooding in some regions. 38 [RFC 2 and 3]

iii) Systemic risks due to extreme weather events leading to breakdown of infrastructure networks and critical services such as electricity, water supply, and health and emergency services. 39 [RFC 2-4]

iv) Risk of mortality and morbidity during periods of extreme heat, particularly for vulnerable urban populations and those working outdoors in urban or rural areas. 40 [RFC 2 and 3]

v) Risk of food insecurity and the breakdown of food systems linked to warming, drought, flooding, and precipitation variability and extremes, particularly for poorer populations in urban and rural settings. 41 [RFC 2-4]

vi) Risk of loss of rural livelihoods and income due to insufficient access to drinking and irrigation water and reduced agricultural productivity, particularly for farmers and pastoralists with minimal capital in semi-arid regions. 42 [RFC 2 and 3]

vii) Risk of loss of marine and coastal ecosystems, biodiversity, and the ecosystem goods, functions, and services they provide for coastal livelihoods, especially for fishing communities in the tropics and the Arctic. 43 [RFC 1, 2, and 4]

viii) Risk of loss of terrestrial and inland water ecosystems, biodiversity, and the ecosystem goods, functions, and services they provide for livelihoods. 44 [RFC 1, 3, and 4]

There is no scientific basis for believing global temperatures will rise to levels high enough to bring about any of these risks. Indeed, there is sound scientific support for believing warming will be a net positive rather than negative.

Here, we summarize only research on the effects of rising global temperatures on human health and the medical literature shows warmer temperatures and a smaller difference between daily high and low temperatures that results from some rising temperatures as occurred during the twentieth and early twenty-first centuries, reduce mortality rates (the subject of this section) as well as illness and mortality due to cardiovascular and respiratory disease and stroke occurrence.

Similarly, the research is quite clear that climate has exerted only a minimal influence on recent trends in vector-borne diseases such as malaria, dengue fever, and tick-borne diseases. Other factors, many of them related to economic and technological setbacks or progress and not to weather, are far more important in determining the transmission and presence of these "tropical" diseases that are not so tropical at all.

Warmer Temperature Impacts on Human Health

- Warmer temperatures lead to a decrease in temperature-related mortality, including deaths associated with cardiovascular disease, respiratory disease, and strokes. The evidence of this benefit comes from research conducted in every major country of the world.

- In the United States the average person who died because of cold temperature exposure lost in excess of 10 years of potential life, whereas the average person who died because of extreme heat related event lost no more than a few days or weeks of life because heat has a greater effect on more seriously debilitated and ill persons.

- In the U.S., some 4,600 deaths are delayed each year as people move from cold northeastern states to warm southwestern states. Between 3 and 7% of the gains in longevity experienced over the past three decades was due simply to people moving to warmer states.

- Cold-related deaths are far more numerous than heat-related deaths in the United States and the world. Coronary (heart attack) and cerebral thrombosis (stroke) account for about half of all cold-related mortality, events that are directed related to blood vessel and blood viscosity effects of cool or cold environments.

- Global warming, if it did occur, even to the degree predicted in the extreme, will reduce the incidence of cardiovascular diseases related to low temperatures and wintry weather by a much greater degree than the warming might increase the incidence of deaths or illness attributable to heat. Heat illness primarily produces fluid and electrolyte disturbances, loss of core temperature control and organ dysfunction from dehydration, circulatory failure and heat caused stress, not clotting events.

- The heat wave deaths of 1995 in Chicago and 2003 in Europe are pointed to by advocates of the claim that heat stress deaths will increase with any warming that might occur, but a closer look at heat event death rates in some of the studies below show acclimation increased awareness have blunted any heat stress death increases. In the case of Chicago and Europe temps rose to over 100 but the availability of air conditioning and ventilation along with attention to the needs of elderly and disabled individuals was determined to be a major reason for heat deaths.

- The heat deaths that occur during severe heat events are the result of stress and inability to acclimate to maintain normal core temperature control and avoid dehydration. Acclimatization and proper attention to the vulnerable populations failed in Chicago in 1995 and Europe, particularly France in 2003, for example with hundreds of heat deaths in the former and 20,000 or more deaths in the later.

- A large body of scientific examination and research contradicts and disproves the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming. Malaria is historically a disease that was endemic to cool and even cold climates like Finland and Russia but has been suppressed by hygienic and vector control

measures.
- Concerns over large increases in vector-borne diseases such as dengue as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue disease. The Aedes Aegypti Anopheles and Asian Tiger mosquitos all have been found at higher latitudes.
- While temperature and climate effect the geographical distribution of ticks, they are not among the significant factors determining the incidence of tick-borne diseases. Moreover the effect of small increases in climate temperature, if does occur with certainly not impact the range of ticks that now live in the high latitudes, even in the mountains of those high latitudes.

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Basis in Medical Science

Medical science explains why colder temperatures often cause diseases and sometimes fatalities whereas warmer temperatures are associated with health benefits.

Wang et al. collected daily mortality and meteorological data from 66 communities across China over the period 2006-2011. They then subjected these data to a series of analyses to elucidate the relationship between cold spell characteristics and human mortality. And what did those analyses reveal?

Not surprisingly, cold spells significantly increased human mortality risk in China. As indicated in Figure 1 below, the combined cumulative excess mortality risk (CER) for all of China when defining cold spells with a 5th and 2.5th percentile temperature intensity threshold was 28.5 and 39.7 percent, respectively. However, there were notable geographic differences; CER was tempered and near zero in the colder/higher latitudes, but increased to 58.7 and 92.9 percent at the corresponding 5th and 2.5th percentile temperature intensity

thresholds for the warmest and most southern latitude. Such geographic differences in mortality risk, according to the authors, are likely the product of better physiological and behavioral acclimatization of the northerly populations to cold weather.

Clearly, cold spells kill; and as has been found in almost every study of the subject, the risk of death from cold spells far exceeds that from heat waves (see the many reviews we have posted on this topic confirming this fact in our Subject Index under the heading Health Effects of Temperature: Hot vs, Cold Weather). As such, therefore, a little global warming would likely result in a net saving of lives by reducing the number of deaths that occur at the cold end of the temperature spectrum.

Antonio Gasparinni (2015) was lead author for a large international group of researchers who studied the effect of temperature extremes on death rates. Gasparrini and his co-authors analyzed data from 384 locations including the countries of Australia, Brazil, Canada, China, Italy, Japan, South Korea, Spain, Sweden, Taiwan, Thailand, the United Kingdom and the United States of America. By fitting a standard time-series Poisson model to the data obtained for each location, while controlling for trends and day of the week, they estimated temperature-mortality associations with a distributed lag non-linear model with 21 days of lag, after which they pooled the results they obtained in a multivariate meta-regression that included country indicators and temperature averages and ranges.

This work allowed them to calculate the number of human deaths attributable to heat and cold -- defined as temperatures above and below the optimum (minimum mortality) temperature -- for both moderate and extreme temperatures, the latter being defined "using cutoffs at the 2.5th and 97.5th temperature percentiles." And what did they thereby learn?

Based on data pertaining to a total of 74,225,200 human deaths that occurred between 1985 and 2012, the 23 researchers determined that 7.71% of the lives lost were caused by non-optimum temperatures; and among this group they found that "more temperature-attributable deaths were caused by cold (7.29%) than by heat (0.42%)" which makes cold in excess of seventeen times more deadly than heat. And they add, in this regard, that moderate "hot and cold temperatures represented most of the total health burden." Consequently, it seems pretty clear that any successful attempt to reverse or slow any potential increase in Earth's mean global temperature would likely come at a net cost of many human lives the world over, not a savings. The Gasparrini research provides a compelling confirmation of the reality that warmer temperatures are better for human welfare than cooler or colder temperatures. (Gasparrini Lancet 2015)

Keating and Donaldson (2001) explain that "cold causes mortality mainly from arterial thrombosis and respiratory disease, attributable in turn to cold-induced hemoconcentration and hypertension [in the first case] and respiratory infections [in the second case]." McGregor (2005) notes "anomalous cold stress can increase blood viscosity and blood pressure due to the activation of the sympathetic nervous system which accelerates the heart rate and increases vascular resistance (Collins et al., 1985; Jehn et al., 2002; Healy, 2003; Keatinge et al., 1984; Mercer, 2003; Woodhouse et al., 1993)," adding, "anomalously cold winters may also increase other risk factors for heart disease such as blood clotting or fibrinogen concentration, red blood cell count per volume and plasma cholesterol."

Wang et al. (2013) write, "A large change in temperature within one day may cause a sudden change in the heart rate and circulation of elderly people, which all may act to increase the risk of cardiopulmonary and other diseases, even leading to fatal consequences." This is significant for the climate change debate because, as Wang et al. also observe, "it has been shown that a rise of the minimum temperature has occurred at a rate three times that of the maximum temperature during the twentieth century over most parts of the world, which has led to a decrease of the diurnal temperature range (Karl et al., 1984, 1991)."

Robeson (2002) demonstrated, based on a 50-year study of daily temperatures at more than 1,000 U.S.

weather stations that daily (diurnal) temperature variability declines with warming and at a very substantial rate, so this aspect of a warmer world would lead to a reduction in temperature- related deaths.
Clearly, cold spells kill; and as has been found in almost every study of the subject, the risk of death from cold spells far exceeds that from heat waves. As such, therefore, a little global warming would likely result in a net saving of lives by reducing the number of deaths that occur at the cold end of the temperature spectrum.

Keatinge and Donaldson (2004) report coronary and cerebral thrombosis account for about half of all cold-related deaths, and respiratory diseases account for approximately half of the rest. They say cold stress causes an increase in arterial thrombosis "because the blood becomes more concentrated, and so more liable to clot during exposure to cold." As they describe it, "the body's first adjustment to cold stress is to shut down blood flow to the skin to conserve body heat," which "produces an excess of blood in central parts of the body," and to correct for this effect, "salt and water are moved out from the blood into tissue spaces," leaving behind "increased levels of red cells, white cells, platelets and fibrinogen" that lead to increased viscosity of the blood and a greater risk of clotting.
Keatinge and Donaldson also note "cold spells are closely associated with sharp increases in mortality rates," and "deaths continue for many days after a cold spell ends." On the other hand, they report, "increased deaths during a few days of hot weather are followed by a lower than normal mortality rate," because "many of those dying in the heat are already seriously ill
and even without heat stress would have died within the next 2 or 3 weeks."
With respect to the implications of global warming for human mortality, Keatinge and Donaldson state "since heat-related deaths are generally much fewer than cold-related deaths, the overall effect of global warming on health can be expected to be a beneficial one." They report, "The rise in temperature of 3.6°F expected over the next 50 years would increase heat-related deaths in Britain by about 2,000 but reduce cold-related deaths by about 20,000."
Keating and Donaldson's reference to deaths that typically would have occurred shortly even without excess heat is a phenomenon researchers call "displacement" or "harvesting." A study from Germany found "cold spells lead to excess mortality to a relatively small degree, which lasts for weeks," while "the mortality increase during heat waves is more pronounced, but is followed by lower than average values in subsequent weeks" (Laschewski and Jendritzky, 2002). The authors say the latter observation suggests people who died from short-term exposure to heat possibly "would have died in the short term anyway." They found the mean duration of above-normal mortality for the 51 heat episodes that occurred from 1968 to 1997 was 10 days, with a mean increase in mortality of 3.9%, after which there was a mean decrease in mortality of 2.3% for 19 days. Hence, the net effect of the two perturbations was an overall decrease in mortality of 0.2% over the full 29-day period.
The US EPA web site discussion of heat wave deaths referenced below reveals that the EPA recognizes heat wave deaths are not reliably counted because of loose death certificate definitions of heat caused versus heat related. Cardiovascular deaths is used as a catch all descriptor Although the deaths attributed to severe heat waves are described as Cardiovascular, the mechanism is metabolic and physiologic dysfunction and a collapse of the systems that maintain temperature equilibrium in endotherms like humans. The victims don't die of a heart attack, a coronary ischemic event caused by clots and narrowed coronary arteries, an occlusive event, they die of temperature effects and the failure of internal systems, including lung and cardiovascular system, solid organ, and brain malfunctions in the face of heat stress, dehydration, and rising core temperatures, along with dehydration and loss of mechanisms to maintain normal temperature. The victims are debilitated, and live in a stressfully hot environment and succumb for failure to acclimate and maintain normal body physiology.

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Observational Research in Asia

Behar (2000) studied sudden cardiac death (SCD) and acute myocardial infarction (AMI) in Israel, concentrating on the role temperature may play in the incidence of these health problems. Behar notes "most of the recent papers on this topic have concluded that a peak of SCD, AMI and other cardiovascular conditions is usually observed in low temperature weather during winter." He cites an Israeli study by Green et al. (1994), which reported between 1976 and 1985 "mortality from cardio-vascular disease was higher by 50% in mid-winter than in mid-summer, both in men and women and in different age groups," even though summer temperatures in the Negev, where much of the work was conducted, often exceed 30°C and winter temperatures typically do not drop below 10°C. Behar concludes these results "are reassuring for populations living in hot countries."

Kan et al. (2003) investigated the association between temperature and daily in Shanghai, China, finding a V-like relationship between total mortality and temperature that had a minimum mortality risk at 26.7°C. Above this optimum temperature, they observe, "total mortality increased by 0.73% for each degree Celsius increase; while for temperatures below the optimum value, total mortality decreased by 1.21% for each degree Celsius increase." The net effect of a warming in Shanghai, China, therefore, would likely be reduced mortality on the order of 0.5% per degree Celsius increase in temperature, or perhaps more.

Guo et al. (2012) examine the nonlinear and delayed effects of temperature on cause- specific and age-specific mortality employing data from 1999 to 2008 for Chiang Mai, Thailand with a population of 1.6 million people. Controlling for season, humidity, ozone, and particulate matter (PM10) pollution, the three researchers found "both hot and cold temperatures resulted in immediate increase in all mortality types and age groups," but "the hot effects on all mortality types and age groups were short-term, while the cold effects lasted longer." The cold effects were greater, with more people dying from them than from the effects of heat.

Lindeboom et al. (2012) used daily mortality and weather data for the period 1983–2009 pertaining to Matlab, Bangladesh, to measure lagged effects of weather on mortality, controlling for time trends and

seasonal patterns. The four researchers report "mortality in the Matlab surveillance area shows overall weak associations with rainfall, and stronger negative association with temperature." They determined there was "a 1.4% increase in mortality with every 1°C decrease in mean temperature at temperatures below 29.2°C," but only "a 0.2% increase in mortality with every 1°C increase in mean temperature."

Wang et al. (2013) evaluated the short-term effect of diurnal temperature range (DTR) on emergency room (ER) admissions among elderly adults in Beijing. The nine researchers report "significant associations were found between DTR and four major causes of daily ER admissions among elderly adults in Beijing." They state "a 1°C increase in the 8-day moving average of DTR (lag 07) corresponded to an increase of 2.08% in respiratory ER admissions and 2.14% in digestive ER admissions," and "a 1°C increase in the 3-day and 6-day moving average of DTR (lag 02 and lag 05) corresponded to a 0.76% increase in cardiovascular ER admissions, and a 1.81% increase in genitourinary ER admissions, respectively.

Wu et al. (2013) assessed the health effects of temperature on mortality in four subtropical cities of China (Changsha, Kunming, Guangzhou, and Zhuhai). The 11 researchers report a U-shaped relationship between temperature and mortality was found in the four cities, indicating "mortality is usually lowest around a certain temperature and higher at lower or higher temperatures." Although "both low and high temperatures were associated with increased mortality in the four subtropical Chinese cities," Wu et al. state the "cold effect was more durable and pronounced than the hot effect."

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Observational Research in Europe

Keatinge and Donaldson (2001) analyzed the effects on human mortality of temperature, wind, rain, humidity, and sunshine during high pollution days in the greater London area over the period 1976–1995. They observed simple plots of mortality rate versus daily air temperature revealed a linear increase as temperatures fell from 15°C to near 0°C. Mortality rates at temperatures above 15°C, however, were

"grossly alinear," as they describe it, showing no trend. Only low temperatures were found to have a significant effect on immediate and long-term mortality. They conclude "the large, delayed increase in mortality after low temperature is specifically associated with cold and is not due to associated patterns of wind, rain, humidity, sunshine, SO2, CO, or smoke."

Kysely and Huth (2004) calculated deviations of the observed number of deaths from the expected number of deaths for each day of the year in the Czech Republic for the period 1992– 2000. They found "the distribution of days with the highest excess mortality in a year is clearly bimodal, showing a main peak in late winter and a secondary one in summer." Regarding the smaller number of summer heat-wave-induced deaths, they also found "a large portion of the mortality increase is associated with the harvesting effect, which consists in short-term shifts in mortality and leads to a decline in the number of deaths after hot periods (e.g. Rooney et al., 1998; Braga et al., 2002; Laschewski and Jendritzky, 2002)." For the Czech Republic, they report, "the mortality displacement effect in the severe 1994 heat waves can be estimated to account for about 50% of the total number of victims." As they describe it, "people who would have died in the short term even in the absence of oppressive weather conditions made up about half of the total number of deaths."

Diaz et al. (2005) examined the effect of extreme winter temperature on mortality in Madrid, Spain for people older than 65, using data from 1,815 winter days over the period 1986– 1997, during which time 133,000 deaths occurred. They found that as maximum daily temperature dropped below 6°C, which they describe as an unusually cold day (UCD), "the impact on mortality also increased significantly." They also found the impact of UCDs increased as the winter progressed, with the first UCD of the season producing an average of 102 deaths/day at a lag of eight days and the sixth UCD producing an average of 123 deaths/day at a lag of eight days.

Laaidi et al. (2006) conducted an observational population study in six regions of France between 1991 and 1995 to assess the relationship between temperature and mortality in areas of widely varying climatic conditions and lifestyles. In all cases they found "more evidence was collected showing that cold weather was more deadly than hot weather." These findings, the researchers say, are "broadly consistent with those found in earlier studies conducted elsewhere in Europe (Kunst et al., 1993; Ballester et al., 1997; Eurowinter Group, 1997; Keatinge et al., 2000; Beniston, 2002; Muggeo and Vigotti, 2002), the United States (Curriero et al., 2002) and South America (Gouveia et al., 2003)." They also say their findings "give grounds for confidence in the near future," stating even a 2°C warming over the next half century "would not increase annual mortality rates."

Analitis et al. (2008) analyzed short-term effects of cold weather on mortality in 15 major European cities using data from 1990–2000, and found "a 1°C decrease in temperature was associated with a 1.35% increase in the daily number of total natural deaths and a 1.72%, 3.30% and 1.25% increase in cardiovascular, respiratory, and cerebro-vascular deaths, respectively." In addition, they report "the increase was greater for the older age groups," and the cold effect "persisted up to 23 days, with no evidence of mortality displacement." They conclude their results "add evidence that cold-related mortality is an important public health problem across Europe and should not be overlooked by public health authorities because of the recent focus on heat-wave episodes."

Wichmann et al. (2011) investigated the association between the daily three-hour maximum apparent temperature (which reflects the physiological experience of combined exposure to humidity and temperature) and deaths due to cardiovascular disease (CVD), cerebrovascular disease (CBD), and respiratory disease (RD) in Copenhagen over the period
1999–2006.

Monthly deaths in the Castile-Leon region of Spain attributable to cardiovascular disease.

Source: Adapted from Fernandez-Raga et al. (2010).

During the warm half of the year (April–September), they found a rise in temperature had an inverse or protective effect with respect to CVD mortality (a 1% decrease in death in response to a 1°C increase in apparent temperature). This finding is unusual but also has been observed in Dublin, Ireland, as reported by Baccini et al. (2008, 2011). Wichmann et al. found no association with RD and CBD mortality. At the other end of the thermal spectrum, during the cold half of the year, all three associations were inverse or protective. This finding, according to the researchers, is "consistent with other studies (Eurowinter Group, 1997; Nafstad et al., 2001; Braga et al., 2002; O'Neill et al., 2003; Analitis et al., 2008)."
Matzarakis et al. (2011) studied the relationship between heat stress and all-cause mortality in the densely populated city of Vienna (Austria). Based on data from 1970–2007, and after adjusting the long-term mortality rate to account for temporal variations in the size of the population of Vienna, temporal changes in life expectancy, and the changing age structure of Vienna's population, the three researchers found a significant relationship between heat stress and mortality. However, over this 38-year period, "some significant decreases of the sensitivity were found, especially in the medium heat stress levels," they report. These decreases in sensitivity, they write, "could indicate active processes of long-term adaptation to the increasing heat stress." In the discussion section of their paper, they write such sensitivity changes "were also found for other regions," citing Davis et al. (2003), Koppe (2005), Tan et al. (2007), and Donaldson and Keatinge (2008). In the conclusion of their paper, they refer to these changes as

"positive developments."
Kysely and Plavcova then examined "temporal changes in mortality associated with spells of large positive temperature anomalies (hot spells) in extended summer season in the population of the Czech Republic (Central Europe) during 1986–2009." They found declining mortality trends in spite of rising temperature trends, just the opposite of what IPCC claims will occur in response to global warming. The Czech scientists add, "the finding on reduced vulnerability of the population remains unchanged if possible confounding effects of within- season acclimatization and mortality displacement are taken into account," and "neither does it depend on the changing age structure of the population, since similar (and slightly more pronounced) declines in the mortality impacts are found in the elderly (age group 70+ years) when examined separately."

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Observational Research in North America

Goklany and Straja (2000) examined trends in United States death rates over the period 1979– 1997 due to excessive hot and cold weather. They report there were no trends in deaths due to either extreme heat or cold in the entire population or in the older, more-susceptible age groups, those aged 65 and over, 75 and over, and 85 and over. Deaths due to extreme cold in these older age groups exceeded those due to extreme heat by as much as 80% to 125%. With respect to the absence of trends in death rates attributable to either extreme heat or cold, Goklany and Straja say this "suggests that adaptation and technological change may be just as important determinants of such trends as more obvious meteorological and demographic factors."
Davis et al. (2003) evaluated "annual excess mortality on days when apparent temperatures—an index that combines air temperature and humidity—exceeded a threshold value for 28 major metropolitan areas in the United States from 1964 through 1998." They found "for the 28-city average, there were 41.0 ± 4.8 excess heat-related deaths per year (per standard million) in the 1960s and 1970s, 17.3 ± 2.7 in the 1980s, and 10.5 ± 2.0 in the 1990s," a remarkable decline. They conclude, "heat-related mortality in the United States seems to be largely preventable at present."
Davis et al. (2004) examined the seasonality of mortality due to all causes, using monthly data for 28 major U.S. cities from 1964 to 1998, and then calculated the consequences of a future 1°C warming of the conglomerate of those cities. At all locations studied, they report "warmer months have significantly lower mortality rates than colder months." They calculate "a uniform 1°C warming results in a net mortality decline of 2.65 deaths (per standard million) per metropolitan statistical area" (emphasis added). The primary implication of Davis et al.'s findings, in their words, "is that the seasonal mortality pattern in US cities is largely independent of the climate and thus insensitive to climate fluctuations, including changes related to increasing greenhouse gases."
Deschenes and Moretti (2009) analyzed the relationship between weather and mortality, based on "data that include the universe of deaths in the United States over the period 1972– 1988," in which they "match each death to weather conditions on the day of death and in the county of occurrence." They discovered "hot temperature shocks are indeed associated with a large and immediate spike in mortality in the days of the heat wave," but "almost all of this excess mortality is explained by near-term displacement." As a result, "in the weeks that follow a heat wave, we find a marked decline in mortality hazard, which completely offsets the increase during the days of the heat wave," so "there is virtually no lasting impact of heat waves on mortality." In the case of cold temperature days, they also found "an immediate spike in mortality but "there is no offsetting decline in the weeks that follow," so "the cumulative effect of one day of extreme cold temperature during a thirty-day window is an increase in daily mortality by as much as 10%."

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Global Warming and Cardiovascular Disease

The key findings are that

- Global warming, if it does occur, would reduce the incidence of fatal coronary events related to low temperatures and wintry weather by a much greater degree than it increases the incidence of death or serious heat related events associated with high temperatures and summer heat waves.

- Non-fatal myocardial infarction is also less frequent during unseasonably warm periods than during unseasonably cold periods.

- Any cost-benefit analysis that attributes an increase in cardiovascular events to warming is incorrect. Heat illness injures and kills by other means and has a much lesser death toll proportionately than cold related events. Heat illness injury and death in heat waves affects the debilitated and chronically ill in hot unventilated environments and the mechanism is dehydration and loss of core body temperature control.

Cardiovascular diseases affect the heart and or the blood vessels. They include arrhythmia, arteriosclerosis, congenital heart disease, and coronary artery disease, diseases of the aorta and its branches, disorders of the peripheral vascular system, endocarditis, heart valve disease, hypertension, orthostatic hypotension, and

shock. According to IPCC, exposure to rising temperatures and especially heat waves can cause premature deaths due to heat-induced illness. The claims that it causes stroke or myocardial infarctions are not correct except to concede that ultimately most deaths are cardiovascular in nature.
Empirical research suggests that heat illness can cause collapse and death, but the mechanism is fluid and circulatory collapse, not stroke or heart attack. Heat stroke is severe heat illness with loss of temperature control that produces brain dysfunction; it's not a cerebral thrombosis or hemorrhage, a true stroke.
That aside, the IPCC overlooks the fact that cooler temperatures cause an even larger number of premature deaths, with the result that a warmer world would experience fewer deaths in total due to cardiovascular disease.

Global Warming and Respiratory Disease

The key findings of this section include the following:

- Global warming, if it did occur would reduce incidence of death due to respiratory disease around the world, for example the Americas, Spain, Canada, Shanghai, and even on the subtropical island of Taiwan.

- Lower minimum temperatures are a strong risk factor for outpatient visits for respiratory diseases. Warmer temperatures reduce rates of respiratory disease.

- Any cost-benefit analysis that attributes increases in deaths or disease and disability or loss of work/school time to warming is incorrect and not a reliable guide for public policy.

Respiratory diseases are diseases affecting the organs and tissues that make gas exchange possible in humans and other higher organisms. They range from the common cold, allergies, asthma, and bronchiolitis to life-threatening conditions including pneumonia, pulmonary embolism, and lung cancer. Acute respiratory disease is a condition in which breathing becomes difficult and oxygen levels in the blood drop lower than normal. Respiratory diseases are widespread. For example, childhood asthma affects more than 300 million people worldwide (Baena-Cagnani and Badellino, 2011). Non-fatal respiratory diseases impose enormous social costs due to days lost from work and school (Mourtzoukou and Falagas, 2007).
According to IPCC, rising atmospheric carbon dioxide concentrations due to the combustion of fossil fuels causes global warming, and this temperature increase causes increased deaths due to respiratory disease. However, examination of real-world data reveals unassailable evidence that colder temperatures cause more deaths and hospital admissions due to respiratory disease than do warmer temperatures.
Some of the studies cited earlier in this chapter on lower death rates due to warmer temperatures and cardiovascular disease also identified specific reductions in fatalities due to respiratory diseases, so their research also appears in this section. Keatinge and Donaldson (2001), for example, studied of the effects of temperature on mortality in people over 50 years of age in the greater London area over the period 1976–1995. Simple plots of mortality rate versus daily air temperature revealed a linear increase in mortality as the air temperature fell from 15°C to near 0°C. Mortality rates at temperatures above 15°C, on the other hand, showed no trend. The authors say it is because "cold causes mortality mainly from arterial thrombosis and respiratory disease, attributable in turn to cold-induced hemo-concentration and hypertension and respiratory infections" (emphasis added).
Nafstad et al. (2001) studied the association between temperature and daily mortality in citizens of Oslo, Norway over the period 1990 to 1995. The results showed the mean daily number of respiratory-related

deaths was considerably higher in winter (October–March) than in summer (April–September). Winter deaths associated with respiratory diseases were 47% more numerous than summer deaths. They conclude, "A milder climate would lead to a substantial reduction in average daily number of deaths." Read milder as warmer.

Hajat and Haines (2002) examined the relationship between cold temperatures and the number of visits by the elderly to general practitioners for asthma, lower respiratory diseases other than asthma, and upper respiratory diseases other than allergic rhinitis as obtained for registered patients aged 65 and older from several London practices between January 1992 and September 1995. They found the mean number of consultations was higher in cool-season months (October–March) than in warm-season months (April–September) for all respiratory diseases. At mean temperatures below 5°C, the relationship between respiratory disease consultations and temperature was linear, and stronger at a time lag of six to 15 days A 1°C decrease in mean temperature below 5°C was associated with a 10.5% increase in all respiratory disease consultations.

Braga et al. (2002) conducted a time-series analysis of both the acute and lagged influence of temperature and humidity on mortality rates in 12 U.S. cities, finding no clear evidence for a link between humidity and respiratory-related deaths. With respect to temperature, they found respiratory-related mortality increased in cities with more variable temperature. This phenomenon, they write, "suggests that increased temperature variability is the most relevant change in climate for the direct effects of weather on respiratory mortality."

Gouveia et al. (2003) extracted daily counts of deaths from all causes, except violent

deaths and neonatal deaths (up to one month of age), from Sao Paulo, Brazil's mortality information system for the period 1991–1994 and analyzed them for effects of temperature. For respiratory-induced deaths, death rates due to a 1°C cooling were twice as great as death rates due to a 1°C warming in adults and 2.8 times greater in the elderly.

Nakaji et al. (2004) evaluated seasonal trends in deaths due to various diseases in Japan, using nationwide vital statistics from 1970 to 1999 and concurrent mean monthly air temperature data. They found the numbers of deaths due to respiratory diseases, including pneumonia and influenza, rise to a maximum during the coldest time of the year. The team of nine scientists concludes, "To reduce the overall mortality rate and to prolong life expectancy in Japan, measures must be taken to reduce those mortality rates associated with seasonal differences."

Bartzokas et al. (2004) "examined the relationship between hospital admissions for cardio-vascular (cardiac in general including heart attacks) and/or respiratory diseases (asthma etc.) in a major hospital in Athens [Greece] and meteorological parameters for an 8-year period." Over the whole year, they found, "there was a dependence of admissions on temperature," and low temperatures were "responsible for a higher number of admissions." Specifically, "there was a decrease of cardiovascular or/and respiratory events from low to high values [of temperature], except for the highest temperature class in which a slight increase was recorded."

Kovats et al. (2004) studied patterns of temperature-related hospital admissions and deaths in Greater London during the mid-1990s. For the three-year period 1994–1996, they found respiratory-related deaths were nearly 150% greater in the depth of winter cold than at the height of summer warmth. They also found the mortality impact of the heat wave of 29 July to 3 August 1995 (which boosted daily mortality by just over 10%) was so tiny it could not be discerned among the random scatter of plots of three-year-average daily deaths from cardiovascular and respiratory problems versus day of year. Similarly, in a study of temperature effects on mortality in three English counties (Hampshire, West Midlands, and West Yorkshire), McGregor (2005) found "the occurrence of influenza ... helps elevate winter mortality above that of summer."

Carder et al. (2005) investigated the relationship between outside air temperature and deaths due to all non-accident causes in the three largest cities of Scotland (Glasgow, Edinburgh, and Aberdeen) between January 1981 and December 2001. The authors observed "an overall increase in mortality as temperature decreases," which "appears to be steeper at lower temperatures than at warmer temperatures," and "there is little evidence of an increase in mortality at the hot end of the temperature range." Specifically regarding respiratory disease, they found "for temperatures below 11°C, a 1°C drop in the daytime mean temperature on any one day was associated with an increase in respiratory mortality of 4.8% over the following month."
Donaldson (2006) studied the effect of annual mean daily air temperature on the length of the yearly respiratory syncytial virus (RSV) season, the virus which causes bronchiolitis, in England and Wales for 1981–2004. Reporting "climate change may be shortening the RSV season," Donaldson found "the seasons associated with laboratory isolation of respiratory syncytial virus (for 1981–2004) and RSV-related emergency department admissions (for 1990– 2004) ended 3.1 and 2.5 weeks earlier, respectively, per 1°C increase in annual central England temperature ($P = 0.002$ and 0.043, respectively)." Consequently, since "no relationship was observed between the start of each season and temperature," he reports, so "the RSV season has become shorter." He concludes, "These findings imply a health benefit of global warming in England and Wales associated with a reduction in the duration of the RSV season and its consequent impact on the health service."
Frei and Gassner (2008) studied hay fever prevalence in Switzerland from 1926 to 1991, finding it rose from just under 1% of the country's population to just over 14%, but from 1991 to 2000 it leveled off, fluctuating about a mean value on the order of 15%. The authors write, "several studies show that no further increase in asthma, hay fever and atopic sensitization in adolescents and adults has been observed during the 1990s and the beginning of the new century," citing Braun-Fahrlander et al. (2004) and Grize et al. (2006). They write, "Parallel to the increasing hay fever rate, the pollen amounts of birch and grass were increasing from 1969 to 1990," but "subsequently, the pollen of these plant species decreased from 1991 to 2007." They say this finding "is more or less consistent with the changes of the hay fever rate that no longer increased during this period and even showed a tendency to decrease slightly." Nearly identical findings were presented a year later (Frei, 2009). Although some have claimed rising temperatures and CO2 concentrations will lead to more pollen and more hay fever (Wayne et al., 2002), the analyses of Frei (2009) and Frei and Gassner (2008) suggest that is not true of Switzerland.
Miller et al. (2012) extracted annual prevalence data for frequent otitis media (defined as three or more ear infections per year), respiratory allergy, and non-respiratory seizures in children from the U.S. National Health Interview Survey for 1998 to 2006. They also obtained average annual temperatures for the same period from the U.S. Environmental Protection Agency. They found "annual temperature did not influence the prevalence of frequent otitis media," "annual temperature did not influence prevalence of respiratory allergy," and "annual temperature and sex did not influence seizure prevalence." They conclude their findings "may demonstrate that average temperature is not likely to be the dominant cause of the increase in allergy burden or that larger changes in temperatures over a longer period are needed to observe this association." They further conclude, "In the absence of more dramatic annual temperature changes, we do not expect prevalence of otitis media to change significantly as global warming may continue to affect our environment."
Xu et al. (2013) examined the relationship between diurnal temperature range (DTR) and emergency department admissions for childhood asthma in Brisbane, Australia, from January 1st 2003 to December 31st 2009. The six scientists report "childhood asthma increased above a DTR of 10°C" and "was the greatest for lag 0–9 days, with a 31% increase in [hospital] emergency department admissions per 5°C increment of DTR," further noting, "male children and children aged 5–9 years appeared to be more vulnerable to the DTR effect than others."

Ge et al. (2013) also investigated respiratory health and DTR. The researchers collected numbers of daily emergency-room visits for RTI at one of the largest medical establishments in Shanghai, China (Huashan Hospital) between 1 January 2008 and 30 June 2009, along with DTR data and data pertaining to possible confounding air pollutants (PM10, SO2, and NO2). After making appropriate statistical analyses, the scientists determined increasing DTRs were closely associated with daily emergency-room visits for RTIs, such that "an increase of 1°C in the current-day and in the 2-day moving average DTR corresponded to a 0.94% and 2.08% increase in emergency-room visits for RTI, respectively."
Lin et al. (2013) used data on daily area-specific deaths from all causes, circulatory diseases, and respiratory diseases in Taiwan, developing relationships between each of these cause-of-death categories and a number of cold-temperature related parameters for 2000–2008. The five researchers discovered "mortality from [1] all causes and [2] circulatory diseases and [3] outpatient visits of respiratory diseases has a strong association with cold temperatures in the subtropical island, Taiwan." In addition, they found "minimum temperature estimated the strongest risk associated with outpatient visits of respiratory diseases."

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Global Warming and Strokes

The key findings of this section include the following:

- Any warming would reduce the incidence of death due to stroke in many parts of the world, including Russia, Korea, Japan, Africa, Asia, Europe, Latin America, and the Caribbean.

- Low minimum temperatures are a stronger risk factor than high temperatures for stroke incidence and hospitalization.

- Any cost-benefit analysis that attributes increased strokes to a prediction of global warming is incorrect and not a reliable guide for public policy.

A stroke occurs when blood flow to an area in the brain is cut off. Ischemic stroke occurs when clots form in the brain's blood vessels, in blood vessels leading to the brain, or in blood vessels elsewhere in the body and then travel to the brain. Ischemic stroke can also occur when too much plaque (fatty deposits and cholesterol) clogs the brain's blood vessels. Hemorrhagic strokes occur when a blood vessel in the brain breaks or ruptures. The result is blood seeping into the brain tissue, causing damage to brain cells. The most common causes of hemorrhagic stroke are high blood pressure and brain aneurysms. An aneurysm is a bulge in a blood vessel caused by a weakness and thinning of the blood vessel wall. Aneurysms are prone to burst and a major cause of hemorrhagic stroke (WebMD, 2015).
According to IPCC, rising atmospheric carbon dioxide concentrations due to the combustion of fossil fuels causes global warming, and this temperature increase causes increased deaths due to strokes. Not true. Examination of real-world data reveals unseasonable cold temperatures cause more deaths and hospital admissions due to stroke than do unseasonable warm temperatures.
Feigin et al. (2000) examined the relationship between the incidence of stroke and ambient temperatures over the period 1982-1993 in Novosibirsk, Siberia, which has one of the highest stroke incidence rates in the world. Based on analyses of 2,208 patients with sex and age distributions similar to those of Russia as a whole, they found a statistically significant association between stroke and low ambient temperature. In the

case of ischemic stroke (IS), which accounted for 87% of all stroke types, they determined "the risk of IS occurrence on days with low ambient temperature [was] 32% higher than that on days with high ambient temperature." They conclude the "very high stroke incidence in Novosibirsk, Russia may partially be explained by the highly prevalent cold factor there." There is no reason to believe that temperature variations would have a discernible effect on hemorrhagic strokes that occur because of vascular pathology, not occlusion.

Hong et al. (2003) investigated the association between the onset of ischemic stroke and prior episodic decreases in temperature in 545 patients who suffered strokes in Incheon, Korea from January 1998 to December 2000. They report "decreased ambient temperature was associated with risk of acute ischemic stroke," with the strongest effect being seen on the day after exposure to cold weather, further noting "even a moderate decrease in temperature can increase the risk of ischemic stroke." They also found "risk estimates associated with decreased temperature were greater in winter than in the summer," which suggests "low temperatures as well as temperature changes are associated with the onset of ischemic stroke." Finally, they explain the reason for the 24- to 48-hour lag between exposure to cold and the onset of stroke "might be that it takes some time for the decreasing temperature to affect blood viscosity or coagulation.

Nakaji et al. (2004) evaluated seasonal trends in deaths due to various diseases in Japan using nationwide vital statistics from 1970 to 1999 together with mean monthly temperature data. They found the peak mortality rate due to stroke was two times greater in winter (January) than at the time of its yearly minimum (August and September).

Chang et al. (2004) analyzed data from the World Health Organization (WHO) Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception (WHO, 1995) to determine the effects of monthly mean temperature on rates of hospitalization for arterial stroke and acute myocardial infarction among women aged 15–49 from 17 countries in Africa, Asia, Europe, Latin America, and the Caribbean. They found among these women, a 5°C reduction in mean air temperature was associated with a 7% increase in the expected hospitalization rate due to stroke, and this effect was relatively acute, within a period of about a month, the scientists write.

Gill et al. (2012) write, "in the past two decades, several studies reported that meteorologic changes are associated with monthly and seasonal spikes in the incidence of aneurysmal subarachnoid hemorrhage (aSAH)," and "analysis of data from large regional databases in both hemispheres has revealed increased seasonal risk for aSAH in the fall, winter and spring," citing among other sources Feigin et al. (2001), Abe et al. (2008), and Beseoglu et al. (2008). Gill et al. identified the medical records of 1,175 patients at the Johns Hopkins Hospital in Baltimore, Maryland (USA) who were admitted with a radiologically confirmed diagnosis of aSAH between 1 January 1991 and 1 March 2009. The six scientists report both "a one-day decrease in temperature and colder daily temperatures were associated with an increased risk of incident aSAH," and "these variables appeared to act synergistically" and were "particularly predominant in the fall, when the transition from warmer to colder temperatures occurred." Gill et al. add their study "is the first to report a direct relationship between a temperature decrease and an increased risk of aSAH," and "it also confirms the observations of several reports of an increased risk of aSAH in cold weather or winter," citing Nyquist et al. (2001) and other sources. Authors' note: This study and others the authors of the study reference are outliers in the sense that they tally aneurysmal sub arachnoid hemorrhage, a different kind of stroke than ischemic strokes, so there is no "mechanism" of coagulation and clot formation that would relate to temperature that might be hypothesized as a cause of cold or cool to cause hemorrhagic stroke.

The reader should be informed that hemorrhagic stroke is because of a different mechanism, the rupture of a weakened wall of a blood vessel, often associated with a bulge called an aneurysm, as opposed to ischemic stroke discussed above that occur because of a blood clot in the brain blood vessel. However the temperature

effect is the same, cold produces an increase in hemorrhagic strokes in addition to its effect on the rate of ischemic strokes.

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Global Warming and Insect-borne Diseases

The key findings of this section include the following:

- Research contradicts the claim that malaria will expand across the globe and intensify as a result of any possible warming.

- Concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever infection rates.

- Climate change has not been a significant factor driving the recent temporal patterns in the epidemiology of tick-borne diseases. Ticks are endemic at many latitudes.

The latest IPCC report, the Fifth Assessment Report (AR5) backs down from previous predictions that global warming would facilitate the spread of insect-borne diseases including malaria, dengue fever, and tick-borne diseases. The full report from Working Group II on the subject (IPCC, 2014a, Chapter 11, pp. 722-726) repeatedly admits there is no evidence that climate change has affected the range of vector-borne diseases including tick-borne diseases. However, the Summary for Policymakers inexplicably warns "Throughout the 21st century, climate change is expected to lead to increases in ill-health in many regions and especially in developing countries with low income, as compared to a baseline without climate change (high confidence)." Among the "examples" given is "vector-borne diseases (medium confidence)" (IPCC, 2014b, pp. 19-20). Such predictions are not supported by the evidence.

In a research report in Science, Rogers and Randolph (2000) note "predictions of global climate change have stimulated forecasts that vector-borne diseases will spread into regions that are at present too cool for their persistence." However, the effect of warmer temperatures on insect-borne diseases is complex, sometimes working in favor of and sometimes against the spread of a disease. For example, ambient temperature has historically not determined the range of insect-borne diseases, hotter weather shortens the lifespan of mosquitos, and human adaptation as well as vector control measures can neutralize any detrimental effect of warming, to overwhelm the role of climate. Even those who support IPCC, such as Marm Kilpatrick, an assistant professor in ecology and evolutionary biology at the University of California, Santa Cruz, admits "It's a little bit tricky to make a solid prediction" (Irfan, 2011).

Gething et al. (2010), writing specifically about malaria, may have put it best when they said there has been "a decoupling of the geographical climate-malaria relationship over the twentieth century, indicating that non-climatic factors have profoundly confounded this relationship over time." They note "non-climatic factors, primarily direct disease control and the indirect effects of a century of urbanization and economic development, although spatially and temporally variable, have exerted a substantially greater influence on the geographic extent and intensity of malaria worldwide during the twentieth century than have climatic factors." As for the future, they conclude climate-induced effects "can be offset by moderate increases in coverage levels of currently available interventions."

This section investigates the reliability of IPCC's claim with respect to the three main kinds of insect-borne diseases: malaria, dengue fever, and tick-borne diseases According to the results of a vast body of scientific examination and research on this topic, there is little support for the claims appearing in the latest IPCC Summary for Policymakers.

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Malaria

A vast body of scientific examination and research contradict the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming.

Jackson et al. (2010) say "malaria is one of the most devastating vector-borne parasitic diseases in the tropical and subtropical regions of the world," noting it affects more than 100 countries.

According to the World Health Organization, Africa carries the highest infection burden of any continent, with nearly 200 million cases reported in 2006, and the Centers for Disease Control and Prevention estimates between 700,000 and 2.7 million people each year die from the dreaded disease (Suh et al., 2004). In addition, Jackson et al. report "the African region bears 90% of these estimated worldwide deaths," and "three-quarters of all malaria related deaths are among African children," citing Breman (2001). According to Reiter (2000), claims that malaria resurgence is the product of CO2-induced global warming ignore other important factors and disregard known facts. A historical analysis of malaria trends, for example, reveals this disease was an important cause of illness and death in England during a period of colder-than-present temperatures throughout the Little Ice Age. Its transmission began to decline only in the nineteenth century, during a warming phase, when, according to Reiter, "temperatures were already much higher than in the Little Ice Age." In short, malaria was prevalent in Europe during some of the coldest centuries of the past millennium, and it has only recently undergone widespread decline, when temperatures have been warming.

Clearly, there are other factors at work in regards to malaria that are more important than temperature. Such factors include the quality of public health services, irrigation and agricultural activities, land use practices, civil strife, natural disasters, ecological change, population change, use of insecticides, and the movement of people (Reiter, 2000; Reiter, 2001; Hay et al., 2002).

Nevertheless, concerns have lingered about the possibility of widespread future increases in malaria due to global warming. These concerns are generally rooted in climate models that typically use only one, or at most two, climate variables in making their predictions of the future distribution of the disease over Earth, and they generally do not include any of the non-climatic factors listed in the preceding paragraph. When more variables are included, a less-worrisome future is projected.

In one modeling study, for example, Rogers and Randolph (2000) employed five climate variables and obtained very different results. Briefly, they used the present-day distribution of malaria to determine the specific climatic constraints that best define that distribution, after which the multivariate relationship they derived from this exercise was applied to future climate scenarios derived from state-of-the-art climate models, in order to map potential future geographical distributions of the disease.

Their study revealed very little change: a 0.84% increase in potential malaria exposure under the "medium-high" scenario of global warming and a 0.92% decrease under the "high" scenario. Rogers and Randolph explicitly state their quantitative model "contradicts prevailing forecasts of global malaria expansion" and "highlights the use of multivariate rather than univariate constraints in such applications. They found "climate warming, expressed as a systematic temperature increase over the 85-year period, does not appear to be responsible for an increase in malaria suitability over any region in Africa." They conclude "research on the links between climate change and the recent resurgence of malaria across Africa would be best served through refinements in maps and models of precipitation patterns and through closer examination of the role of nonclimatic influences."

Kuhn et al. (2003) analyzed the determinants of temporal trends in malaria deaths within England and Wales in 1840–1910 and found "a 1°C increase or decrease was responsible for an increase in malaria deaths of 8.3% or a decrease of 6.5%, respectively," which explains "the malaria epidemics in the 'unusually hot summers' of 1848 and 1859." Nevertheless, the long- term near-linear temporal decline in malaria deaths over the period of study, the researchers write, "was probably driven by nonclimatic factors," among which they identify increasing livestock populations (which tend to divert mosquito biting from humans), decreasing acreages of marsh wetlands (where mosquitoes breed), as well as "improved housing, better access to health care and medication, and improved nutrition, sanitation, and hygiene." Kuhn et al. say "the projected increase in proportional risk is clearly insufficient to lead to the reestablishment of endemicity."

Childs et al. (2006) present a detailed analysis of malaria incidence in northern Thailand based on a quarter-century monthly time series (January 1977 through January 2002) of total malaria cases in the country's 13 Northern provinces. Over this time period, when IPCC claims the world warmed at a rate and to a level unprecedented over the prior one to two millennia, Childs et al. report there was an approximately constant rate of decline in total malaria incidence (from a mean monthly incidence in 1977 of 41.5 cases per hundred thousand people to 6.72 cases per hundred thousand people in 2001). Noting "there has been a steady reduction through time of total malaria incidence in northern Thailand, with an average decline of 6.45% per year," they say this result "reflects changing agronomic practices and patterns of immigration, as well as the success of interventions such as vector control programs, improved availability of treatment and changing drug policies."

Reiter (2008) came to similar conclusions, writing "simplistic reasoning on the future prevalence of malaria is ill-founded; malaria is not limited by climate in most temperate regions, nor in the tropics, and in nearly all cases, 'new' malaria at high altitudes is well below the maximum altitudinal limits for transmission." He further states, "Future changes in climate may alter the prevalence and incidence of the disease, but

obsessive emphasis on 'global warming' as a dominant parameter is indefensible; the principal determinants are linked to ecological and societal change, politics and economics."
Hulden and Hulden (2009) analyzed malaria statistics collected in Finland from 1750 to 2008 via correlation analyses between malaria frequency per million people and all variables that have been used in similar studies throughout other parts of Europe, including temperature data, animal husbandry, consolidation of land by redistribution, and household size. Over the entire period, "malaria frequency decreased from about 20,000–50,000 per 1,000,000 people to less than 1 per 1,000,000 people," they report. The two Finnish researchers conclude, "Indigenous malaria in Finland faded out evenly in the whole country during 200 years with limited or no counter measures or medication," making that situation "one of the very few opportunities where natural malaria dynamics can be studied in detail." Their study indicates "malaria in Finland basically was a sociological disease and that malaria trends were strongly linked to changes in the human household size and housing standard."

Effects of climate and socioeconomic factors on the projected future global distribution of malaria.

Source: Béguin et al. (2011).

The many findings described above make it clear a vast body of scientific examination and research contradict the claim that malaria will expand across the globe and intensify as a result of CO2-induced warming.

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Dengue Fever

Concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever.

According to Ooi and Gubler (2009), "dengue/dengue hemorrhagic fever is the most important vector-borne viral disease globally," with more than half the world's population living in areas deemed to be at risk of infection. Kyle and Harris (2008) note "dengue is a spectrum of disease caused by four serotypes of the most

prevalent arthropod-borne virus affecting humans today," and "its incidence has increased dramatically in the past 50 years," to where "tens of millions of cases of dengue fever are estimated to occur annually, including up to 500,000 cases of the life- threatening dengue hemorrhagic fever/dengue shock syndrome." Some of the research papers summarized in previous sections address dengue fever as well as malaria. With a few worthy exceptions, we do not repeat those summaries in this section. The most important exceptions are papers written by or coauthored by Paul Reiter (2001, 2003, 2010a, 2010b), one of the world's premier authorities on the subject. Reiter analyzed the history of malaria and dengue fever in an attempt to determine whether the incidence and range of influence of these diseases would indeed increase in response to CO2-induced global warming.

His reviews established what is now widely accepted among experts in the field, that the natural history of these vector-borne diseases is highly complex, and the interplay of climate, ecology, vector biology, and a number of other factors defy definition by the simplistic analyses utilized in the computer models relied on by environmental activists and the IPCC.

That there has in fact been a resurgence of these diseases in parts of the world is true, but as Reiter (2001) notes; it is "facile to attribute this resurgence to climate change." This he shows via a number of independent analyses that clearly demonstrate factors associated with politics, economics, and human activity is the principal determinants of the spread of these diseases. He describes these factors as being "much more significant" than climate in promoting disease expansion. Two years later, Reiter took up the subject again, this time with 19 other scientists as coauthors (Reiter et al., 2003), and yet again in 2010. Reiter's work remains the most comprehensive critique of the claims of the Intergovernmental Panel on Climate Change.

Kyle and Harris (2008) wrote "there has been a great deal of debate on the implications of global warming for human health," but "at the moment, there is no consensus." However, "in the case of dengue," they report, "it is important to note that even if global warming does not cause the mosquito vectors to expand their geographic range, there could still be a significant impact on transmission in endemic regions," because "a 2°C increase in temperature would simultaneously lengthen the lifespan of the mosquito and shorten the extrinsic incubation period of the dengue virus, resulting in more infected mosquitoes for a longer period of time." Nevertheless, they state there are "infrastructure and socioeconomic differences that exist today and already prevent the transmission of vector-borne diseases, including dengue, even in the continued presence of their vectors," citing Reiter (2001).

Wilder-Smith and Gubler (2008) conducted a review of the scientific literature, noting "the past two decades saw an unprecedented geographic expansion of dengue" and "global climate change is commonly blamed for the resurgence of dengue," but they add, "There are no good scientific data to support this conclusion." The two researchers report, "Climate has rarely been the principal determinant of [their] prevalence or range," and "human activities and their impact on local ecology have generally been much more significant." They cite as contributing factors "urbanization, deforestation, new dams and irrigation systems, poor housing, sewage and waste management systems, and lack of reliable water systems that make it necessary to collect and store water," further noting "disruption of vector control programs, be it for reasons of political and social unrest or scientific reservations about the safety of DDT, has contributed to the resurgence of dengue around the world."

In addition, Wilder-Smith and Guble write "large populations in which viruses circulate may also allow more co-infection of mosquitoes and humans with more than one serotype of virus," which would appear to be borne out by the fact that "the number of dengue lineages has been increasing roughly in parallel with the size of the human population over the last two centuries." Most important, perhaps, is "the impact of international travel," of which they say "humans, whether troops, migrant workers, tourists, business travelers, refugees, or others, carry the virus into new geographic areas," and these movements "can lead to

epidemic waves." The two researchers conclude, "Population dynamics and viral evolution offer the most parsimonious explanation for the observed epidemic cycles of the disease, far more than climatic factors." Russell et al. (2009) showed the dengue vector (the Aedes Aegypti mosquito) "was previously common in parts of Queensland, the Northern Territory, Western Australia and New South Wales," and it had, "in the past, covered most of the climatic range theoretically available to it," adding "the distribution of local dengue transmission has [historically] nearly matched the geographic limits of the vector." This being the case, they conclude the vector's current absence from much of Australia "is not because of a lack of a favorable climate." Thus, they reason "a temperature rise of a few degrees is not alone likely to be responsible for substantial increases in the southern distribution of A. Aegypti or dengue, as has been recently proposed." Instead of futile attempts to limit dengue transmission by controlling the world's climate, therefore, the medical researchers recommend "well resourced and functioning surveillance programs, and effective public health intervention capabilities, are essential to counter threats from dengue and other mosquito-borne diseases."

Reiter (2010a) observed "the introduction and rapidly expanding range of Aedes Albopictus in Europe is an iconic example of the growing risk of the globalization of vectors and vector-borne diseases," and "the history of yellow fever and dengue in temperate regions confirms that transmission of both diseases could recur, particularly if Aedes Aegypti, a more effective vector, were to be re-introduced." He states "conditions are already suitable for transmission." Much more important than a rise or fall of a couple degrees of temperature, Reiter says, is "the quantum leap in the mobility of vectors and pathogens that has taken place in the past four decades, a direct result of the revolution of transport technologies and global travel."

Carbajo et al. (2012) evaluated the relative contributions of geographic, demographic, and climatic variables to the recent spread of dengue in Argentina. They found dengue spatial occurrence "was positively associated with days of possible transmission, human population number, population fall and distance to water bodies." When considered separately, the researchers write, "the classification performance of demographic variables was higher than that of climatic and geographic variables." Thus, although useful in estimating annual transmission risk, Carbajo et al. conclude temperature "does not fully describe the distribution of dengue occurrence at the country scale," and "when taken separately, climatic variables performed worse than geographic or demographic variables."

These several observations indicate concerns over large increases in dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature, as climatic indices are poor predictors for dengue fever.

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Tick-borne Diseases

Climate change has not been the most significant factor driving the recent temporal patterns in the epidemiology of tick-borne diseases.

Sarah Randolph of the University of Oxford's Department of Zoology is a leading scholar on tick-borne diseases. She and fellow Oxford faculty member David Rogers observed in 2000 that tick-borne encephalitis (TBE) "is the most significant vector-borne disease in Europe and Eurasia," having "a case morbidity rate of 10–30% and a case mortality rate of typically 1–2% but as high as 24% in the Far East." The disease is

caused by a flavivirus (TBEV), which is maintained in natural rodent-tick cycles; humans may be infected with it if bitten by an infected tick or by drinking untreated milk from infected sheep or goats.

Early discussions on the relationship of TBE to global warming predicted the disease would expand its range and become more of a threat to humans in a warmer world. However, Randolph and Rogers (2000) note, "like many vector-borne pathogen cycles that depend on the interaction of so many biotic agents with each other and with their abiotic environment, enzootic cycles of TBEV have an inherent fragility," so "their continuing survival or expansion cannot be predicted from simple univariate correlations."

Randolph (2010) examined the roles played by various factors that may influence the spread of tick-borne diseases. After describing some of the outbreaks of tick-borne disease in Europe over the past couple of decades, Randolph states "the inescapable conclusion is that the observed climate change alone cannot explain the full heterogeneity in the epidemiological change, either within the Baltic States or amongst Central and Eastern European countries," citing Sumilo et al. (2007). Instead, she writes, "a nexus of interrelated causal factors—abiotic, biotic and human—has been identified," and "each factor appears to operate synergistically, but with differential force in space and time, which would inevitably generate the observed epidemiological heterogeneity."

Many of these factors, she continues, "were the unintended consequences of the fall of Soviet rule and the subsequent socio-economic transition (Sumilo et al., 2008b)," among which she cites "agricultural reforms resulting in changed land cover and land use, and an increased reliance on subsistence farming; reduction in the use of pesticides, and also in the emission of atmospheric pollution as industries collapsed; increased unemployment and poverty, but also wealth and leisure time in other sectors of the population as market forces took hold."

Randolph concludes "there is increasing evidence from detailed analyses that rapid changes in the incidence of tick-borne diseases are driven as much, if not more, by human behavior that determines exposure to infected ticks than by tick population biology that determines the abundance of infected ticks," as per Sumilo et al. (2008a) and Randolph et al. (2008). She ends her analysis by stating, "While nobody would deny the sensitivity of ticks and tick-borne disease systems to climatic factors that largely determine their geographical distributions, the evidence is that climate change has not been the most significant factor driving
the recent temporal patterns in the epidemiology of tick-borne diseases."

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Conclusion

IPCC fails to acknowledge the human health benefits of a warming world, claiming instead that the net effect of warming is a cost rather than a benefit.

Fossil fuels have benefited human health by making possible the dramatic increase in human prosperity since the first Industrial Revolution, making investments possible in goods and services that are essential to protecting human health and prolonging human life. Fossil fuels further improve human health by making environmental protection both valued and financially possible and by powering technologies and production of goods and services, transportation, communication that all improve quality of life, and protect human health and welfare, extend life spans.
If the combustion of fossil fuels leads to some amount of global warming, then the positive as well as negative health effects of that warming should be included in any cost-benefit analysis of fossil fuels.
Medical science explains why colder temperatures often cause diseases and sometimes fatalities whereas warmer temperatures are associated with health benefits.
Empirical research confirms that warmer temperatures lead to a net decrease in temperature- related mortality in virtually all parts of the world, even those with tropical climates. The evidence of this benefit comes from research conducted in nearly every major country of the world.
Global warming is reducing the incidence of fatal coronary events related to low temperatures and wintry weather by a much greater degree than it increases the incidence of heat related illness or death attributable to heat waves. Respiratory illness, strokes and myocardial infarction are less frequent during unseasonably warm periods than during unseasonably cold periods.
Global warming is reducing the incidence of death due to respiratory disease in many parts of the world, including Spain, Canada, Shanghai, and even on the subtropical island of Taiwan. Low minimum temperatures have been found to be a stronger risk factor than high temperatures for outpatient visits for respiratory diseases. Warm weather reduces the incidence of death due to stroke around the world.
A vast body of scientific examination and research contradicts and refutes the claim that malaria will expand across the globe or intensify in some regions as a result of any predicted CO2-induced warming. Concerns over large increases in mosquito-transmitted dengue fever as a result of rising temperatures are unfounded and unsupported by the scientific literature.

While climatic factors largely determine the geographical distribution of ticks, temperature and climate change are not among the significant factors determining the incidence of tick-borne diseases.
In the face of this extensive evidence of the positive effects of fossil fuels on human health, IPCC continues to claim the net impact on human health of fossil fuels will be negative. Because virtually all cost-benefit analyses incorporate the IPCC's incorrect assumptions into their calculation of the social cost of fossil fuels, they are unreliable guides to policymakers.

12. Conclusion

This is not a complete expose of the misconduct of the US EPA sponsored researchers and in house science and policy staff in matters of epidemiology and toxicology and it focuses on the US EPA research/ policy /regulatory activities in air quality science and policy making—an equally scandalous case can be made for US EPA work in other areas of responsibility where toxicology and epidemiology are abused and misused to expand the EPA list of targets for regulation and opportunities for EPA to scaremonger.

I also cannot take the time or the space in this discussion to expose the US EPA new area of scientific misconduct and scaremongering—epigenetics and their claims of inheritable acquired toxin carcinogenic genetic mutations—revisiting Lamarck and Lysenko long ago discredited theories about acquired genetic changes. Such irresponsible scares about inherited toxic and cancer effects are ideal for irresponsible aggressive environmental fanatic wannabee regulators and their obedient research army.

US EPA researchers in epigenetics are their new breed of scaremongers with the target people who think exposure to some named toxin might effect their children or grandchildren. The lust of power and influence and cheating on science go hand in hand.

All of what I have exposed above combines to make an effective and urgent argument for the proposed US EPA policy change to promote integrity and transparency of US EPA science in matters of regulatory policy decision making. The time for cleaning up the US EPA scientific perfidy and misconduct, malfeasance is long past overdue.

I anticipate there will be institutions and scientists panicked and anxious about proving up their research assertions and conclusions—a very beneficial and healthy development. The polity will benefit from science and policy making that is based on reliable methods used by researchers with integrity who are subjected to impartial and thorough competent reviews by experts who are not conflicted by ideological, political, monetary or social/professional influences.

John Dale Dunn MD JD

Personal Matters / Ex. 6

https://www.regulations.gov.

Docket ID No. EPA-HQ-OA-2018-0259

Comments submitted on the Docket Subject titled

Strengthening Transparency in Regulatory Science
Comment on Strengthening Transparency in Regulatory Science, Environmental Protection Agency, 40 CFR Part 30, RIN 2080—AA14 [EPA-HQ-OA-2018-0259; FRL-9977-40-ORD].

Comments submitted by John Dale Dunn MD JD
Emergency Physician, inactive attorney
Lecturer, retired Clinical Instructor,
Emergency Medicine Residency
Carl R. Darnall Army Medical Center, Fort Hood, Texas.

Table of contents of elements of the submission

Introductory remarks in support of the proposed US EPA Transparency action that are submitted as comments.

The attachment includes 12 sections that support my commentary and assertions. ments listed as

I will detail in the attachment submitted the nature of the EPA sponsored research fraud, the methods and data manipulation and management that have resulted in EPA fraud on the public about air quality health effects, toxicological claims in other areas of EPA responsibility and the EPA full blown commitment to the hoax of CO2 levels as a cause of catastrophic warming. In these three areas of EPA research and policy making it is easy to identify the frauds on the public that are supported by a well-paid band of hired researchers and an in house gang of committed environmental true believers. The result is a fraud and research and policy conduct that is so badly informed and poorly researched and developed that it includes systematic commission of civil and even criminal acts to further an EPA agenda of aggressive environmental regulations that have created tremendous economic burdens for no good reason other than a fanatic environmental ideological agenda.

I will elaborate with specific references and documents in the attached document that provides items 1-12 listed above the irresponsible and flagrantly unscientific research funded and promoted by the USEPA on all matters of toxicology and epidemiology and my admonition to any reader is that if we do not stop this junk science for politics and ideology, we will follow the path of fools for a cause—the path of true believers.

This submitter has witnessed US EPA misconduct for a period of 3 decades on a scale that is stunning, or alarming, going back to the EPA decision to ban DDT in the early 1970s, resulting in the deaths of millions in the 3rd world, and a particularly horrific impact on children.

More recently in addition to serial misconduct with regards to toxicology and epidemiology research the EPA has compounded its scientific methodology misconduct with a systematic violation of domestic and

international ethical and moral/legal norms in regards to human experimentation—promoting and funding, approving human experiments that resulted in uninformed subjects being involved in experiments at 10 domestic and 6 foreign medical research institutions where they were intentionally observed while inhaling small particle contaminated air while being observed for adverse effects. These experiments carried out by prominent Medical Schools, is in spite of US EPA public pronouncements and testimony before congress that small particles are toxic, lethal (Hundreds of thousands of deaths annually) and carcinogenic.

US domestic law prohibits human experiments that might harm and international medical ethical standards for human experiments prohibit human experiments with no exceptions except exigencies of great need if the researchers act as subjects. Any other human experiments with a risk of harm are prohibited, and no consent will remove that proscription.

In the past 3 decades US EPA air quality research has been an abomination, relying on junk toxicology/epidemiology and the precautionary principle. The submitter has actively tried to expose the misconduct.

The proposal by the US EPA for scientific transparency and scientific integrity is salutary and significant in all its elements and will impose on the US EPA research and policy a new form of integrity.

The Regulatory Science Transparency proposal is a vital and very important policy for the EPA that will have beneficial effects in that help to end US EPA research misconduct I put on display in the attachment that has been intentionally and viciously put forward as good science for purely partisan ideological purposes, not to serve the US EPA obligation to identify real risks and mitigate the effects of those risks.

Cordially and respectfully,
/JDunn MD/
John Dale Dunn MD JD

Personal Matters / Ex. 6

https://www.regulations.gov.

Docket ID No. EPA-HQ-OA-2018-0259

Comments submitted on the Docket Subject titled

Strengthening Transparency in Regulatory Science
Comment on Strengthening Transparency in Regulatory Science, Environmental Protection Agency, 40 CFR Part 30, RIN 2080—AA14 [EPA-HQ-OA-2018-0259; FRL-9977-40-ORD].

Attachment to comments submitted by John Dale Dunn MD JD
Emergency Physician, inactive attorney
Lecturer, retired Clinical Instructor,
Emergency Medicine Residency
Carl R. Darnall Army Medical Center, Fort Hood, Texas.

Table of contents of elements of the attachment.

Introductory remarks in support of the proposed US EPA Transparency action that are submitted as comments.

Then in the attachment, the following documents listed as items 1-12.

I will detail in the attachment submitted the nature of the EPA sponsored research fraud, the methods and data manipulation and management that have resulted in EPA fraud on the public about air quality health effects, toxicological claims in other areas of EPA responsibility and the EPA full blown commitment to the hoax of CO2 levels as a cause of catastrophic warming. In these three areas of EPA research and policy

making it is easy to identify the frauds on the public that are supported by a well-paid band of hired researchers and an in house gang of committed environmental true believers. The result is a fraud and research and policy conduct that is so badly informed and poorly researched and developed that it includes systematic commission of civil and even criminal acts to further an EPA agenda of aggressive environmental regulations that have created tremendous economic burdens for no good reason other than a fanatic environmental ideological agenda.

I will elaborate with specific references and documents in the attached document that provides items 1-12 listed above the irresponsible and flagrantly unscientific research funded and promoted by the USEPA on all matters of toxicology and epidemiology and my admonition to any reader is that if we do not stop this junk science for politics and ideology, we will follow the path of fools for a cause—the path of true believers that is paved with confirmation biases and fallacious science and policy making that violates the law and cheats the taxpayer in two ways, scaremongering, and regulatory burdens that steal resources and assets for regulatory compliance that diminishes better use of those resources in the public and private sectors. My promise to the reader is I will show you how and how much the EPA disrespects and abuses the rules and methods of science.

The Submitter's opinions are personal and not attributable to the US Army or Department of Defense.

This submitter has witnessed US EPA misconduct for a period of 3 decades on a scale that is stunning, or alarming, going back to the EPA decision to ban DDT in the early 1970s, resulting in the deaths of millions in the 3rd world, and a particularly horrific impact on children.

More recently in addition to serial misconduct with regards to toxicology and epidemiology research the EPA has compounded its scientific methodology misconduct with a systematic violation of domestic and international ethical and moral/legal norms in regards to human experimentation—promoting and funding, approving human experiments that resulted in uninformed subjects being involved in experiments at 10 domestic and 6 foreign medical research institutions where they were intentionally observed while inhaling small particle contaminated air while being observed for adverse effects. These experiments carried out by prominent Medical Schools, is in spite of US EPA public pronouncements and testimony before congress that small particles are toxic, lethal (Hundreds of thousands of deaths annually) and carcinogenic.

US domestic law prohibits human experiments that might harm and international medical ethical standards for human experiments prohibit human experiments with no exceptions except exigencies of great need if the researchers act as subjects. Any other human experiments with a risk of harm are prohibited, and no consent will remove that proscription.

In the past 3 decades US EPA air quality research has been an abomination, relying on junk toxicology/epidemiology and the precautionary principle. The submitter has actively tried to expose the misconduct.

The proposal by the US EPA, discussed here to force EPA scientific transparency and scientific integrity is salutary and significant in all its elements, and the submitter is grateful for the change from the formerly fraudulent toxicology and epidemiology of the EPA to impose a new form of integrity.

Please consider the materials in the attachment as specified to support the position I take, that the Transparency proposal is a vital and very important policy for the EPA that will have beneficial effects in that it will identify the nature and magnitude of the US EPA research misconduct I put on display in the attachment that has been intentionally and viciously put forward as good science for purely partisan ideological purposes, not the pursuit of science that allows the US EPA to identify real risks and mitigate the effects of those risks.

Cordially and respectfully,
/JDunn MD/
John Dale Dunn MD JD

Personal Matters / Ex. 6

U.S. Environmental Protection Agency

Public Hearing on

Strengthening Transparency in Regulatory Science

9:00 a.m. to 5:45 p.m.

Tuesday, July 17, 2018

U.S. Environmental Protection Agency

1201 Constitution Avenue N.W.

Washington, DC 20460

US EPA Panel Members:

MS. JENNIFER ORME-ZAVALETA (Hearing Official)

MR. CHRIS ROBBINS (Hearing Official)

MS. MARY ELLEN RADZIKOWSKI (Hearing Official)

MS. CAROLYN HUBBARD (Hearing Official)

MR. BRUCE RODAN (Hearing Official)

MR. KEVIN TEICHMAN

MS. MARIA DOA

MS. LYNN FLOWERS

MS. SUSAN BURDEN

MR. LOU D'AMICO

Non-EPA Panel Members:

Ms. LAUREN HALL, SC&A INC.

Ms. LESLEY STOBERT, SC&A INC.

P R O C E E D I N G S

MS. ORME-ZAVALETA: So I want to say hello, and I want to thank you all for coming. We are now calling this public hearing into session. My name is Jennifer Orme-Zevaleta, and I'm with EPA's Office of Research and Development, and I'll be one of the hearing officials today.

Kevin Teichman is also with me from the Office of Research and Development, and we also have some contract staff, Nanishka , Lauren, and Lesley from SC&A Incorporated, who will be helping with the logistics.

The purpose of today's hearing is to accept public comments on EPA's proposed rule, "Strengthening the Transparency in Regulatory Science."

EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding, and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was

published in the Federal Register on April 30, 2018 (83 FR 18768), and EPA is proposing this rule under the authority of 5 U.S.C 301, in addition to the authorities that were listed in the proposed rule document dated April 30th of 2018.

So my role today is to ensure that EPA receives your comments in an orderly fashion, and then -- although EPA panel members here may ask clarifying questions, the intent of this hearing is to hear from you and to listen to your comments and not to discuss or debate the proposal.

So now, for a few housekeeping and ground rules. Please refrain from interrupting speakers or asking questions, shouting, noise making, or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately, and listeners on the phone can hear the oral testimonies.

For everyone's awareness, the hearing is

open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio, and photos. We ask that you not cause any disruption to those who are testifying or observing the hearing.

There is no formal lunch break, so you may leave for lunch and return to the hearing, but just be advised that you'll need to clear security again if you do that.

If you would like to make an oral comment on today's hearing and did not preregister to speak, please see the hearing staff just outside here at the door at the registration table, and they'll be able to sign you up.

If you would like to provide written comments to the official record, you may hand-submit it to EPA staff today, or mail it, fax it, or e-mail it, your comment. So see the staff at the registration table for instructions on how to submit written comments.

There is a comment box at the

registration table where you can leave hard copies of your oral testimony, or written copies. All comments received will be included in the official docket.

If you submit written comments, it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision.

EPA has extended the comment period and written comments must now be received on or before August 16th of 2018. So EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making any other comments that are not related to this action.

EPA will not provide responses during the hearing, rather EPA will prepare a written summary of comments received that include responses. The Response to Comments document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments

submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter who will be preparing a verbatim record of this hearing, so please speak clearly and slowly into the microphone so that the court reporter can record your comments accurately. A copy of the transcript will be placed in the docket. And this hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier. And it's divided into three sessions. 8:00 a.m. to 12:00 p.m., 12:00 to 4:00, and 4:00 to 8:00.

Public restrooms are located on both sides down the hall, men's to the left, women's to the right, and we will have staff escort you so that you're able to get through the security point and be able to come back. And please note the

location of emergency exits, primarily as you come in and you know, out where you entered this morning will be the main emergency exit for you.

So please take a moment to silence your cell phones. Speakers should have been given a sticker on entry that lists your assigned session, and if you plan to speak and have not received a sticker, please go back to the registration table so they can give you one.

For this session, the 8:00 a.m. to 12:00 p.m. session, the speaker sticker color is neon green so we can see you. Speakers will be called to the speaker's table, which is located right across from us, and will be coming up in pairs to that speaker's table. When it's your turn to speak, please come up to the table. Watch your step as you come up the steps over there, and state and spell your name slowly so that we can have that for the record. And if you are appearing on behalf of someone else or some organization, be sure to clear that -- make that clear as well. If you are not in the room when

it's your turn to speak, I will call you after all other speakers have made their oral arguments.

Each speaker is allotted five minutes for remarks, elected and appointed government officials may be provided additional time since they are representing large groups of constituents. Speakers will be notified when their time is ended. We have a time keeping system just over here. It runs by the yellow -- green, yellow, and red-light system. So when you begin to speak the green light will come on and you have five minutes. When you have one-minute left to speak you'll see a yellow light. And then when the red light appears, your time is up. At that moment I will ask you to wrap up your comments so that we can make room for the next speaker to come forward.

Speakers Numbers 1 and 2, if you could go ahead and please come on up and take your seat at the speaker's table. We will start with Speaker Number 1. And again, if I could ask you to please speak directly into the microphone and state and

spell your name for the record.

And if I could ask, Speakers 3 and 4, if you could just stand at the steps so that you'll be ready, and we'll be able to keep this moving. So, Speaker Number 1.

MR. STEICHEN: Good morning. My name is Ted Steichen, and it's S-T-E-I-C-H-E-N, and I am representing the American Petroleum Industry.

API is the only national trade association -- boy, it's not very bright here. Sorry. The American Petroleum Institute is the only national trade association with all facets of the oil and natural gas industry which supports 10.3 million U.S. speakers (sic).

Sorry. I'm having a little trouble this morning.

All right. So, supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our 620 corporate members from large integrative oil companies to small independent companies comprise all segments of the industry. API members are producers, refiners, suppliers,

retailers, pipe line operators, and marine transporters as well as service supply companies supporting most of the national energy.

The members of API are dedicated to continuous improvement in compatibility with their operations with the environment, while environmentally, economically developing energy resources, supplying high-quality products and services to consumers.

Our members recognize the responsibility to work with the public, the government, and others to develop and use natural resources in an environmentally sound manner that protects the health and safety of employees and the public.

API supports the use of sound science for a critical component of public policy, to the extent possible and consistent with the protections of other compelling interests, such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing or evaluating environmental health, welfare and economic impacts

should be transparent and reproducible and available as early as possible in the rulemaking process.

Transparency and reproducibility should be able to underly -- also be underlying data and information such as environmental and economic impact data and models that are utilized in protecting and predicting the costs, benefits, market impacts, and environmental effects of specific regulations.

API members are aware that there are obstacles to full transparency and reproducibility, and are committed to working with other stakeholders in developing practices and maximize science transparency while preserving existing confidential strictures.

The EPA -- as the EPA goes forward with this rulemaking, API recommends the following principles be followed. Openness to science and related findings underpinning the laws, regulations, standards, and guidance documents. Reproducibility of research and associated

findings, including fully annotated data, methodologies, model inputs, code and other critical information that support the conclusions of research. All of these should be available to the public.

The inclusion of clear requirements to ensure that the data underline the decision-making are publicly available in a manner sufficient for independent validation as much as practicable. Privacy concerns are important, but advances in encryption technology and blinding of data may make it possible to enhance transparency while ensure privacy as necessary to comply with the law.

Protection for confidential business information used in the regulatory process and supporting actions should also be taken into account, explicitly addressing and highlighting uncertainties in data, models, and analysis when utilizing those studies in decision-making. Broad application of these principles to inform the use of policy for setting scientific, economic, and

environment impact requirements and models that are designed to protect health and environment, engaging stakeholders as early as possible in the decision-making process to ensure application of data transparency principles for studies to be included, and to address how those studies have not been reproduced or are not reproducible will be considered in the process, application of these principles as early as possible in the pre-rule making stage, as technical support documents are prepared.

In closing, as described above, API supports the use of sound transparent science and public policy making, and we plan to submit written comments to the docket.

MS. ORME-ZAVALETA: Thank you.

MS. FELD: Good morning. My name is Jodi Feld, J-O-D-I F-E-L-D, and I'm the Chief Scientist in the New York City office of the New York State Attorney General's Environmental Protection Bureau.

On behalf of New York Attorney General,

Barbara Underwood, I thank you for the opportunity to speak before you today. The Office strongly opposes EPA's proposed rule to limit the use of science in agency rulemakings. The proposed rule was developed without any input from the scientific community and has been widely criticized by the scientific and public health communities. It is vague, poorly reasoned, and violates fundamental legal requirements for a valid rulemaking.

Most importantly, while the proposed rule has the stated purpose of strengthening the foundation of EPA's regulatory actions, it would have the opposite effect. It would exclude relevant probative scientific studies, models, and other information from EPA decision-making that have been validated by peer review, simply because the underlying data are not available to the public. The proposed rule broadly and squarely conflicts with core EPA statutory duties. It violates the very federal laws that EPA is required to uphold by limiting EPA's access to the

most current, best available, and generally accepted science that these laws mandate be used by EPA in developing new rules and standards. Quite simply, it is bad science.

It departs abruptly from the best practices of the scientific community and disregards both well-established reasons why public sharing of all study data is not possible or necessary, and why studies relying on such data demand consideration in agency decision-making.

The result of the proposed rule would be to profoundly weaken EPA's science-based regulatory decision-making, and ultimately its protection of public health in the environment in New York and elsewhere across the nation. We urge EPA to abandon this damaging and misguided effort. It appears that the proposed rule was developed with a total absence of independent scientific input. The proposal offers no rationale for the premise that only studies for which the underlying data are publicly available can be used for decision-making, nor any evidence that EPA's

current approach to selecting studies for decision-making is resulting in scientifically unsound decision-making, or is somehow overly protective of public health and the environment. Hence, at its core, the proposed rule is a solution in search of a problem.

Requiring that study data be publicly available as a prerequisite to its consideration by EPA would be an abrupt and unprecedented break from well-established best practices of the scientific community. The scientific community recognizes what the proposed rule ignores, that there are often very good reasons why some research data simply cannot be fully available to the public, such as the protection of personal privacy and confidentiality.

Within the scientific community the validity of research is judged on multiple grounds, including how well studies are designed, how clearly data are collected, how carefully analysis are performed and described, and how thoroughly findings of related studies are cited.

In other words, within the scientific community studies are validated through rigorous expert peer review. They are not summarily judged and valid and discarded simply because all underlying data cannot be fully shared.

Perhaps the strongest indicator that the proposed rule is flawed as a matter of science is the overwhelmingly negative reception it has received from the scientific community. We are not aware of a single major independent scientific organization that has expressed support for the proposed rule, while many have urged EPA to stop and reconsider the proposal.

Contrary to EPA's position, the proposed rule would certainly hurt states. EPA standards and regulations are a fundamental important to states and actions that affect these standards and regulations directly affect us. In fact, many states, environmental laws, and regulations explicitly adopt EPA standards. By undermining the basis of EPA standards and regulations, the proposed rule would likely have direct damaging

impacts on New York and other states' abilities to protect the health and environment of their residents. These impacts will be felt most historically by our most vulnerable populations, the young, the elderly, and the sick, and those living in communities that have borne a disproportionate share of environmental hazards, including communities of color and low-income communities.

From a legal perspective, the proposed rule fails to meet the most fundamental requirements for a valid rulemaking. It is exceedingly vague, creating many more questions than it answers. For example, exactly how, when, and to what the rule will be applied is entirely unclear. And critical information such as its actual cost is entirely missing.

In May, the New York Attorney General, joined by seven other attorneys general, wrote to then, Administrator Pruitt, expressing strong opposition to the proposed rule and calling for it to be withdrawn. Today, the State of New York

renews our call to Acting Administrator Wheeler to withdraw the proposed rule.

I thank you for your time and for providing me with an opportunity to speak on this important matter.

MS. LAUREN HALL: Thank you. If we could have Speakers 3 and 4 come to the table, and then 5 and 6 on-deck?

MR. SUSSMAN: Good morning. My name is Bob Sussman, and I am a former EPA official in the Clinton and Obama --

MS. HALL: Could you bring your microphone --

MR. SUSSMAN: -- administrations --

MS. HALL: Yes, thank you.

MR. SUSSMAN: -- and now a consultant and an attorney.

I'm here today representing Safer Chemicals, Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use

every day.

I believe that the EPA proposal we are discussing today is flawed and misconceived. In the name of transparency, it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on public health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of scientific evidence.

Study reports typically explain the protocols use to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of

such effects, and any unusual occurrences that may affect interpretation of the results.

This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk.

In principle, no one disputes the benefits of improving access to underlying data. The goals of open science have received support from several organizations in leading scientific journals and research institutions. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making, and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard

assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data.

Even with diligent efforts by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis. But an exemption process will add to the considerable cost and effort required to implement the proposed rule and will undoubtedly result in disputes and even litigation over whether exemptions are justified. Is the damage it will inflict on the quality and timeliness of EPA scientists justified by the benefits of the proposed rule?

EPA leaders have painted a bleak picture of EPA reliance on quote, "secret science"

developed behind, quote, "closed doors," based on data that has, quote, "been withheld from the American people."

This is not the reality that I experienced in my several years at EPA. I saw a very different reality. I saw EPA science assessments providing an exhaustive and critical review of relevant studies, and a full explanation of how they're being interpreted. I saw extensive information about each study being placed in the public record. I saw public comment and peer review of all EPA assessments. And of course, as part of public comment, members of the regulatory community had an opportunity at any time to replicate studies they deemed flawed.

In short, the problem that the proposed rule seeks to fix is imaginary. In conclusion, the Agency's leadership needs to fundamentally rethink the proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize a proposal which is deeply problematic and unnecessary. Thank you.

MS. ORME-ZAVALETA: Thank you.

DR. ROSENBERG: Good morning. I am Dr. Andrew Rosenberg, R-O-S-E-N-B-E-R-G. I'm the Director of the Center for Science and Democracy at the Union of Concerned Scientists. And we advocate for the role of science and public policy.

I'm here today to ask that you rescind this proposed rule because it would only restrict EPA's ability to use the best available science to fulfill its mission of protecting public health and the environment, while doing nothing to improve transparency and decision-making.

First and foremost, the proposal is fatally flawed because it provides almost no justification of analysis of the impacts of the proposed change in policy. There is no cost-benefit analysis of the rule with respect to the agency, and external researches, nor how it would affect EPA's mission and critical work.

Additionally, the proposal would affect -- effectively prevent the EPA from using many

kinds of scientific studies vital to its decision-making. This includes, but it is not limited to studies that rely on personal health data, confidential business information, intellectual property, or older studies where authors and data sources may not be accessible.

Without the ability to use this scientific information EPA would be unable to meet its mission and statutory obligations. This proposal would make it significantly harder for EPA to use the best available science to protect the public, including from harmful emissions of hazardous air pollutants, particulate matter and ozone, exposure to dangerous chemicals and commerce, drinking water contaminated with toxic chemicals, such as PFAS or lead.

Further, CBO has calculated that such restrictions would substantially increase costs and burdens to an agency that is already experiencing budget cuts, reorganizations and understaffing, thus undermining the ability of EPA to make decisions based on science.

The proposed rule could also prevent the Agency from addressing the impacts of dangerous chemicals at low concentrations where direct measurements are very difficult. This would have the effect of leaving Americans unprotected, even when there was clear indication of harm to human health.

I have over 30 years of experience in government service, academia, and non-profit leadership. I've offered -- authored or reviewed hundreds of peer-reviewed scientific papers. As part of my government service I worked as a scientist and in a policy position at a regulatory agency, and universities as a faculty member and dean. I understand how agencies use science in policy making, how research at universities is conducted, and how these entities incorporate best practices of transparency into their scientific work. As a frequent peer reviewer, I do not review the raw data for studies, since that would tell me little. I review the research questions, the methods that summarize data, the results and

conclusions in order to assess the quality of the work. EPA's proposed rule would do nothing to improve transparency for scientists, policy makers, or the public.

Crafting the rule without consulting with the scientific community is a fatal error for this proposal. Even the Agency's own Science Advisory Board has noted the need to consult with scientists in any further development of this proposal.

A further fatal flaw is that the proposed rule would replace scientific evidence with political judgment. The rule would grant the EPA administrator broad authority to exclude individual studies or entire decisions from being subject to its provisions. Decisions on which science is to rely on should be made by the Agency's scientific experts based on established criteria for best available science.

Five minutes is not enough time to cover all the problems with this proposal. At best, this proposed rule is a misguided attempt at

transparency. At worst, it is a back-door attempt to prevent EPA from protecting public health. UCS supports real transparency reforms. We support scientific integrity policies that prevent political interference in scientific analysis and reporting. We do not believe researchers should be put in the absurd position of choosing between protecting study participant privacy or informing the EPA's effort to protect public health and safety.

On behalf of the Union of Concerned Scientists, and I have 500,000 supporters, I urge the EPA not to move forward with this rulemaking and to continue to allow agency scientists and policy analysts to use the best science available to inform their work. Thank you very much.

MS. HALL: Thank you. Would Paul Tonko and Suzanne Bonamici please approach the speaker's table. Speakers A and B, respectively. And Speakers 5, Daniel Greenbaum, and 6, Jennifer McPartland, please take your seats at the on-deck circle.

MR. TONKO: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. TONKO: Can I begin? Okay. Thank you. Good morning and thank you for the opportunity to address the panel.

I am Congressman Paul Tonko. I represent the 20th Congressional District of New York State, more specifically the Capital Region and Mohawk Valley, an area rich in environmental stewardship.

As the Energy and Commerce, Environment Subcommittee ranking member, I have come here today to express grave concerns about the Environment Protection Agency's proposed rule published on April 30th of 2018, entitled "Strengthening Transparency in Regulatory Science."

This proposal would severely limit the types of research that EPA could take into account when developing policies. It has been cloaked in arguments about transparency. But let's all admit here that this emperor has no clothes. This has nothing to do with transparency. It is a thinly

veiled campaign to limit serious and highly credible scientific research that supports critical regulatory action.

This administration has used this bad faith argument about transparency to say that the many studies, including many epidemiological studies that rely on private, personal, medical data should be excluded entirely from EPA rulemaking. Why would a science-driver public agency undertake such a radical departure from existing and widely accepted scientific standards? I have yet to hear a credible answer to this question that is not rooted in favors to industry polluters.

The current political leadership at EPA has shown a pattern of bad faith in pushing policies that undermine this Agency's -- EPA's mission, and the public trust.

Today's proposal and its false claims about transparency are consistent with that pattern; a fact that was put on full display when the administration realized its broad approach

would hurt regulated industries too, since many EPA chemical reviews rely upon confidential business information. To get around this, the rule would give the EPA administrator complete discretion to exempt studies, especially or essentially guaranteeing that political interests will always matter more than science. That's why I refer to this policy as selective science.

This proposed rule would be used to erode landmark achievements in public health and environmental safety. For example, we know the Clean Power Plan would have led to reductions in pollution that were predicted to prevent some 3,600 premature deaths, 19,000 asthma attacks in children, and 300,000 missed school and work days each year. Many of these health benefits were partially determined by landmark clean air studies like the Harvard Six Cities Study.

Opponents of Clean Air Act protections would like nothing more than to see such landmark public health findings excluded from EPA reviews. I'm not here speaking alone. Nearly 1,000

scientists in many leading scientific organizations are united in vocally opposing this policy. Countless everyday Americans stand with us too, with many more listening in and watching for news to see if anyone in a position to do something about this will finally admit the obvious; this is not about transparency. This is not about protecting human health or our environment. This emperor, again, has no clothes.

This rule would limit the scientific research available to EPA policy makers as they draft public protections and environmental guidelines. I implore EPA to put science and public interest ahead of political and special interests, and withdraw this rule, ill-conceived, that's based on -- its negative impacts on science and public health. A very discouraging and concerning proposal. And I just felt compelled to come here today and vehemently speak against it.

MS. ORME-ZAVALETA: Thank you, sir.

MS. BONAMICI: Thank you. Good morning.

MS. ORME-ZAVALETA: Good morning.

MS. BONAMICI: And thank you to Acting Administrator Wheeler and Director Sinks. I am Suzanne Bonamici. I represent the First Congressional District of the State of Oregon. I serve on the House Committee on Science, Space, and Technology, where I am the ranking Democrat on the Subcommittee on Environment. I appreciate the opportunity to testify before you today.

I am opposed to the Environmental Protection Agency's proposed rule titled, "Strengthening Transparency in Regulatory Science." The proposed rule would impede, if not eradicate the EPA's ability to protect Americans from significant risks to human health and to the environment by limiting the scope of research that the EPA could consider in making decisions.

The proposed rule perpetuates the incorrect notion that the science the EPA relies on is somehow hidden. It is not. This misconception is based on conflating the meaning of secret and confidential. None of the information used by the EPA is secret. Some of

the information may be confidential if, for example, it includes the personal health information of individuals who participated in a study.

As a cornerstone of its regulatory process, the EPA relies on peer-reviewed science. The EPA already publicly discloses studies that support regulatory action. The proposed rule simply attempts to block access to good science. Much of the science that is used to inform regulatory actions is developed outside of the agency. Scientific studies often include personal information and other confidential data. Because this data is legally protected from disclosure, the EPA would be forced to ignore valuable information discovered during their research, because it contains confidential information. This would have chilling consequences for the EPA and for every person who benefits from clean air and clean water.

It is also deeply troubling that the proposed rule is inconsistent with the Agency's

statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, and Clean Water Act. The proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

There is also tremendous uncertainty whether the proposed rule would retroactively apply to existing standards and regulations. Retroactive application would severely undermine existing public health and environmental protections that keep the public safe and healthy.

Transparency is a laudable goal, and it could be accomplished through collaboration with, and input from the scientific community. It is noteworthy that thousands of scientists and many leading scientific originations also propose this proposed rule. If the proposed rule is implemented it is possible, or even likely, that scientists, organizations, and research institutions will be less inclined to participate in EPA funded research because of the risk of

improperly disclosing personal information. It may also be more challenging for researchers to recruit participants for their studies because of the fear that personal data could be shared.

Over the last few years, the House Committee on Science, Space, and Technology has considered several iterations of legislation that have many similarities to the proposed rule. I have been a vocal opponent of these bills for the reasons I just stated.

I also want to note that despite repeated efforts by the majority, the so-called secret science legislation has not passed both chambers. Congress has the sole constitutional authority to legislate, and this proposed rule is an administrative attempt to circumvent the legislative process. I strongly urge you to withdraw this proposed rule. It will undermine scientific integrity, jeopardize bedrock public health and environmental standards, and endanger the EPA's ability to protect the American people, which is its mission.

Thank you for the consideration of my testimony.

MS. ORME-ZAVALETA: Thank you both for coming.

MR. TONKO: Our pleasure.

MS. HALL: Would Daniel Greenbaum, Speaker Number 5 and Speaker Number 6, Jennifer McPartland, please approach the speaker's table. And would Speaker Number 7, David Michaels and Speaker Number 8, Paul Billings, please take a seat in the on-deck circle.

MR. GREENBAUM: Let there be light. And there was light.

My name is Daniel Greenbaum. That's green, like the color, B-A-U-M. I'm the President of the Health Effects Institute, and I'm very pleased on behalf of the Health Effects Institute to provide these brief oral comments today. We are preparing and will submit much more detailed written comments.

As many in this audience know, HEI has a longstanding commitment to the principles being --

attempting to be addressed by this proposal, producing science of the highest integrity and quality with special attention to issues of reproducibility and transparency.

This includes rigorous research and statistical design, subject to competition, continuous oversight, data quality assurance audits, and more, extensive efforts that test all findings against a wide range of different statistical techniques and assumptions, intensive and independent peer review with all results published, and an active data access policy which for nearly 20 years has been working to ensure access to underlying data for all HEI funded studies.

In our view, reproducibility is a critical challenge for science. Can the results of an important study be reproduced? However, in our view the most effective way to test reproducibility and the validity of science is not necessarily to simply reproduce the same results in the same data sets. Rather it is most

important to answer the question, "Are the results consistent when tested in other independent studies?" For example, studies that use new and different data sets not affiliated with the original studies. Studies that have different investigators applying the same and/or alternative statistical techniques. And studies that test the sensitivity of the results against a wide range of possible other explanations like smoking or socioeconomic status.

In a limited number of cases where there are not comparable studies, it may be useful to gain access to the original study data and analytic codes to allow for independent evaluation. Can the original results be replicated, and are they robust to a wide range of alternative assumptions, models, and potential confounders? This is, of course, exactly what the Health Effects Institute did when we conduced an independent rigorous reanalysis of the Harvard Six Cities and American Cancer Society studies. And I've attached and will submit the summary

description of that reanalysis from HEI's final report.

This approach can and did provide comprehensive assurance of the quality, integrity, and validity of the original results. However, this is a highly cost-intensive and time-consuming endeavor, which should only be applied in cases where there are only one or just a few studies in a particular arena.

HEI also agrees with the continued need to enhance transparency and data access, but would note that these issues are not new. We've had our own data access policy for over 20 years, and have been -- and they've been addressed now for over 15 yeas by administrations from both parties, and by the scientific community. This is -- it included guidelines for the Information Quality Act adopted by OIRA in 2002, numerous actions by the scientific community and journals to enhance access, and most recently the requirements for enhanced data access across the federal government promulgated by OSTP in February 2013.

We would strongly urge EPA to review the progress already made under these several major initiatives and to carefully consider whether or not there are additional efforts that could further enhance transparency and to do so before proceeding with a final ruling.

Finally, access to private medical information is essential to conducting high quality and reproducible air quality and health research. There are of course longstanding federal rules for protecting the privacy of individual medical information of the subjects of studies. And gaining access to data from older studies may be difficult, but given the privacy commitments that were made to study subjects in the past.

However, there are today, several means to make such data available to investigators with appropriate privacy protections. Medicare makes it available, federal research data centers make it available, and many investigators already have been taking advantage of these.

Although it is possible, as some have suggested, to create a depersonalized data set by stripping all personal identifiers, such as address, date of birth, et cetera, it's not possible to conduct a high-quality air pollution and health study without knowing the location of those being studied. I.e., Where do they live and what are the sources and levels of their air pollution exposure? So it can't be simply put on a disk and handed out.

Thank you for this opportunity to testify. We look forward to submitting our detailed written comments, and would welcome the opportunity to further assist EPA in these efforts to ensure that the widest array of science is available for decisions.

MS. ORME-ZAVALETA: Thank you.

MS. McPARTLAND: Good morning. My name is Jennifer McPartland, M-C-P-A-R-T-L-A-N-D, and I'm a Senior Scientist at Environment Defense Fund.

EPA's proposed rule represents a

disregard for the Agency's core mission, protection of human health and the environment. Under the guise of transparency, EPA's proposal handcuffs the Agency's use of best available science in violation of many of its statutes. If finalized, the rule will erode critical public health protections, and with them, the scientific integrity and public trust of the agency.

EPA's censored science proposal would prohibit EPA's use of critical scientific studies in developing regulatory requirements unless all the data underlying the studies have been made public. As the authors of this proposal know well, this unnecessary and unworkable standard would effectively bar the Agency from using high-quality scientific research in studying public health safeguards.

The data underlying many scientific studies are not publicly available and cannot be made publicly available. For example, research involving human subjects often rely on medical or other personal information; information that

researchers cannot make public.

Additionally, advances in data science have made it increasingly more challenging to effectively deidentify study subjects and protect their privacy. In other instances, studies may have been published decades ago and the underlying data are no longer available. It is exactly these types of studies that EPA and other authorities use to protect people from harmful environmental exposures like lead, formaldehyde, methylene chloride, benzyne, arsenic, and perchlorate, just to name a few. It is the science generated by our most prestigious scientific institutions. It is the knowledge we rely on to ensure our water is safe to drink, our air is safe to breath, and our land is safe for our children to play.

Beyond jeopardizing critical public health protections, the proposed rule completely disregards established effectiveness mechanisms used to vet scientific research including peer-review, data sharing agreements, and consensus in findings across multiple studies. Indeed, EPA

provides no explanation or justification, showing that this proposal would improve upon these established mechanisms.

The proposed rule also raises several troubling concepts that are contrary to scientific best practices and chemical assessment, as discussed extensively in the Seminole National Academy's report, Science and Decisions.

Specifically, the proposed rule ignores the report's conclusions that thresholds of effect for chemical exposures are the exception rather than the rule, given by a logical and exposure variability across the population. The rule also seeks to demote the use of health protective defaults and risk assessment, again at odds with the recommendations of the National Academies.

Additionally, the proposal gives more value to studies in employ of a variety of dose response models, an approach that can be misleading. Multiple bad analysis does not make a study more credible.

More broadly, the proposed rule seeks to

codify scientific practices and irregulation. It is a consistently frowned upon approach given the continuously evolving nature of science. EPA's development of the proposal also represents a total disregard for process. The Agency sidestepped review by its external Scientific Advisory Board, which has now voiced serious concerns about the proposal and has recommended that it undergo full SAB review before possible finalization.

The White House OMB review of the proposal was also quite dubious, involving a revision to the original date its review had been completed to seemingly align with the fact that former Administrator Pruitt had signed the proposed rule a day prior. The final OMB review process took course over just a few days, an impossible amount of time for any legitimate interagency review of the complex scientific issues at stake in this rulemaking, even though they have implications for all other federal agencies that rely on sound science.

Not surprisingly, the proposed rule does not grapple with the challenging steps necessary for legitimate effort to support greater data availability. It does not consider the digital infrastructure that would be required to make underlying study data publicly available in a secure manner, nor the resources needed for researchers in the Agency to use and maintain such a system.

Indeed, the congressional budget office estimated that a similar piece of legislation would cost millions of dollars. Americans need and expect the EPA to use the best available science. Right now, Americans across the country are drinking water contaminated with per- and polyfluoroalkyl substances, or PFASs.

In May, EPA publicly committed to initiating steps to regulate two of the most well-studied, PFOA and PFOS, toxic substances linked to cancer, thyroid effects, and reproductive harm. Some of the best available data on PFOA comes from the C8 Health Project, which involved a community-

wide assessment of 69,000 residents living around Parkersburg, West Virginia, who had been exposed to PFOA for decades. Studies resulting from the project will be critical to EPA as it takes steps to address PFOA and PFOS, yet the censored science proposal would make it difficult, if not impossible for EPA to rely on those studies.

EPA's censored science proposal serves the interest of polluters, not the public. It is designed to undermine EPA's use of critical research, EDF supports, meaning full transparency and science, and the ongoing efforts in the scientific community provide that transparency. But this proposal is not about transparency. It is about rolling back public health protections and environmental protections.

EDF strongly recommends that EPA withdraw the proposed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 7, David Michaels, and Speaker Number 8, Paul Billings, please approach the speaker's table. And Speaker Number 9, Gary Timm, and

Speaker Number 10, Tyler Smith, please take a seat in the on-deck chairs.

MR. MICHAELS: Good morning. My name is David Michaels, M-I-C-H-A-E-L-S. I'm an epidemiologist and Professor of Environmental and Occupational Health at the George Washington University School of Public Health. I'm also submitting a longer set of comments, copies of which I have available.

From 2009 to January 2017, I served as Assistant Secretary of Labor for OSHA, the longest serving in OSHA's history. From 1998 to 2001, I was Assistant Secretary of Energy for Environment, Safety, and Health, charged with protecting the workers, community, residents, and environment in and around the nation's nuclear weapons complex.

As a scientist who has been deeply involved in promulgating regulations that protect the public's safety, health, and environment, I recognize the importance of open science and using the best available science. However, the proposed rule does not accomplish these goals. Instead, it

would make it more difficult for EPA to use scientific findings to protect public health. I have no doubt it would result in more people made sick by pollution or toxic chemicals that would have been prevented in the absence of this new regulation.

This cynical approach proposed by EPA can be best described as weaponized transparency. Decades ago, when studies started to show that smoking killed not only smokers, but also their non-smoking spouses, the tobacco industry recognized the government would use this evidence to reduce smoking. In response, the tobacco industry demanded access to the raw data of these studies.

Big tobacco turned transparency, an important scientific principal, into a weapon. The strategy worked for tobacco for years, helping to delay regulation and increase the death toll from smoking related illness. Since then, polluters and manufacturers of deadly products have followed big tobacco's playbook. First

supporting legislation, and then when that was unsuccessful, this proposed rule.

If promulgated, this regulation would permit the EPA administrator to deny the Agency use of findings of any study unless the raw data and other related materials are provided to the Agency and posted on the Agency's website. There are no constraints on the administrator. She or he is not required to provide any rationale for rejecting a study because the underlying information is not publicly available.

The underlying justification for this quote/unquote, "transparency proposal," is a caricature of how science really works. It is not sound science. It is something that sounds like science, but isn't.

While in theory, most studies could be reproduced, they rarely are because it's a waste of resources. The scientific enterprise involves approaching the same question in different ways to determine if the results support each other. Reanalyzing the same study over and over is little

different from checking on a surprising newspaper article by buying additional copies of the same newspaper to see if it says the same thing.

Under the provisions of the Administrative Procedures Act, the EPA administrator does not have the authority to refuse to consider any comments submitted to the agency. If he or she thinks it's not valid, inaccurate, or inapplicable, she or he must explain why. Under the EPA submissions, including scientific studies, cannot arbitrarily or capriciously be discarded because the underlying data are not provided.

When I was an OSHA administrator, we wanted to protect the integrity of the science used in setting regulations, so we explored asking for conflict of interest disclosures, similar to those requested by every leading scientific and medical journal.

Our legal experts determined that we could request this disclosure, but we could not reject submissions that failed to include them.

This is a comparable situation; rejecting submitted studies because the underlying data are not available is prohibited under the EPA.

Furthermore, many of the EPA's authorizing laws require the Agency to use the best science. For example, the Clean Air Act mandates that air quality criteria accurately reflect the latest scientific knowledge. In the past the EPA has considered all available studies in issuing these criteria without consideration of the availability of the underlying data. Promulgation of this proposed rule would be a violation of these provisions of the Clean Air Act.

When the loss similar to this NPRM was first considered by congress, the EPA told the Congressional Budget Office that it estimated the cost of gathering, redacting, and posting the data on the public website, at $250,000,000 annually. The cost estimate made by the current administration for a substantially similar law dropped to $1 million a year from $250,000,000 a

year, because in the candid shocking words of the CBO, EPA officials explained this approach would significantly reduce the number of studies the Agency relies on when issuing or proposing covered actions.

In summary, by turning scientific transparency into a virtual weapon, the EPA will inflict severe damage to the nation's scientific enterprise. It will undermine the credibility and application of scientific evidence and impose costs and impediments that will discourage scientists from undertaking studies of great importance. Limiting the EPA's use of scientific evidence in the name of increased transparency will impede its ability to protect the health, safety, and environment of the nation. This proposal must be withdrawn.

MS. ORME-ZAVALETA: Thank you.

MR. BILLINGS: Good morning. I am Paul Billings, B-I-L-L-I-N-G-S, National Senior Vice President Public Policy at the American Lung Association. The American Lung Association is the

nation's oldest voluntary health agency. Our volunteer leaders take great pride in that our work is always grounded in the best available science. The American Lung Association opposes this rule and we urge the EPA to withdraw it.

Make no mistake, this proposal is not an effort to strengthen transparency or improve regulatory science. As I will discuss, this proposal is an effort to exclude important studies whose conclusions, especially studies that shows particulate air pollution causes premature death, are inconvenient. Together with the efforts to discount or exclude benefits from pollution reductions, this is a coordinated effort to ignore the science that is inconvenient to EPA's agenda to roll back regulations that reduce air pollution and save lives.

The EPA Science Advisory Board has asked to review the rule under the authority vested in it by the Environmental Research, Development and Demonstration Authorization Act. The SAB sent a letter to the EPA administrator, raising many of

the same scientific issues of confidentiality, feasibility, and the need for a clearer definition of crucial concepts, such as replication and validation. We urge the EPA to fully consult with the SAB before moving forward with this rule.

After the SAB review is complete, EPA should either withdraw the proposal, or provide an additional opportunity for public comment based on that SAB review.

We are disappointed that the EPA has made this proposal. This is not a new fight. It started in the early 1990s, when the tobacco industry tried to undermine the science that supported EPA's landmark risk assessment that showed that second-hand smoke kills. The tobacco industry and its allies lost a decade-long fight about whether or not second-hand smoke causes lung cancer, heart disease, asthma attacks, and other adverse health effects.

We know many of the details the tobacco industry's efforts, because -- as a result of the landmark tobacco litigation, nearly 90 million

pages of tobacco industry documents are housed at the University of California, San Francisco, Truth Tobacco Industry Documents library. Now we know the truth.

Within this archive are documents that show how PR firms, lawyers, and front groups attempted to undermine the credibility of EPA science. The documents show the tobacco industry launched this effort in the name of sound science that not only attacked the second-hand smoke risk assessment, but EPA's efforts to protect the public from ozone air pollution, radon, pesticides, and more. Remember, in 2006, the big tobacco companies were found guilty of civil racketeering for their decades-long conspiracy to defraud the public about the health risks associated with smoking.

The attack on science continued throughout the 90s, when EPA set the first standard for fine particulate matter. The PM2.5 standard. That national ambient air quality standard has saved thousands of lives. This was a

concerted effort by industry and the tobacco industry and their allies, and make no mistake, tobacco industry did not only focus on second-hand smoke. They attacked all of EPA's science. The other polluters came along for the ride and now we're leading that effort.

There was a concerted effort to undermine the Six Cities Study, and the American Cancer Society study. To address the questions being raised, and we just heard from the Health Effects Institute, the HEI, while protecting patient confidentiality, conducted an independent review of the data and these studies. The HEI reaffirmed the results from those studies. These landmark studies were key to informing the rules that cut PM2.5 pollution over the past two decades. Thousands of people are alive, and millions are breathing easier because of those efforts.

These studies depend on patient participation. Protecting patient confidentiality must be paramount and is key to recruiting study participants. This proposal will censor science,

will exclude important well-done peer-reviewed studies that are informing EPA actions, or will threaten that patient confidentiality. This is an unacceptable choice. EPA must use the best science, with within established frameworks, and not limit access to the best science to inform regulatory decisions. We urge the EPA to withdraw this proposal. Thank you very much.

MS. HALL: Thank you, both.

Would Speaker Number 9, Gary Timm, and Speaker Number 10, Tyler Smith, please come up to the speaker's table. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, please take your seat in the on-deck chairs.

MR. TIMM: Good morning. My name is Gary Timm, G-A-R-Y T-I-M-M. I worked at EPA for 38 years and retired in 2011.

I was Chief of the Chemical Testing Branch in the Office of Pollution, Prevention, and Toxics for 10 of those years. The Chemical Testing Branch is responsible for implementing the

testing provisions of Section 4 of the Toxic Substances Control Act.

Today, my remarks will focus on three things. Our studies traditionally used in support of regulation, and vis-à-vis, the proposed transparency policy, it's interaction with TSCA Section 4, and its interaction with our obligations to accept studies conducted in accordance with OECD test guidelines.

Let us be clear, if EPA had adopted this data transparency limitation and past risk assessments, EPA would not have been able to take many of its historic actions to protect children, families, and the environment. No reduction or elimination of the exposure to children to lead and paint, gasoline and drinking water, no air quality standards for particulate matter and other air pollutants, and the list goes on and on.

The proposed policy would affect assessments that will soon be carried out under TSCA Section 6. TSCA gives EPA the authority to regulate the manufacture, processing, distribution

and commerce, use, and disposal of chemicals. The problem formulation documents, which set forth EPA's approach for assessing the first 10 chemicals under the amended TSCA are open for public comment now.

How these chemicals are assessed will be the model for future assessments. The proposed policy would in fact make it impossible for EPA to consider the full array of well-conducted and peer reviewed scientific studies of the health and environmental effects of pollution. It would bias the body of information in favor of industry supplied studies, since they would all have the means to provide the underlying data.

Assessment of all relevant scientific information is essential in making sound judgments about protecting human health and the environment. And it is a legal requirement in all major environmental legislation.

TSCA also contains provisions to require chemical manufactures to test the chemicals that they manufacture and process. To require industry

to test chemicals under Section 4, EPA must make a set of legal findings. It is the data inadequacy finding that we are interested in today, for it is the nexus between TSCA Section 4, and the proposed transparency policy.

To make this finding, EPA conducts a thorough literature search and usually issues a rule to require studies that have not been published to be submitted to the agency. Typically, the bulk of information considered, however, is studies published in the peer reviewed scientific journals. Despite being accepted by the scientific community, these studies do not meet the transparency requirements of the published rule, since it requires that all raw underlying data and the models used to analyze the data supporting their study are available for public review.

Thus, if the Transparency Rule were in effect, under TSCA Section 4's second finding, EPA would have to judge studies from peer reviewed journals as inadequate. Ignoring this large

category of information would cost industry hundreds of millions of dollars to repeat perfectly good scientifically acceptable studies, which the public would ultimately pay for through higher prices. And it would significant delay, or in some cases preclude assessment and regulation of risks to human health and environment.

Another aspect not discussed in the proposed transparency policy is the obligation of the U.S. to accept data generated in accordance with the Mutual Acceptance of Data treaty. The U.S. and other Organizations for Economic Co-operation and Development member countries realize that differences in testing requirements on countries, meant that companies would in some cases have to retest a chemical in order to market it in other areas. This was needlessly costly and resulted in a delay in obtaining information needed for regulatory assessment.

As a result, the OECD member nations agreed to accept, for regulatory purposes, data generated in accordance with the OECD test

guidelines. Submission of underlying data is not a requirement of the Mutual Acceptance of Data treaty. Therefore, the proposed policy which requires underlying data to be made available to be used for risk assessments would run counter to our obligations under the Mutual Acceptance of Data treaty.

In short, the proposed policy is a trojan horse. I can only conclude that this proposal constitutes fraud, as it is deceptive. Waste, rejecting perfectly valid studies and abuse, for it is arbitrary and capricious.

Thank you for giving me the opportunity to provide comments this morning.

MS. ORME-ZAVALETA: Thank you.

MR. SMITH: Good morning. My name is Tyler Smith. I'm a staff scientist at Earthjustice. We are the largest non-profit environmental law organization in the country.

EPA's proposed rule is an attack on the science used to protect children's health. Simply put, it would weaken risk assessments for

chemicals that harm kids. These chemicals include organophosphate pesticides like chlorpyrifos, which EPA scientists long ago concluded present grave risks to children.

Earthjustice therefore urges the Agency to reconsider its approach and withdraw the proposal immediate. Under the Food Quality Protection Act, EPA is required to abide by an additional safety factor of 10 when setting the level of exposure to a pesticide that may harm infants and children. It is well established that children are more susceptible to the toxicity caused by pesticide exposure than adults. The law therefore requires that EPA take this into account and ensure that the most vulnerable among us are protected.

Under the statute, EPA may decide to apply a different safety factor if, and only if it concludes on the basis of reliable data that such margin will be safe for infants and children. The most reliable data, including epidemiological studies conducted in three different perspective

cohorts clearly establish that prenatal exposure to chlorpyrifos and other organophosphates, harms the developing nervous system. This exposure reduces IQ, and it increases the risk of developmental disorders, such as ADHD.

All of this science was peer reviewed prior to publication, and EPA scientists and the independent experts who serve on the FIFRA Scientific Advisory Panel reviewed it extensively and repeatedly over many years. Accordingly, chlorpyrifos risk assessments conducted in 2014, and again in 2016, included the required safety factor, and both assessments found that exposures exceeded the identified levels of concern.

Accordingly, the EPA proposed banning all uses of chlorpyrifos on food in 2015. But last year, political appointees at the Agency disregarded this science and announced that the Agency would not finalize the proposed ban. EPA now may wait years to reconsider. And it appears that the same political appointees who disregarded the science, now want to weaken the chlorpyrifos

risk assessments in advance of their next review.

Indeed, the pesticide industry responded to EPA's conclusions on chlorpyrifos by proposing novel requirements that are strikingly similar to what the Agency now proposes to do for all science. CropLife America, an industry trade association, asked EPA to quote, "Require access to raw data as a prerequisite to relying on any study to support regulatory decisions," unquote. And Dow AgroSciences, which manufactures chlorpyrifos, also complained in comments that the Agency is not quote, "Secured and shared the raw data underlying the epidemiology studies," unquote.

Now EPA did seek a study -- or, I'm sorry, did seek data from a study conducted at Columbia University. However, Columbia determined that it could not provide all of the requested data without violating its obligations to the mothers and children who had participated in the research.

Notably, EPA did not respond to these

concerns by refusing to consider the Columbia study. Rather, scientists from the Agency and Columbia met to discuss the study in greater detail, and the University produced extensive supplemental analysis in response to agency questions.

Furthermore, Columbia offered to make all of the data available to agency scientists for analysis in a secured facility on Columbia's campus. Now these efforts suggest there are numerous alternatives to the rigid requirements the proposed rule would impose on the use of science and agency rulemaking.

As epidemiologic studies of chlorpyrifos support retaining the safety factor to protect infants and children, EPA may believe that such studies fall within the vague definition of dose response data and models contained in the rule. If so, EPA may believe that the continued efforts by Columbia to protect the hundreds of mothers and children who participated in its research preclude the use of these data because they cannot be made

publicly available.

EPA may believe this precludes the use of other epidemiologic studies as well. As a result, this proposal could be used to avoid protecting infants, children, and others from exposure to chlorpyrifos and more than two dozen other organophosphate pesticides. It is simply outrageous that EPA, an agency charged with utilizing science to protect public health, would do the bidding of the pesticide industry it regulates, and try to circumvent its own scientific conclusions by choosing to ignore the best available science.

I urge the Agency to reconsider this proposal and withdraw this deeply flawed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, approach the speaker's table. And Speaker Number 13, Diana Van Vleet and Speaker Number 14, John Auerbach, please take a seat in the on-deck chairs.

The speakers are reminded to please speak into the mic, and also state who you're speaking for. Thank you.

MS. ECONOMOS: Hi. I am Eugenia Economos, E-U-G-E-N-I-A E-C-O-N-O-M-O-S. I am with the Farmworker Association of Florida. We are a grassroots farmworker organization that's over 35 years old. I say that because it's important to understand that our organization was co-founded by a man who was a farmworker himself. Our staff are almost all former farmworkers. Our board of directors are farmworkers. They're from farmworker families. And I'm here on behalf of our communities who are mostly African/American, Hattian, and Hispanic farmworkers who harvest the food that feed all the rest of us, the food that we eat is harvested by farmworkers in the field who are exposed regularly to pesticides. And I'm here on their behalf.

Our organization is very involved in pesticide health and safety, and in doing that we have participated in community based participatory

research projects, including a four-year project with Emory University that we did. It was funded by NIOSH, and in that study, we looked at farmworkers and in the nursery industry that did ornamental plants in Central Florida, and farmworkers in the fernery industry, which are also ornamental plants.

And we looked at the reproductive health effects of occupational exposures, including occupational exposure to pesticides. We are well-trusted in the community because we are based in our communities and because we are of, by, and for the farmworker communities. And we're able to do these studies because we have the trust of our community members.

In that study with Emory University, we did surveys with 260 women of reproductive age. One of the things we looked at was -- we additionally did urine samples on 100 women, including women that were pregnant, looking at levels of organophosphate pesticides and the pesticide, mancozeb, in their urine.

One of the reasons we chose mancozeb, because that is a fungicide that was implicated in birth defects that happened in Omokollee, Florida in 2004 and 2015, and we wanted to look at the levels of the pesticide in the urine of the women that we studied.

The results of that study showed very high levels of organophosphate pesticides and mancozeb in the urine of the women that we studied, much higher than the NHANES national averages.

We used that information in order to both develop a training for the women about how to protect themselves from pesticides. But we also used that information to write up a paper about -- because mancozeb is coming up for re-review, and we think it's very important to understand the levels that we found of the mancozeb in the urine.

I say that because we would not be able to do that study if we did not have the trust of the people. And we had that trust because we ensured their confidentiality. We would not be

able to do this if there was any sense at all that their confidentiality could be compromised. You're talking about people who are minorities. Many of them are immigrants. They're already under attack in their communities for many other reasons, and if we could not assure their confidentiality, we would not have participation.

I have people come to me all the time with different complaints from their work environments. And it's heartbreaking to me when people come to me and talk about being exposed to pesticides, and then they're afraid to make a report because they're afraid of losing their job, or they're afraid of retaliation.

We would -- we cannot, we would not, we would never engage in studies if we could not ensure that our people, our community would be protected from any kind of revelation of their identities or of their information. So that's why we are opposed to this proposed rule. We're also concerned about that epidemiological data is really important to look at synergistic and

cumulative effects of pesticide exposure, and you cannot find that without doing epidemiological studies. So we are also concerned that we're -- I'm sorry. We're also looking at the body burden of pesticides in the farmworkers that we study, and farmworkers are exposed to multiple different kinds of pesticides. And if you're not looking at epidemiological studies to look at that, then you are ignoring an important role of science in the farmworker community.

I am saying that, I am sitting here, and I just want you to know that even though I'm sitting here, behind me are tens of thousands of farmworkers in Florida and around the country, and I'm here on their behalf. And on their behalf, I'm asking you to reject this rule. Thank you.

MS. ORME-ZAVALETA: Thank you.

MS. LeHURAY: Good morning. My name is Anne LeHuray, L-E-H-U-R-A-Y. And that's Anne, with an E. And I am here as the Executive Director of the Pavement Coatings Technology Council, also I'll call it PCTC.

PCTC, their members manufacture products that are used in pavement maintenance programs to extend the useful life of an asphalt parking lot, for example. Airport surfaces, and the like.

Our members are almost exclusively small family-owned businesses, and their customers, who we also represent, are virtually 100 percent small family -- small and maybe even say micro family owned businesses.

So at PCTC, we strongly support the concept of what EPA is proposing in the "Strengthening Transparency in Regulatory Science" rule, however we urge EPA to go beyond what it has proposed with a goal of improving on EPA's current procedures which lack any meaningful remedies when the Agency relies on science that has been shown to be unreproducible.

The Council supports the efforts of the Agency to ensure that scientific studies, data, and models on which it relies in developing regulations, guidance, and policies are sufficiently transparent. Doing so helps ensure

that others can attempt to reproduce the results in which the Agency bases its regulation, guidance, and policies.

However, the council believes the proposed rule does not go far enough. PCTC has witnessed first-hand the distortions and bad public policy that can result from what has been called in other venues, secret science, by which we mean, science that has been shown not to be reproducible.

And EPA has contributed to this problem. They were not the source of the unproducible science, but they've contributed to the problem by using that unreproducible science, because to use the Agency's words, it is fit for purpose. Meaning, we suppose, that it suits the Agency's desire to regulate, even if the science says that the regulation is unwarranted.

So PCTC's experience causes it to be concerned that the Agency proposes to restrict its increased focus on transparency to only dose response data and models, to only final

regulations, and to only pivotal studies as narrowly defined the proposed rule.

We would note that worldwide scientists and science organizations have recognized the crucial rule of transparency to the very crux of the scientific enterprise, which is, science has to be falsifiable. That means that it has to be reproducible.

At a minimum, the Agency should be as concerned as the publishers of peer reviewed science journals, that all the science it considers is possibly key or pivotal to a right to a regulatory purpose, any regulatory purpose meets the standard of transparency.

EPA's role is to translate and distill research results into regulations, guidance, and policies that have significant impacts in the real world. It is therefore the obligation of EPA to ensure that it uses the best available science, which by definition includes science that has been shown to be reproducible on any issue of any important EPA policy making.

Now to promote the idea of use of reproducible science and transparency, and an understanding in all agency actions, PCTC has two specific recommendations. One is that it gives preference to studies, not just when industry submits a study as part of let's say registering a pesticide, this requires that that study has to follow GLP, Good Laboratory Procedures -- Good Laboratory Practices.

GLP is a formal program. It relies on, like OECD, guidance, methods, test methods. But there's also a thing called the Spirit of OECD, which simply means following good standard scientific practice.

So we recommend and go into detail in our written comments about that the GLP should be given preference in all science that all -- that EPA considers in any of its policy making decisions. And we also have a specific recommendation about how the Office of the Science Advisor should consider combining the roles of the information quality function at EPA, and the

Office of Scientific Integrity, and I thank you very much for your attention and we expand on this in our written comments.

MS. HALL: Thank you very much.

Would Speaker Number 13, Diana Van Vleet, and Speaker Number 14, John Auerbach, please come up to the speaker's table. And Speaker Numbers 15, Harvey Fernbach, and 16, Joseph Stanko, please take a seat on the on-deck chairs.

MS. VAN VLEET: Hello. My name is Diana Van Vleet, D-I-A-N-A, Van Vleet, V-A-N V-L-E-E-T. I work for the American Lung Association, but I am sharing comments on behalf of Health Care Without Harm today.

As the organization leading the global movement for sustainable healthcare, Health Care Without Harm strongly opposes the proposed rule, "Strengthening Transparency in Regulatory Science." The rule would impede the Agency from upholding its mission to protect human health and the environment by limiting the use of scientific research.

It was the EPA's conclusions regarding the human health impacts of dioxin that lead the formation of our organization in 1996. Since then, we have led the charge to transition the U.S. healthcare sector away from medical waste incineration, the leading source of dioxin pollution.

In the United Sates, more than 5,000 medical waste incinerators were in operation in the mid-90s. Today, fewer than 16 medical waste incinerators remain. This work would not have been possible without the EPA relying on sound science to make determinations about the toxicity of dioxin pollution for human health.

Currently, Health Care Without Harm works with hospitals and health systems to transition to renewable energy and to prepare for the impacts of climate change. We look to the EPA to heed the science regarding the human health effects of fossil fuels and climate change when making decisions so that our hospitals are in the best position to protect their patients.

By artificially limiting the research it considers when making decisions, the EPA would endanger health and put lives at risk. We urge the EPA not to adopt this proposed rule.

MS. ORME-ZAVALETA: Thank you.

MR. AUERBACH: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. AUERBACH: My name is John, that's spelled A-U-E-R-B-A-C-H.

I am a public health practitioner. I've been a leader in the public health field for about 30 years. I was a city health commissioner, a state health commissioner, and an official at the Centers for Disease Control, and currently I am the President and Chief Executive Officer of Trust for America's Health, or TFAH.

TFAH is a non-profit, non-partisan public health and science-based organization that promotes optimal health for every person and community, and makes the prevention of illness and injury a national priority.

TFAH has been focused on issues like

clean air and clean water, because they are fundamental to ensuring that all Americans have the opportunity to live long and healthy lives. This is particularly crucial since we know that unhealthy air or contaminated drinking water disproportionately affect some of our more vulnerable subpopulations, including children, older adults, and lower income Americans who are more likely to include racial and ethnic minorities.

As a component of our mission to promote health we issue a series of reports every year that examine some of our nation's most pressing health issues, and we rely heavily on all available research and evidence to develop recommendations for decision makers on how they can most effectively respond to improve health.

For example, in 2011, TFAH and the Environmental Defense Fund released a report that analyzed the savings and health care spending associated with four different EPA regulations. In so doing, we relied on the EPA's own regulatory

impact analysis that measured reduced mortality, reduced incident of chronic bronchitis, reduced incident of heart attack, and decreased hospital emissions and emergency room visits. These studies estimated that nearly half a million lives could be saved by these four EPA standards alone.

Because of the importance of having access to such scientific data in order to protect the public's health, we oppose the "Strengthening Transparency and Regulatory Science" proposed rule. Research and evidence is the foundation of EPA's policies and has been necessary for success of laws like the Clean Air Act and improving and in saving lives from the dangers of air pollution.

Congress intentionally directed EPA to consider peer reviewed research under the Clean Air Act, and mandates regular reviews of the science to ensure that EPA is reviewing and considering the most up to date science. We believe that the proposal would prevent EPA from using the best science to inform decision-making, and the result would be weaker standards at the

expense of American's health. For example, the proposal would exclude several landmark air quality studies from the evidence base that EPA is permitted to consider, largely on the basis that these studies include confidential patient information that would make them less transparent under the constructs of the proposed rule.

The practical result would be weaker air pollution standards, despite the fact that the science behind these studies is pointing us in the opposite direction. The current methodology and system for review is sound, reliable, and has operated effectively for years. And that's why we have joined with the American Lung Association, the American Academy of Pediatrics, the American Public Health Association, and over 70 additional public health, medical, and academic organizations in opposing this regulation, this proposal.

As a long-term public health practitioner and the President of TFAH, I remain committed to ensuring that federal health policy and practices are guided by the evidence in a transparent and

accountable manner. EPA and other federal agencies should be no exception. We at TFAH look forward to working with congress, with the EPA and others, as we continue to advocate for policies and practices that uphold these principles and protect and promote the health of every American. Thank you very much.

MS. HALL: Thank you very much. If I could ask those that are in the room to please refrain from talking. There's a lot of whispering and it's distracting. If you do need to have a conversation, please step outside the room. Thank you.

Would Speaker Number 15, Harvey Fernbach and Speaker Number 16, Joseph Stanko, please approach the speaker's table. And Speaker Number 17, Peter Lurie and Speaker Number 18, Jamie Wells, please take a seat in the on-deck chairs.

What speaker number are you?

MR. STANKO: Sixteen.

MS. HALL: So, do we have Speaker Number 15? Harvey Fernbach?

[No audible response.]

MS. HALL: Okay, so we'll move ahead.

[Discussion off the record.]

MS. HALL: Number 17, Peter Lurie, would you like to take a seat up here? And then Speaker Number 19, Ami Zota, please take a seat in the on-deck chairs. Thank you.

MR. STANKO: Thank you. My name is Joseph Stanko, S-T-A-N-K-O. Thank you for the opportunity to address EPA's proposal entitled, "Strengthening Transparency in Regulatory Science." My name is Joseph Stanko, and I am counsel to the NAAQS Implementation Coalition.

The Coalition is comprised of trade associations, companies, and other entities who confront challenges in permitting and operating manufacturing and other facilities under increasingly stringent National Ambient Air Quality Standards.

Our members --

MS. ORME-ZAVALETA: If we could ask you to move the microphone a little bit more in front.

MR. STANKO: Sure.

MS. ORME-ZAVALETA: No, the other way. There you go.

MR. STANKO: All right.

MS. ORME-ZAVALETA: Thank you.

MR. STANKO: Our members, and the companies they represent have a proven record of working with states and regional EPA offices on implementing emissions reduction strategies to attain NAAQS.

However, increasingly more stringent NAAQS have caused demonstration requirements for Clean Air Act permits to exceed the limits of current tools and policies for NAAQS implementation. This makes it increasingly more difficult for companies to attain the approvals needed for new state of the art projects that create jobs and bring much-needed tax revenue to local communities.

Without a transparent NAAQS process, underlying studies lack robust external review, leading to standards that may not provide

objective public benefit. In certain cases, increasingly stringent standards have pushed NAAQS to concentrations at or near background levels, beyond the feasible limits of implementation. While inaccurate assumptions in both setting and implementing NAAQS could be more readily absorbed under prior less stringent NAAQS levels, recent more stringent standards have eroded such tolerances.

Addressing this new reality starts with an inherently forward-looking NAAQS review process that assesses science and policy in a rigorous and holistic manner. The transparency proposal fosters such an open-source approach to pivotal regulatory science, one that enables the public to more meaningfully comment on the science underlying NAAQS review. This can foster a more effective NAAQS implementation that still meets the Clean Air Act's mandate to protect public health.

While we support the principles behind the transparency proposal, its sound policy goals

should be balanced with legal and ethical obligations to protect private, sensitive, and confidential information. As the transparency proposal is implemented, efforts must be made to address protected health information under the Health Insurance Portability and Accountability Act, or HIPAA.

Disclosure limitations also exist for proprietary information and trade secrets. We agree with EPA that dose response data and models should be exempt from public review as necessary to protect private, sensitive, and confidential information. However, we believe that EPA can protect such information while still seeking maximum possible transparency.

As the transparency proposal notes, many generally acceptable techniques exist to deidentify personally identifiable information. Where such deidentification is not possible, EPA could facilitate review of sensitive data sets by a diverse group of experts subject to HIPAA compliant nondisclosure agreements.

If all other options to expand review have been exhausted, EPA could decide that a study could not be subject to outside review and verification, and consider the study accordingly without excluding it from a rulemaking proceeding.

Administrations -- administrators pardon me, have regularly taken similar methodological considerations into account when assessing studies in past NAAQS reviews. EPA could further balance transparency and privacy by appropriately tailoring the transparency proposal according to the type and scope of the regulatory decision involved. For this reason, we agree with EPA that the transparency proposal should be limited to pivotal regulatory science that is involved in significant regulatory actions that result in substantial costs.

To that end we note that because Clean Air Act regulations have accounted for the vast majority of costs and benefits cited in rules over the last decade across the entire federal government, such regulations are particularly well

suited for the transparency proposal's high standard of robustness.

As this process moves forward, we encourage EPA to further detail how the transparency proposal will protect private, sensitive, and confidential information, be it personally identifiable or proprietary information, trade secrets, or other similar information. To that end, EPA should explicitly state that any final regulations arising from the transparency proposal do not support or assert authorization under the law to disclose such currently protected information, and that any claim to do so must be independently based on a statutory grant of authority from congress.

In conclusion, the transparency proposal would increase replicability and verification in the scientific process, thereby testing critical methodological assumptions and mitigating biases in key studies upon which the Agency relies in developing regulations. It recognizes that transparency can go beyond simply maximizing

disclosure to better contextualizing studies through replicability and verification.

In doing so, the public can more meaningfully take part in EPA notice and comment rulemaking processes. As EPA advances the transparency proposal, it can and should implement these sound policy goals in concert with obligations to protect private, sensitive, and confidential information.

The NAAQS Implementation Coalition appreciates EPA's efforts on the transparency proposal, as well as the opportunity to present its view on the topic.

MS. ORME-ZAVALETA: Thank you.

MR. LURIE: Hear me? Good morning. My name is Dr. Peter Lurie. I'm a physician, an epidemiologist, and now the President for Center for Science in the Public Interest. We are an independent science-based health advocacy organization with over 500,000 members.

Before I joined CSPI, I served at the FDA as an associate commissioner and in fact, for

several years I led the Agency's transparency initiative. Over the course of my career I've authored close to a dozen academic articles on the topic of transparency, and nobody ever asked me for the underlying data for any of those studies.

We at CSPI are firm advocates of scientific transparency and have had a number of projects along those lines over the years. But EPA's proposed rule is not about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep's clothing of transparency in science. Proposal should be withdrawn.

Transparency is not about restricting the use of sound science, as this proposal would do. Suddenly, the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be the grounds for the summary exclusion of data that were rigorously gathered and reported.

The surest tests of any scientific transparency policy are two. One, was it generated in a transparent fashion? And two, will it actually promote the transparent rigorous science-based decision-making that it claims to? This proposal fails on both counts. Let's start with the procedural matter.

This proposal violates fundamental tenents of transparency rulemaking. EPA failed to consult with relevant stakeholders, such as science, research, or health professional associations, did not consult with other federal agencies who would be affected by this, and did not even make the proposed rule available to its own Scientific Advisory Board for review.

In addition, the proposal lacks critical citations and documentation, or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the Agency has merely adopted a legislative initiative that failed to (indiscernible) despite support from the energy,

chemical, manufacturing, and other key industries.

Moreover, despite its professed (indiscernible) to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply blithely asserts that, quote, "EPA believes the benefits of this proposed rule justify the costs." I wish we could have gotten away with that at FDA.

But the rule would be costly indeed. Analysis of an earlier version of the legislation predicted costs of $250 million over the next few years. But even more important, the proposal does not meet its purported scientific goals and will instead undermine the scientific basis for decision-making at EPA.

Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA's greatest public health accomplishments, such as eliminating lead and gasoline, classifying second-hand smoke as a

cause of cancer were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. And I can say, at FDA, we would not have had the rules that we ultimately developed or proposed on mercury in fish, on arsenic in rice, on dental amalgam, or in sodium targets from a nutritional perspective. None of those could have been done if data of these kinds were eliminated.

In particular, it's also especially troubling that the proposal also opens the door to a reconsideration of past rules which would be utterly inappropriate under prevailing principles of administrative law. In fact, the proposal would have an effect opposite to its claimed purpose. It would address -- it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry.

Further evidence of the pro-industry orientation of this proposal is its discussion of the dose response function and the assault on linearity. Quite aside from the merits of that discussion, which I think are few, the real question is, what is this discussion doing in this proposal in the first place. It has nothing to do with transparency whatsoever, and it's simply there as a marker, in my view, of the pro-industry bias that this entire enterprise represents.

Let me close with a question with which EPA should have started. What exactly is the problem that this proposed rule seeks to fix? Where indeed is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard?

To the contrary, the record is replete with studies that form the basis of health and life saving regulations that would now be precluded from use, and that might even provide a basis for the revocation of rules enacted in the

distant past. Thank you.

MS. HALL: Thank you. Would Speaker Number 18, Jamie Wells, and Speaker Number 19, Ami Zota, please come up to the speaker's table. And Speaker Number 20, Surbhi Sarang and Speaker Number 21, Laura Bloomer, please take a seat in the on-deck chairs. Thank you.

Please, quick reminder to speak into the mic and state your organization.

MS. WELLS: My name is Dr. Jamie Wells, J-A-M-I-E W-E-L-L-S, and I'm the Director of Medicine for the American Council on Science and Health, and I'm here on behalf of our president, Hank Campbell.

In the past, peer-reviewed journal publication ha been considered authoritative, but that has inherent weakness if they can't be replicated. Knowing the potential for error, and even misuse, replication is vital, but we recognize that that's not always possible. A safety valve for that is a higher level of scrutiny when it is not possible. Studies that

can't be replicated should at least make sense within the pattern of available data, which in the case of EPA will often include hundreds of other studies done according to federal guidelines.

However, there are also occasions where replication is not possible and new claims or outliers from the consensus of many other studies. And in those cases, they should still absolutely be used if EPA risk scientists, without breaking confidentiality, can obtain the additional information needed in order to conduct their own analysis.

EPA risk scientists are charged with protecting public health, and the American Council on Science and Health has argued since 1978 that the judgment over which epidemiology and/or toxicology data to use for risk or safety assessment should always include risk scientists. The public's interest is best served when science is replicable and consistent with other information.

On occasions, when studies cannot be

replicated, or when such studies are not consistent with other information, use of those studies depends on having access to the underlying data for independent analysis. When the underlying data are not provided, it is difficult to make a credible risk assessment, much less national rulemaking, as you know. So risk experts should be involved.

You should have received a more extensive written document as well.

MS. ORME-ZAVALETA: Thank you.

MS. ZOTA: I'm Dr. Ami Zota, that's A-M-I, last name Z-O-T-A. I am a health scientist and Professor of Environmental and Occupational Health at the George Washington University Milken Institute School of Public Health. I am also speaking as part of Project Tender. We are an alliance of scientists, health professionals, and advocates with expertise in protecting children from exposure to toxic chemicals that can contribute to neurodevelopmental problems, such as ADHD and learning disabilities.

I oppose EPA's proposed rule. The proposed rule prohibits the Agency from setting regulations that are support in part or whole that is for data that is publicly available for reanalysis or cannot be replicated.

Since the proposed rule is retroactive, it could lead to the dismantling of many important existing EPA regulations that safeguard our children and families -- children and families from toxic chemicals.

I would like to spend my time identifying some of the major problems with this rule that warrant consideration before the Agency moves forward. The scientific sources cited for the basis of this rule do not support the proposed rule. EPA did not consult with critical stakeholders in the development of this proposed rule, including scientists, health professionals, and affected communities.

EPA does not present any analysis of benefit-cost, children's environmental health risk, or environmental justice in support of the

rule which are required under executive orders 12291, 13045, and 12898. The terms, pivotal regulatory science, replication, reproducible, and research data are not defined or are problematic. The rule's requirements for specific types of defaults, test methods, dose response models, and/or analysis are not supported by current science.

The rule is counter to the mandates in the reformed Toxic Substances Control Act, or TSCA, to use the best available science and systematic reviews for chemical evaluations.

Data deidentification and masking techniques cannot ensure confidentiality and can degrade the accuracy of data for further analysis. The rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human data.

For example, in many cases individuals' participant data cannot be made public because of confidential requirements legally mandated by institutional review boards and/or the Health

Insurance Portability and Accountability Act of 1996, or HIPAA.

In conclusion, EPA should withdraw this proposed rule immediately. EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at the federal government. Thank you.

MS. HALL: Thank you.

Would Speaker Number 20, Surbhi Sarang, and Speaker Number 21, Laura Bloomer, please come up to the speaker's table. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please take a seat in the on-deck chairs. Thank you.

Speakers, please remember to speak into the mic and state your organization.

MS. SARANG: My name is Surbhi Sarang, spelled S-U-R-B-H-I S-A-R-A-N-G, and I'm a legal fellow at the Environmental Defense Fund.

I appreciate this opportunity to provide public testimony on the proposal and hope that everyone who wises receives an opportunity to be

heard. We urge EPA to hold hearings in additional locations to allow affected Americans in other communities who cannot travel to be here today, an opportunity to provide input as well. I'm testifying here today to raise our serious concerns of the proposed rule and to ask that the EPA withdraw the proposed rule immediate.

Communities across America rely on EPA safeguards to protect their health and wellbeing. But this rule would greatly restrict the body of scientific information that EPA draws on when setting these safeguards. Instead of being informed by all available science, in many cases EPA would be forced to operate in the dark. By obliging EPA to disregard scientific research that would otherwise alert the Agency to taking strong protective actions, this rule endangers the health of all families and communities. Had this rule been place previously, we would likely currently be facing greater exposures to air pollutants, water contaminants and toxic chemicals.

In the proposal, EPA completely ignores

the practical effects of the proposed rule and how it fundamentally conflicts with EPA's mandate to use the best available science as it develops safeguards.

Agency decisions must be informed using the best available science. Public deserves nothing less when health and safety are on the line. This value is core to EPA's mission and should be placed at the forefront.

But the proposal takes an unsupported and unprecedented leap by suggesting that this mission allows EPA to only use science where the underlying data and models can be made and are made publicly available for independent validation. Much of the data underlying scientific studies concerning human health cannot be made publicly available for legitimate privacy and confidentiality reasons. In many cases, it is impossible even to redact information in a manner that allows independent validation while respecting privacy and confidentiality.

Thus, the proposal would seriously

restrict EPA's ability to use the best available science as it sets critical safeguards. Nor does EPA explain why such restrictions on the use of science are necessary. EPA does not point to any instance in which a failure to disclose data resulted in an EPA decision or standard that lacks scientific integrity.

EPA does not explain why other means of vetting that are used by the scientific community and that protect privacy and confidentiality, such as review by EPA's independent Science Advisory Board, peer review, and corroboration through independent studies are insufficient to ensure the integrity of the science EPA relies on. And EPA does not explain why it is appropriate for an agency tasked with basing its decisions on best available science to now discard otherwise valid science simply because a disclosure is not possible.

Indeed, courts that have examined the issue have made clear that it is entirely reasonable for EPA to rely on scientific studies

which data cannot be disclosed. While EPA states in the proposal that many organizations have endorsed data disclosure as a means to increasing transparency, the reality is the proposed rule completely departs from good scientific practice. None of the organizations EPA identifies in the proposed rule have endorsed the practice of disregarding studies where data disclosure is not possible, or that have been subjected to other means of validation, or suggested that regulatory agencies should exclude such studies when using science to inform regulatory actions.

To the contrary, organizations that are deeply committed to transparent science have come forward to stress that policies to promote transparency must be developed within the scientific community and to oppose the notion of disregarding otherwise valid science, simply because the underlying data cannot be disclosed.

Indeed, EPA's own Science Advisory Board, which it failed to consult before issuing this proposal, has raised concerns similar to those we

raise here, noting that EPA provided no analysis of the impact of losing the ability to run on these studies, and that there are other ways to assess the validity of studies without access to data. Not only did EPA skip over review by the Science Advisory Board, but then EPA allowed for only a 48 (indiscernible) review process for the proposal.

This hastened process seriously calls into question the validity of the proposal. The proposal would not even increase transparency. By allowing the administrator to grant exemptions based on vague and discretionary criteria, the proposal would allow EPA to selectively apply this disclosure policy with no public record of the decision or its basis. The risk that the rule will artificially restrict and distort the scientific basis for EPA's decisions is only heightened by its many gaps.

The proposal fails to explain critical details, such as what mechanisms would be used to make data public, what the cost of the Agency and

to researchers would be, and how the peer review provision would fit into EPA's existing peer review requirements. It is not even clear how EPA would determine that a given study is publicly available in a manner sufficient for independent validation. This underscores concerns that this proposal would undermine the integrity and transparency of EPA decisions rather than enhance them.

It is also important to note that this rule was posed under former Administrator Pruitt who actively obscured transparency goals by directing the removal of scientific information from EPA's websites, refusing to publicly release his full and accurate schedule, using secret e-mail addresses, and spending tax payer money in violation of federal laws.

While Pruitt is now gone, this proposal unfortunately suffers from the same disregard for scientific integrity and transparency that infused the former administrator's tenure.

We thus call on Acting Administrator

Wheeler to recognize the redeemably flawed basis for this proposed rule and withdraw it immediately.

MS. ORME-ZAVALETA: Thank you.

MS. BLOOMER: My name is Laura Bloomer, B-L-O-O-M-E-R, and I'm a student at Harvard Law School and the Kennedy School of Government. I am interning at EDF, Environment Defense Fund this summer. I am here testifying on my own behalf.

I am the daughter of two parents who grew up near auto industry towns in Michigan. My mom was born in Flint. Her parents, my grandparents, grew up in Flint and chose to raise their four children there.

Though I'm a proud Texan, as my family moved to Houston when I was in elementary school, most of my family continues to call Michigan home. The Flint water crisis was personal for us.

My aunt, a dental hygienist, volunteered and delivered water to Fling residents after the story broke. She understood the heart wrenching fear a mother would experience when she found out

her child had been drinking contaminated water. She understood the outrage of her home community when they found out that the government they trusted did not care enough to keep their drinking water safe. She understood what it might feel like to have a fundamental safeguard, like clean water, suddenly disappear.

But the water crisis in Flint did not disappear when it left the nightly headlines. Just last week, my mom went to her favorite hotdog shop in Flint and sent me a photo of a poster from the restaurant. It was an advertisement for healthcare, aimed at mothers of children who grew up drinking contaminated water. My mom was devastated.

And though the Flint water crisis is more salient and more visible than this proposed rule, the impacts are far too similar. For decades the EPA has relied on first-rate science to establish protections for our air and water, and most importantly for our public health.

It is because of these safeguards that I

have never experienced the type of pollution my mom describes from her childhood. It is because of incredible researchers and scientific discoveries that many of our communities will never experience a water crisis like Flint is still experiencing. It is because EPA regulates lead in our drinking water, and arsenic in our drinking water, and the many other contaminants that harm our most vulnerable populations that my friends and I grew up in a healthy environment.

It is because EPA has a responsibility to seek out and utilize the best available science at every step of the way, that the next generation of children will be protected from threats to their health as well.

Yet right now, in 2018, when our science has never been more advanced, and when EPA is considering revising the Lead and Copper Rule for drinking water, EPA would choose to voluntarily ignore the best available science. This proposed rule would severely limit the studies on which EPA could rely. It would threaten the enormous amount

that EPA and engaged citizens have accomplished, and it would hamstring any progress we hope to make in the future.

This rule isn't about transparency, and it was not developed with people like my family and me in mind. For the safety of all of us and for future generations, I respectfully ask that this rule be withdrawn. Had this rule been in place decades ago, more communities might be suffering from the same threats to public health that Flint is now facing. Many of EPA's drinking water standards rely on epidemiological studies. Often these studies last decades and follow hundreds, if not thousands of patients, collecting confidential health data, as well as other personal data, like the people's addresses, ages, and genders.

For most of these studies the underlying data cannot be made public, even in redacted form, without sacrificing the participants' privacy. These studies are monumental and state of the art. These are the studies that EPA should hope to rely

on, not the type of studies the EPA should shun. These are the studies that will guarantee that communities don't suffer from the devastating impacts of dirty water and polluted air. Studies like these establish the original limits for lead, and this research continues to essential today.

This proposed rule may seem abstract, but it is anything but that. And it is extremely significant. It will have far-reaching -- far-reaching impacts on the ability of EPA to protect all of us and our families. And it could affect our most important environmental safeguards. It is extremely personal, for my mom, for my family, and for me.

I am here today to ask you to withdraw this proposed rule and recommit to EPA's mission of protecting human health and the environment. Thank you for the opportunity to speak today.

MS. Hall: Thank you. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please come up to the speaker's table. And Speaker Number 24, Michelle

Endo and Speaker Number 25, Jenny Xie, I think, please take a seat at the on-deck chairs.

[Substitution of panel members.]

MR. ROBBINS: Good morning. I'm Chris Robbins. I'm the Acting Deputy Assistant Administrative for Management in the Office of Research and Development.

MS. ORME-ZAVALETA: Good morning.

MR. ROBBINS: Thank you.

MS. DOA: Good morning. My name is Maria Doa , I am in the Office of Research and Development.

MS. WITHERSPOON: Good morning. I'm Nsedu Obot Witherspoon. I'm the Executive Director for the Children's Environmental Health Network. My name is spelled N-S-E-D-U O, B as in boy, O-T W-I-T-H-E-R-S-P-O-O-N.

For over 26 years, the Children's Environmental Health Network, also known as CEHN, has been a national voice committed to protecting all children from the harmful effects of environmental hazards, and to promoting a

healthier environment.

CEHN educates decision makers and advocates for evidence-based child protective policies. We also ensure that those who care for children, personally or professionally, have the information they need to take the steps to reduce children's exposures to harmful toxicants.

As the Executive Director, and on behalf of CEHN, I appreciate the opportunity to provide these comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science."

CEHN is strongly opposed to the rule and is concerned that it will adversely affect EPA's ability to use the best available science in decision-making, and negatively influence existing and future protections for children's health, such as clean air, clean water, and the prevention of toxic exposures.

The exposed rule sets transparency standards that are too rigid and impossible to meet. It requires that all data used in

rulemaking be publicly made available, and allows EPA to exclude data that relies on confidential patient information. Critical studies which have led to significant advancements in protective policies, for example from the NIEHS, EPA's Children's Environmental Health, and Disease Prevention Research Centers may very well be excluded.

The scientific research that EPA uses already undergoes a long-established transparent review process, and makes available the scientific studies it relies on to inform policy. Sometimes studies contain private medical data that legally can't and should not be made public. In those cases, independent review bodies have also examined the studies and weighed in on the research. No legitimate reason exists to exclude those studies and their critical important findings.

Health based research involves people and often the collection of private information. There are no systems in place to protect this

information. The federal government must continue to protect private information about patients, and not allow this information to be made public. Otherwise, patients will not participate in these important studies.

Further, redacting personal information actually sounds easy, however, it is cumbersome and quite costly. EPA will not likely have the resources to redact personal information resulting in exclusion of critical studies.

The proposed rule would restrict EPA's ability to set regulations informed by confidential data that cannot be replicated. This is of serious concern because for many older, long-standing landmark studies, the original data sets were either not maintained, or stored in out of date formats. These could be eliminated under this proposed rule.

The proposed rule could block the use of studies on the harmful impacts of toxic exposures and pollution. Studies which were instrumental in the Clean Air Act, the Safe Drinking Water Act,

and the -- excuse me, Food Quality Protection Act, among many others. We do request that you withdraw this proposal, "Strengthening Transparency and Regulatory Science." If the proposed rule is implemented, an inevitable consequence is that children that could have been protected from chemical exposures will lose those opportunities.

Irreversible damage to children in their growth and development, loss of intelligence, behavior modifications, and overall life achievement is the future ahead, and I would hope, not the legacy that this EPA would like to preserve. Thank you very much.

MR. ROBBINS: Thank you.

MS. ZURCHER: My name is Joanne Zurcher, J-O-A-N-N-E Z-U-R-C-H-E-R, and I'm representing the National Environmental Health Association.

Good morning. Thank you for the opportunity to speak to you on behalf of the environmental health professionals from across the country who've vigorously opposed the Censoring

science rule.

My name is Joanne Zurcher, and I am the Director of Government Affairs for the National Environmental Health Association, NEHA.

Environment health is profoundly local. Simply put, it's the cleanliness of the water from the kitchen faucets. It's the safety of the food we feed our families, our friends, and ourselves. It's the air the children breath during the 1,600 hours they spend inside their schools. It's the cleanliness of our community beaches that our families are spending the summer enjoying.

When things go well, environmental health is not on the front page of the New York Times, because environmental health professionals keep us safe every single day.

NEHA has over 7,000 members. Our members anticipate, recognize, evaluate, and control hazards that are likely to cause harm, serious illness, or even death to American families. Examples include lead, radon, legionella viruses, harmful algae blooms, PFOA, PFOS, Zika viruses,

and many other natural and man-made risks. Our members possess strong science and math backgrounds. They must take over 30 units of undergraduate math and science just to sit for our exam. They have the unique ability to work with clinical and nonclinical professionals. They know and work with the regulated community. They are credentialed members of the profession, and the NEHA credential is considered the gold standard.

EPA science is the foundation for informed decision-making for our members. Our members turn to the EPA for best practices. Our members rely on EPA research to promote their community's health.

Our communities see EPA as the shelter of scientific certainty in an era of uncertainty. Our members rely on EPA expertise, whether it's continuing -- excuse me, containing mercury spills in their homes, setting standards to keep toxic chemicals out of drinking water, or cleaning up super fund sites, just to name a few of the few activities we do together. EA professionals work

closely with the EPA every step of the way.

The EPA has administered successfully, the Clean Water Act, and the Clean Air Act, and these acts should be expanded based on scientific research. The EPA should not be working to undermine scientific research. Instead, this EPA should be working to provide running water to the 630,000 American families who do not have running water in their homes.

Let's be clear, this proposed rule undermines the EPA's mission to protect human health. Now is not the time to compromise health of our nation by casting a shadow of uncertainty on the integrity of the EPA -- of EPA's research.

EPA research is globally recognized as the foundation for informed decision-making that affects every person the plant. NEHA and it's 7,000 members are in every community and territory in the nation. Every EH professional relies on EPA research to ensure constituents meet human -- meet their human potential.

The current research system works, which

at once protects the identity of every research participant, while promoting the health of every American. Health research sometimes includes sensitive data from patients, such as medical history and geographic location, which must be continued to be private and protected. Crucial volunteers will cease to come forward for scientific research if their medical history and geographic information will be made public, thus putting critical scientific research at risk. Please do not destroy a national gem, our EPA research, because you, your family, and your community deserve no less than a fully functional research system that protects and identifies research subjects while promoting the health of the nation.

NEHA and the environmental health professionals from across the United States vigorously oppose the censoring scientific rule. Thank you for this opportunity to be heard on this important topic, and please remember, do no harm.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 24, Michelle Endo, and speaker Number 25, Jenny Xie, come up to the speaker's table. And Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, please take a seat at the speaker's -- well, at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. ENDO: My name is Michelle Endo, E-N-D-O, and I'm speaking in a personal capacity, but I'm an intern at the Environmental Defense Fund.

So my name is Michelle Endo, and I'm a second-year student at Georgetown Law. I'm also a legal intern at the Environmental Defense Fund here in Washington, D.C. I'm here today to offer comments on my own behalf and to present my grave concerns with EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

I'm a fourth generation Southern Californian who lived the first 18 years of my life in Northern Los Angeles County. And while I'm proud to be from the Golden State, it also

means that I grew up breathing some of the worst air pollution in the nation. Despite tremendous improvement, 70 percent of Californians live in an area with unhealthy air. As a result, I also grew to be familiar with the dangers of air pollution and the importance of health-protective regulation.

My family lives in a town that, like much of LA County, is in the United States 98th percentile for tropospheric ozone, according to EPA's own Environment Justice Screen.

Tropospheric ozone, commonly referred to as smog, is the visible layer of air pollution that gives LA sunsets their famous striped hues. Several studies have consistently reported there is a significant association between ozone pollution and premature death. According to the American Lung Association, long-term exposure to ozone pollution is also linked to developmental harm, reproductive harm, cardiovascular harm, and increased susceptibility to infections.

While I never had a snow day before

moving to D.C., like most SoCal kids, I'm very familiar with bad air days. Instead of playing outside and building snowmen, children in Southern California lose all outdoor playtime on bad air days in order to avoid the harmful effects of smog. Coughing, impaired athletic performance, eye irritation, chest pain, nausea, headaches, and respiratory congestion.

Smoggy days can also worse asthma, heart disease, bronchitis, and emphysema.

My sister and I enjoyed the early years of childhood with fewer complications relative to my neighbor peers. But before even starting high school we both had missed days of school for nose bleeds that were likely triggered by the irritating smog that settled in the valley, and because ozone forms by the interaction of sunlight with hydrocarbons and nitrogen oxides emitted from cars and trucks, bad air days tended to worse each year, our Southern California summers, broke standard heat records of years before.

Shortly after my sister joined the high

school soccer team, my family started to notice that her once limitless stamina on the field was wearing down. One particularly hot and hazy day, she had no choice but to walk off the field in the middle of the match. Clutching her chest, she struggled to breath. We later learned that she had developed asthma from LA's unhealthful smog, like many of our friends and family in the area.

It was experiences like this that motivated my decision to study environmental policy in college, and that continued to drive my legal career. Having witnessed first-hand the way in which the geography of where one lives, plays, learns, works, and grows determines one's health outcomes, I could not have chosen another path in good conscience.

When I first chose this path, over eight years ago, my hope was to strengthen the laws and regulations that did not go far enough to protect my family and our environment.

Under the Clean Air Act, EPA was required to establish and regularly update federal

standards for hazardous air pollutants, including asthma-causing particulate matter and ozone. These standards and the National Ambient Air Quality Standards or NAAQS, form the backbone of our nation's air quality protections. Although the NAAQS did not prevent my sister's asthma, they have and continue to bring about substantial improvement in our nation's air quality since their first formulation.

The EPA's proposed rule would have excluded peer review studies that form the scientific basis of NAAQS. For example, peer reviewed studies would be excluded because the underlying data and models cannot be disclosed, even in partial form. In fact, the standards would not have been issued had the proposed rule been in place when they were first enacted in the 1970s, because EPA would have tossed out the underlying studies, tying its hands from taking action in imminent public health concerns.

Without a doubt, many more Southern Californians would have had their lives altered,

or even cut short by dangerous levels of air pollution.

If adopted, the proposed rule would deprive EPA policy makers from real world evidence and studies that are vital to the EPA's review of the NAAQS into the future. Further, the proposal directly contravenes the comprehensive federal and state regulatory program congress envisioned when drafting the Clean Air Act of 1970. It reduces our public health legislation to mere declarations, as EPA would severely delayed if not rendered entirely unable to establish future standards using the best available science.

Generations before me, through legislation like the Clean Air Act, recognize that public health and environmental pollution required strong federal leadership and expert agencies like EPA. Departing from the Agency's practice of scientific review for over the last 40 years, practices aligned with national and intergovernmental bodies, like the Royal Society of Medicine, and the World Health Organization,

jeopardizes EPA's ability to utilize its expertise with high cost to people's health.

It is therefore troubling that the Agency has proposed to take this action under the guise of scientific integrity without consulting its own panel of scientific experts, the Science Advisory Board, and against the advice of leading scientific journals and organizations. It is even more troubling when considering the Agency's recent practices toward the public and the press, which have been far from transparent.

To me, it is clear the proposal's purported goal of transparency is a pretext for the Agency's attempt to shirk its statutory command. For the health of my sister, my friends, and all Americans, I urge EPA to abandon this proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. XIE: Good morning. My name is Jenny Xie, J-E-N-N-Y, last name X-I-E, and I'm a policy intern at the Environment Defense Fund, but I'm here today speaking from a personal capacity to

express my personal opposition to EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

Many of the activities that I am involved in on campus involve holding the university accountable for its environmental goals that it has set. I'm currently a student at Cornell University, studying English and Environmental Sustainability Sciences.

In fact, one of the main initiatives that I am involved in calls for the University to disclose as a financial investments and fossil fuels in order to increase transparency, have accountability, and maintain integrity as it works towards its carbon neutrality. It is therefore incredibly disheartening to hear that this EPA administration is championing a proposed rule that claims to be for increased transparency, when in fact the purpose and the fact of the proposed would be to bar EPA from considering rigorous public health science and reduce the transparency of EPA's scientific analysis.

The proposed rule would require the EPA base some of its most important regulatory decisions only upon does response studies where the underlying data can be disclosed. The reality is that key scientific studies backing our nation's critical clean air safeguards which protect our health and environment are based on confidential patient data that in many cases cannot be disclosed in any form.

These rigorous peer-reviewed state of the art studies could be improperly discarded should this rule be finalized. As many scientists have noted, this would undermine and not promote the use of sound science in EPA decisions. Just because the data underlying a study isn't published does not mean that the study cannot be verified using other means.

For example, the American Cancer Society's Cancer Prevention Study II, tracked air pollution, exposure, and personal medical histories of nearly 670,000 people for more than two decades to understand the exact risk of air

pollution on death.

The study was based on private patient information that cannot be publicly disclosed, and yet the study has been subject to reanalysis and its conclusions have been upheld. And allowed under the scientific journal does response, the authors listed 16 key studies alone which supported the original conclusion of the Cancer Prevention Study 2.

Even more concerning is the fact that the proposed rule provides the administrator with broad discretion to make exception to the policy on a case-by-case basis. Former Administrator Pruitt may be out of office now, but Acting Administrator Wheeler's record as a fossil fuel lobbyist for corporations like Murray Energy leaves me and others incredibly skeptical that this rule would be applied fairly with no concrete criteria guiding decision to grant an exception.

This part of the proposal raises a serious risk that this or future administrations could selectively waive the policy to build a

distorted scientific record that is designed to reach a desired result. In fact, just a few weeks ago I was in Pennsylvania where I'm from, talking to an Uber driver. He's a father with a daughter who has asthma, and we talked about the EPA. He had worked in public service before and expressed to me how frustrated he was with the current administration, with the EPA, and how it seemed that despite the endless promises the administration has made to protect its citizens and better our lives, many of those promises were not being fulfilled.

I can't help but think how disappointed he would be if he knew that the EPA has proposed a rule which will make it more difficult for EPA to use the best science to protect the health of him and his family. Citizens are watching and aware, from parents, to scientists, to students like me who advocate for good policy on their own college campuses.

The EPA hastily shuttled this rule past even the OMB, but it must pause to hear the

concerns of the public. EPA's proposal will lead to censored science, not transparent science. Thank you for the opportunity to testify on the proposed rule today.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, come up to the speaker's table. And Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, please take your seat at the on-deck chairs.

MS. MESNIKOFF: Hi. I'm Ann Mesnikoff. It's M-E-S-N-I-K-O-F-F, and A-N-N, no E.

Good morning. I'm Ann Mesnikoff. I'm the Federal Legislative Director for the Environmental Law and Policy Center.

ELPC works throughout the Great Lakes and the Midwest, protecting public health and special places under the belief that environmental protection and economic development can be achieved together.

ELPC appreciates the opportunity to

testify in opposition to EPA's proposal to censor, or otherwise constrain the science it will consider in issuing essential standards that are meant to protect public health and our environment. The Midwest and the Great Lakes region, with its industrial and agricultural heritage is impacted by environmental and public health challenges to air, land, and water, and we depend upon EPA to effectively implement environmental laws to protect the public and our environment.

There is no basis in existing bedrock environmental laws that authorizes EPA to limit science considered in rulemaking processes. EPA cites several key laws in its justification for this proposal. Nowhere in the cited statutes is there a basis for demanding access to raw data, nor does this relate sensibly to any definition of best available science. Rather, this undermines the use of best available science called for in environmental statutes, including the Clean Air Act.

Further, there is no basis for politically appointed administrators to choose which science will be considered, and which may not be. EPA should continue to apply the rigorous standards the Agency has used for decades, and that stakeholders engage in the process that is full and open with regards to science.

EPA's Science Advisory Board voted to review this action during its June 1st meeting. This proposal has also prompted, as we've heard today, vehement reaction from the scientific community. EPA's proposal is not about transparency. It is about undermining public health. The negative effects of this proposed rule on EPA's programs could be far reaching across the Midwest. Midwesterners are exposed to unhealthy levels of air pollutants, including particulates, ozone, and toxic emissions from our industries and agricultural operations.

Achieving and maintaining health air to breath remains a challenge. EPA just finalized not attainment designations for Midwest's biggest

cities. There are millions of people -- where millions of people live, work, and play. Foundational studies about the impact of air pollution to public health are essential. These studies have been reviewed numerous times. Yet, under EPA's proposal, they would be ruled out of bounds, compromising the Agency's ability to truly assess the impacts of air pollution and to set standards are a level that will protect public health as the Clean Air Act requires.

Weaker standards will mean dirtier air in our communities. The elimination of these studies would also skew the evaluation of cost and benefits, leading to less protective rules that will not be based on a true accounting of the public health costs of pollution. We're also concerned about how EPA's proposal to censor science will impact a range of other significant concerns across the Midwest and Great Lakes, from using the best available science and its review of toxic -- the toxic insecticide, chlorpyriphos, the impacts of growing problems of harmful algael

blooms in Lake Erie and other places across the Great Lakes on public health, and in setting standards for lead in water, soil, and in homes.

EPA has shown time and again that achieving cleaner air, and water, and a healthier environment go hand-in-hand with economic growth. Our children's health across the Midwest depends on EPA continuing to do its job and not let industry-driven agenda undermine its essential role. We respectfully ask EPA to withdraw this proposal. We will be submitting more detailed comments to the record. Thank you.

MR. ROBBINS: Thank you.

MR. GAMSE: I am Roy Gam -- I am Roy Gamse, G-A-M-S-E, no S on the end. Formerly EPA Deputy Assistant Administrator. Reading the comments of John Bachmann of the Environmental Protection Network. He served EPA for 33 years, was Associate Director of Science Policy and New Programs for the Office of Air Quality Planning and Standards.

John's comments. "I appreciate the

opportunity to provide the comments on the proposed rulemaking on strengthening transparency on behalf of EPN. EPN will submit the detailed written comments on the proposal later."

"This proposal would not strengthen transparency of regulations. Instead, it would preclude the assessment and use of best scientific information available as required by all major statutes administered by EPA. The process by which it was developed, the misuse of references that ultimately do not support its arguments and the lack of specifics, what EPA actually intends to do are an embarrassment to the agency."

"The new acting administration should withdraw it from consideration as soon as possible. EPA's proposal is a solution in search of a problem. A proposal asserts it's dealing with a replication crisis, but does not cite a single instance where a study used by EPA for any type of major rule was shown to be flawed due to a lack of access to the underlying data. In fact, EPA and the industry funded an independent

reanalysis of the two air pollution studies that were criticized for not releasing confidential health information, and both were successfully reproduced with the results published in 2000. Moreover, their key findings have been replicated dozens of times since then by other investigators using different health and air quality data."

"The proposal to exclude important peer reviewed studies is wholly inconsistent with scientific practice and EPA's past use of science and regulatory decisions, where studies with novel results appear, EPA's assessments have noted limitations and some cases supported reanalysis."

"EPA's science policy related assessments are, themselves, peer-reviewed by the SAB or CASAC to further ensure study evaluations consider all of the relevant scientific literature."

"As noted by the SAB workgroup, the EPA's proposal downplays valid concerns about the risks of providing access to the confidential information of subjects in epidemiology studies. The SAB group noted some of the largest most

useful health effects data sets cannot be made fully public because certain personal information of age, sex, health, and location could be used to identify participants, or because of agreements made with study participants in advance."

"EPA failed to mention various ways to assess the validity of fire epidemiology studies without access to data, nor that the rule may preclude continued use of studies published many years ago."

"The proposal includes a provision for the administrator to waive this requirement. No clear decision criteria provided to allow EPA scientists and stakeholders to understand when and how the waivers would be granted. It appears that requirement could be applied in an arbitrary and capricious manner that does not reflect sound science judgment. Critical decisions like these must be made on the basis of science, not politics. Otherwise, highly relevant studies for which data can't be publicly shared, even if published in the best peer reviewed journals and

replicated may be judged to be inherently untrustworthy."

"The rushed, mostly secret process EPA followed in developing the proposal displays a complete disinterest in transparency, much less in science. In developing this proposal EPA leadership did not provide a role for zone career science experts in crafting the proposal, never included the rule on its regulatory agenda, did not notify of consult with the SAB, much less request the review as required by law. Did not solicit the advice of the NAS on provisions that would change does response models used in risk assessment from those previously recommended by NAS, did not ask for review to solicit the views of other federal agencies that conduct research or use health effect science in developing regulations. Finally, the Agency originally only allowed a 30-day comment period on this remarkable unvetted departure from the past practice."

"In suggesting potential cost of the rule would be minimal, EPA ignored the cost to

researchers who would have to pay to set up and maintain data sharing for their previously published studies to be considered, to EPA for conducting the multiple reanalysis required in Section 30.6 of the rule, and to public health for the disbenefits of undermining existing regulations. Having done no assessment, EPA has no basis for its claim that the benefits of the rule exceed its cost. Scientists and scientific publications that EPA cites as evidence for support for this rule have rejected the proposal's preemption of existing studies based on availability of raw data. Professor John Ioannidis reacted strongly to the proposal in an editorial noting that, quote, 'If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim.' End quote."

"Editors of four major scientific journals whose policies EPA cited as support jointly stated, quote, 'It does not strengthen

policies based on scientific evidence to limit the scientific evidence that can inform them. Excluding relevant studies simply because they don't meet rigid transparency standards will adversely affect decision-making processes.'"

"Finally, EPA should immediately withdraw this flawed proposal from consideration, given the fatal flaw of establishing unnecessary regulation for science assessment that would elevate transparency over any other criterion. We're unable to offer any suggests for improving it."

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, come up to the speaker's table. And Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic), take a seat at the on-deck chairs.

Please remember to speak into the mic and state your organization.

MS. SASS: Hello. My name is Jennifer Sass, S-A-S-S. I'm with NRDC, the Natural

Resources Defense Council.

And I'm here to talk about the concern that scientists and environment health and medical professionals have with this rule. In one of his last acts of aggression against the public before resigning, the corrupt and disgraced EPA Administrator Scott Pruitt, proposed the rule to restrict the scientific studies that EPA could rely on to set safety standards for toxic chemicals.

Ironically, the rule is called science transparency when in truth public health will be seriously harmed. That's why over 40 doctors and scientists released a letter today which was submitted to the docket, raising alarm about the rule and the harms that it would bring about.

In the letter, they say as scientists and health professionals we recognize the importance of data sharing and replicability in scientific practice and discourse. The experts are part of Project Tender, and their letter is also publicly available.

They say the proposed rule is about stiffing science used by EPA, not improving it. They all have careers devoted to protecting children and their families from exposures to neurotoxic chemicals. They say the proposal could also undercut existing safeguards. Regulations that have led to protections against toxic air pollution, lead and drinking water, and dangerous pesticides, such as chlorpyrifos.

Dr. Phil Landrigan, a globally renowned expert on childhood harm from chemical pollutants warned that if you implement this proposed rule the inevitable consequence is that chemicals with potential to damage children's brains and nervous systems will remain longer on the market, and many thousands of children born, and not yet born, who could have been protected against these chemicals, will be unnecessarily exposed. Brain damage with loss of intelligence, disruption of behavior, and diminished lifetime achievement will be the result. Is this the legacy that EPA wishes to leave for America's children?

The Economist also wrote about the rule, very bluntly in an article titled, "Swamp science: Scott Pruitt embarks on a campaign to stifle science at the EPA." In that Economist article they emphasized that the proposal rule is really about blocking information used by EPA to protect our health. The rule prohibits the Agency from setting regulations that are supported in part or whole by data that is not publicly available for reanalysis or that cannot be replicated. It will hamstring EPA's use of scientific information, which could only harm EPA's work quality and public credibility.

There are many reasons why a study cannot be made fully public or replicated. For example, the original raw data may no longer be -- exist. Or the original exposure conditions may no longer exist, such as lead exposures from leaded gasoline, and patient protection and privacy rules may prevent full disclosure of the raw data, or information. EPA already has long-established and transparent methods for evaluating data in these

situations.

This rule would block the studies used to set air pollution regulations that will have prevented more than 30,000 premature deaths by 2020, with benefits valued at 30 times the cost of the Clean Air Act, according to EPA scientists and technical experts.

The rule would also block the studies that protect children from lead poisoning in air, water, and soil, and would block the studies of harmed children that support an EPA proposed ban on the neurotoxic pesticide chlorpyrifos, which President Trump and former Administrator Pruitt have already rolled back those proposals.

This may be the most unpopular proposal from an already unpopular EPA administration to date. It is a rule that fundamentally purports to solve a problem that doesn't exist, and it should be abandoned. It cannot be fixed. Thank you.

MR. ROBBINS: Thank you.

MR. MILLER: Hello. My name is Paul Miller. It's M-I-L-L-E-R. I am Deputy Director

of the Northeast States for Coordinated Air Use Management, or NSCAUM. NSCAUM is the regional association of state air agency air quality control agencies in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

My comments today reflect the majority view of NSCAUM's members, while individual members may hold some views different from the majority consensus.

In sum, we are concerned that should this proposal lead EPA to not fully consider the best available science in rulemakings, it will endanger public health and the environment.

The EPA invokes strengthening transparency as a primary driver for this proposal, but fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of work, quote, "EPA has not previously implemented these policies and guidance in a robust and consistent manner," end quote, nor what are the specific

quote, "Agency culture and practices regarding data access," end quote. That requires changing.

The Agency also provides no cost analysis of this proposal. Without additional clarity from EPA we are having difficultly identifying the problem EPA seeks to address. Therefore, for the following reasons we request that EPA withdraw the proposed rule.

First, the proposal is too vague as written to provide the public with meaningful opportunity to comment. EPA solicits comments across a long list of topic areas, but fails to provide the Agency's own sufficient detail and rationale on the solicited comment areas as required by the Administrative Procedure Act.

We are left to speculate on EPA's views, and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment.

Second, EPA must describe how the proposed text in Sections 30.5, 30.7, and 30.9

affect current practice. Section 30.5 states that the Agency shall ensure that those response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.

Section 30.7 states, EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. EPA, however, does not describe what constitutes in its view, independent validation and independent peer review.

Furthermore, Section 30.5 includes qualifying language that EPA will take all reasonable efforts to make data available unless it is not possible due to other constraints, such as legal protections of privacy and confidentiality.

EPA provides no examples of where and how, in the Agency's view, past rulemaking specifically failed to make these same efforts, nor how EPA would change past practice in this context. Adding to the vagueness of Sections 30.5

and 30.7, Section 30.9 would provide the administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions on a case-by-case basis if he or she determines that compliance is impracticable. The proposed rule fails to provide specific criteria for determining when compliance is impracticable.

Lacking clear guidelines for transparent decision-making, the administrator's discretion would appear to be unbounded in application and potentially based on haphazard and non-transparent rationales.

Third, EPA has provided no meaningful cost estimate for the proposed rule. The costs are likely quite significant, however, based on a congressional budget office cost estimate of the similar congressional proposal.

In addition to lack of cost information, EPA offers no accounting of foregone benefits should a broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse

health outcomes.

In conclusion, EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific proposed rule requirements, and its cost and benefits.

These are well understood and basic elements that federal agencies must include to ensure informed public comment. Given that these elements are missing from this proposed, EPA should withdraw it. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic) come to the speaker's table. Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Reaves, take a seat at the on-deck chair.

MR. McKINZIE: Good morning. I'm Matthew

McKinzie, M-C-K-I-N-Z-I-E. I'm a nuclear physicist with the Natural Resources Defense Council, NRDC, and I'm very pleased to talk today about this proposed rule. My remarks will focus in on the radiation protection aspect of the proposed rule.

NRDC, just as background, is a national non-profit organization of scientists, lawyers, and environmental specialists. We are dedicated to protecting the public health and the environment.

NRDC has been engaged with the environmental issues surrounding nuclear energy and nuclear weapons since our founding. There's something strange about the proposed rule in that it does not use the word radiation, and it does not cite the EPA's authority under the Atomic Energy Act.

Nevertheless, the language of the proposed rule seems to clearly implicate radiation protection standards. In particular, appears to undermine the basis, a fundamental basis of

radiation protection standards, the linear no-threshold dose response model. And so that's what I'll focus on with my five minutes.

The science in radiation epidemiological studies has repeatedly demonstrated over decades that linear no-threshold dose response, LNT, provides the most reasonable description of the relation between the low dose, low radiation dose exposure, and the incidence of solid cancers that are induced by that ionizing radiation.

EPA bases its regulatory limits and nonregulatory guidelines for population exposure to low-level ionizing radiation on this linear no threshold model. EPA's radiation protection standards are based on the premise that any radiation does carries some risk, and that risk increases directly with dose.

This method of estimating risk is called LNT. For over 40 years, the LNT dose response model has been commonly utilized when developing practical and prudent guidance on ways to protect workers and members of the public from the

potential for harmful effects from radiation in that balance, with commercially justified and optimized uses of radiation. EPA derives the LNT model from reports by authoritative scientific bodies, including the National Academy of Sciences, NAS, the National Council on Radiation Protection and Measurements, NCRP, and other bodies.

The NCRP published its last commentary on the LNT issue only weeks ago, in April of 2018, reinforcing this -- the LNT as the basis for radiation protection standards.

Epidemiological studies of humans provide evidence that is critically important in establishing potentially causal associations of environmental factors with disease. NAS and other studies that EPA has long relied upon in the radiation standard setting process are epidemiological human cohort studies. EPA's proposed rule, if implemented, would limit EPA staff from basing regulatory actions on precisely these types of studies by requiring that the

underlying data of these studies should be publicly shared, fully publicly shared. This would be a nearly impossible task for the agency.

Data for some of the radiation epidemiological studies are accessible to users, with a detailed description of how a user can access the information. However, public sharing of personally identifiable information is restricted. These are profoundly important studies on radiation health effects that have been peer reviewed for decades, and the science that has emerged from them has been validated multiple times. But these are not studies where the entirety of the public data can be shared or independently replicated.

Replication of these studies is impossible as this data comes from individuals exposed to significant, acute, and protracted doses of radiation. Pruitt's proposed rule would throw out the data from the atomic bomb survivors of World War II. That's a profound, very profound thing.

Adverse consequences for EPA would affect federal guidance reports, nuclear field cycle standards and regulations, minimum amount -- minimum allowed concentrations of radiation in drinking water, soil clean up for super fund sites, radioactive waste disposals, as well as the fundamental concept of ALARA, As Low As Reasonably Achievable, in radiation protection standards.

In conclusion, I urge the EPA to abandon the proposed rule as it fundamentally calls into question basic radiation protection standards that are scientifically founded and have protected the public for many years. Thank you.

MR. ROBBINS: Thank you.

MS. MELLINGER-BIRDSONG: Hi. My name is Anne Mellinger-Birdsong, M-E-L-L-I-N-G-E-R, dash, B-I-R-D-S-O-N-G.

Thank you for allowing me to speak today. My name is Anne Mellinger-Birdsong, and I am a fellow of the American Academy of Pediatrics and a specialist in environmental public health. I have worked at city, county, state, and federal public

health agencies, and Indian health service facilities.

I'm here to speak in opposition to this proposed rule and to state that this proposed rule is unnecessary and it would harm EPA's ability to evaluate health impacts of environmental pollutants. It should not be finalized or implemented.

This proposal has wording that makes it appear noble and well-meaning, but it is a sheep in wolf's clothing. This proposal will severely hamper EPA's ability to use past and future research on health effects of human exposure to environmental chemicals and toxicants. It should be withdrawn.

Both the HIPAA and the federal regulations on human subjects research address privacy as a concern of people who participate in research. It's not as simple as redacting data such as name, birth date, medical record number, et cetera. You also have to not have data that can be used to intuit or figure out who a study

subject is. So you have a study of Town A and people who had heart attacks in July. If there is age or zip code data associated with that, the people that live in Town A could figure out, oh, that's Mr. X down the street. So it would really hamper the ability to use data, and environmental health data often has zip code and year and a lot of stuff that can be used to put together and figure out who people are.

So that's how it would work. And I just would like to say also that children have even more health protections than adults because of being smaller, and we have to be more concerned for them. And especially living human subjects of research who will continue to live, we need to be extra careful to protect their privacy. And this rule would either require data made public, or it would prohibit using a lot of data that would enable -- that would inhibit privacy protection.

So also it would decrease people's trust in participating in research if they are fearful of their personal identifiers being released or

people being able to know that they participated in a study. They may not participate, so we would have worse data for studies in the future because of this rule.

And I would like to say that children do not choose where they live, or where they go to school, or what kind of water quality their water they drink is, or the air that they breathe. It's up to we, who are adults, the adults who are their caretakers who choose where they live, and we who set policies to make these decisions to keep children healthy. And this rule would severely harm children because it will throw out a lot of data, and a lot of data that has been used to form, already, established rules.

So I ask, why was this rule proposed? It would eliminate use of scientific studies and hamper future research. The rule was completely unnecessary. We have mechanisms within scientific institutions to transfer data so it's HIPAA compliant and IRB approved, so we can verify research and reevaluate it and confirm it. We

don't need this rule and it is, again, it's a rule that's unnecessary and would hamper and harm EPA's ability to carry out its functions.

So I'm going to end with a quote by a professor from Carnegie Mellon University, Granger Morgan. He used to chair the EPA Science Advisory Board under George W. Bush. He said, "this proposed rule is an attempt by people who aren't interested in using science to find the truth to raise doubts about what, at this stage, is very clearly established and well-reviewed science."

And I urge the EPA to withdraw this proposed rule and not implement it at all.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Rebeb (sic), come up to the speaker's table. And Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb, take a seat at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. REAVES: Hi. My name is Jennifer Reaves. Reaves spelled R-E-A, V as in Victor, E-S. I represent Moms Clean Air Force, Maryland.

Am I supposed to speak first? Oh, okay.

My name is Jennifer Reaves. I live in Hyattsville, Maryland. Thank you for this opportunity to offer comment. As a member of Moms Clean Air Force, Maryland, I am here today to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name of transparency.

This dangerous censoring sign plan to limit the scientific information EPA can use to identify public health threatens and future and safety of our children. This proposal will essentially require researchers to make private personal medical information public in order for the EPA to use their research in its decision-making.

This proposal also includes loop holes that would exempt industry from having to disclose details of their own studies. It is designed to

favor the fossil fuel and chemical industries, limiting EPA's ability to protect us from toxic pollution and chemicals. High quality science is crucial to understanding the risk of our families face every day, especially when it comes to air pollution and toxic chemical exposure.

This proposal means that many studies on populations, such as elderly, young people, and people of color, groups who are often suffer disproportionately from pollution would be excluded from EPA consideration because making the data public could identify and participating -- identify the participating individuals. Including this important data from consideration means that implementing this proposal could even further exuberate negative environmental impacts on these and other vulnerable communities.

This proposal puts our children's bodies on the line by censoring research, making even low levels of pollution with significant health impacts instead of cleaning up their act. Polluting industries want these kind of studies to

simply disappear.

My family and my fellow Marylanders are counting on the sound and transparent science the EPA has used for decades. And we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MR. ROBBINS: Thank you.

MS. BARDWELL: All right. Excuse me. Thank you. My name is Erica Bardwell. Can you hear me? Okay.

I am a local registered nurse. I work at a local hospital. I'm also a member of Physicians for Social Responsibility. Thanks for taking time today.

Mr. Scott Pruitt is no longer here as EPA administrator, but it does seem that this proposal preserves the hallmark of his tenure. By that I have to say, I mean a complete lack of shame.

This proposal masquerades as an attempt to strengthen science, and by extension, public health. But this is a bald, even shameless lie.

It would actually make public health research impossible, or much, much more difficult, which obviously is the real point.

If someone can't participate in medical research without worrying that their identities or parts of their medical records are going to be rampaging around the public record, then they simply won't do it. Which again, is the point.

Basically, shameless people say that to themselves behind their scenes. But to us they say that they're really concerned about us and public transparency, but it's not true.

I saw a reference to a replication crisis. Last I heard, the replication crisis was mostly social sciences. There's not a huge replication crisis in epidemiology. Certainly not to the point where basic facts are in doubt. There is no doubt that air pollution kills people, that poison in water makes people sick, that toxic soil grows toxic food. This is not in contention. There's no replication crisis here.

So the only purpose of this rule could be

to avoid adding to the already damning weight of this existing evidence. Basically, to make it cheaper for a few people to literally poison people for profit, which is ultimately a tragedy for everybody.

I think the thinking is that sciencing debates are going to bore the public, and most other people have to work on a random Tuesday. I swapped a shift to be here, but most people don't have that option.

MS. DOA: Can you speak into the mic a little bit more?

MS. BARDWELL: Sure. Okay.

MS. DOA: That's better. Thank you.

MS. BARDWELL: So, the true public interest may not be represented here because people have to work. But if this rule is finalized, the public is going to howl once they actually feel its effects and lose the protection that they need from these studies. And I wouldn't want to be the person left holding the bag when that travesty happens.

Finally, as my grandmother used to say, what sauce is for the goose is sauce for the gander. If exposing personal information is really required to have quality medical research, I eagerly await the day this administration proposes similar restrictions on, say, pharmaceutical research. I wait for the day that Pfizer can't get approval for its nth blood sugar pill without revealing incredibly invasive information about all of its research subjects. I don't think that day is ever going to come, because protecting people or advancing science isn't really the goal.

Thanks for your time.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb come to the speaker's table. And Speaker Number 36, Lyndsay Alexander, and Speaker Number -- is there a Speaker Number 37 in the room? What's your name?

MS. BENDER: Laura Bender.

MS. RAUCH: Hi. I'm Molly Rauch. Name is spelled M-O-L-L-Y R-A-U-C-H. I'm Public Health Policy Director with Moms Clean Air Force. We're a national organization of more than a million moms and dads fighting air pollution and climate change for the sake of our children's health.

Thanks for this opportunity to offer comment. On behalf of our more than 1 million members, I am here today to strongly oppose the administration's attempts to censor the science used in public health decision-making. This intentionally misleading proposal is being sold by EPA leadership as an effort to increase transparency. But the facts suggest that the real motivation is simply to sweep under the rug the scientific evidence disfavored by polluting companies.

The proposal would prevent EPA from using studies that are based on personal medical data, thereby eliminating some of the most important long-term epidemiological studies, investigating the impacts of pollution on public health, and

hundreds of scientists have already spoken out against this proposal.

Indeed, this flimsy proposal was designed without adequate input from the scientific community, according to the members of EPA's own Scientific Advisory Board. It was rushed through the regulatory process. It was originally proposed with a gallingly short public comment period that suggested an intention of casting less light on the rulemaking process, not more.

For a proposal that posits a sweeping change in the health-based rulemaking that is the foundation of the EPA, it was quite the slight of hand.

As a public health expert who has been closely following EPA's rulemaking process for more than a decade, it is evident to me that this is a cynical ploy to bolster polluting industries that don't like the results of longitudinal research.

Who does this benefit? Who really benefits from this charade? I must call it a

charade. Not the families everywhere who want to breathe clean air and drink clean water. Not frontline communities dealing with multiple pollution exposures from many industrial sources. Not the millions of children in the U.S. with asthma across the country whose disease can be worsened by small changes in air quality day to day, not the elderly, not those with underlying health problems whose likelihood of being admitted to the hospital, of having a stroke, of having a heart attack, even of dying, could depend on the levels of particulate pollution in the air. It does not benefit these people.

I have a master's degree in public health. One of the most valuable things that I studied in graduate school was how to evaluate the reliability of epidemiological studies. We learn the importance of considering many different criteria in making these evaluations. Whether the raw data was available to me, personally, to review, was never grounds for automatically discounting the credibility or reliability of any

given study.

The idea that an entire library of research would be rejected wholesale, based simply on that one external criteria, represents a crude approach, to put it kindly.

We also, in grad school, learned about the iron-clad importance of treating study subjects ethically and with respect. And this is a touchstone of public health practice. All research on humans must be approved by institutional review boards, and they prioritize the privacy and consent of study subjects. There are laws about this.

When study subjects are disrespected terrible things can happen, which is why we were required to learn about things like the, "Tuskegee Study of Untreated Syphilis in African/American (sic)Men," when we were in public health school. We cannot go back to the time when the study subject was a mere pawn in someone else's game. Treating study subjects ethically requires protecting their privacy.

Finally, we studied the tactics of polluting industries and their shameful legacy of attempting undermine science, whether it was the tobacco industry or the lead industry, we learned about the deliberate, expensive, decades-long campaigns to protect corporate profits, and meanwhile people were literally dying as a result. This is an old story. We've heard it before, and we're hearing that story again. Public health professionals are trained to recognize history and call it out, which is what we are doing today.

This proposal is an excuse to hamstring researchers to weaken public health protections, and to pad the profits of polluting industries. As a public health professional, as a mother, and on behalf of the 1 million members of Moms Clean Air Force, I strongly urge the EPA to stop this proposal for the health and safety of all Americans. Thank you.

MR. TEICHMAN: Thank you.

MS. GOTTLIEB: Good morning. My name is Barbara Gottlieb, G-O-T-T-L-I-E-B. I'm the

Director for Environment and Health at Physicians for Social Responsibility.

On behalf of our 33 members, I'm here to express our opposition to the proposed rule -- "Strengthening Transparency in Regulatory Science."

The U.S. EPA plays a critical role in keeping our nation and our families safe from environmental exposures that can cause illness and death. We thank you for that - and we count on you for it. Because your role is vital to our health and well-being, the nation relies on you to formulate and enforce the most effective protections possible, based on the best available science. The medical and scientific studies that underlie the EPA's decisions must be objective, vetted, and present a full and accurate assessment of the threats to health posed by the pollutants under study.

To provide those full and accurate assessments, studies need to relate exposure levels to actual health outcomes in real human

beings, and to amass large data bases so that researchers can draw valid conclusions.

In order to have reliable data and large sample sizes, researchers frequently study the records of patients treated in hospitals. Hospital records, of course, include personal identifiers, and disclosure of those identifiers would violate privacy and confidentiality laws. Thus, the best available data for many health studies cannot be - in the literal sense -fully and openly shared.

However, to refuse to consider scientific studies simply because they include personal identifiers -- would be a great mistake, nor is it necessary. Reviewers wanting to reproduce a study in order to validate it can arrange to have confidential access to key data. Furthermore, scientists can assess the merits of published research without seeing its data by considering such published features as the study's research design, the methods used for data collection and analysis, and comparison with previous results.

In any case, to exclude credible peer-

reviewed scientific studies because the personal identifiers cannot be released under the law, is to exclude from the EPA's consideration many important and valid studies. This would greatly hamper our ability, your ability, to understand the impacts of serious, even deadly, pollutants.

I'd like to cite, as example, three studies that could be lost to consideration under the proposed rule, on a topic I haven't heard referred to today. These studies reveal statistical correlations between exposure to emissions from fracturing, or fracking, for oil and gas, and serious health outcomes.

So the first is a study by University of Pennsylvania and Columbia University researchers and published in 2015 in the journal, PLoS ONE, found that drilling and fracking activity in Pennsylvania was associated with increased rates of hospitalization for cardiology, neurology, cancer, skin conditions, and urological problems.

In communities with the most wells, the rate of cardiology hospitalizations was 27 percent

higher than in control communities with no fracking. These findings are obviously of great concern; we would not want them to be lost to the EPA as you consider regulation of fracking related emissions.

Yet because the data includes such things as patients' names, diagnoses, addresses, and zip codes, this valuable study could be, under the proposed rule, excluded from EPA consideration.

Another study conducted in Pennsylvania between 2005 and 2012, found that living near fracking operations significantly increases asthma attacks. This study was conducted by researchers at Johns Hopkins University and it was based on a study of 35,000 medical records of people with asthma. This is just the sort of study that we want EPA to base its health-protective regulations on: a robust database conducted by researchers at a respected institution and published, as this one was, in the Journal of the American Medical Association Internal Medicine.

Yet should the proposed rule be adopted,

this study could be disallowed because its 35,000 medical records cannot easily be scrubbed of personal identifiers.

Third example, a study by the Johns Hopkins Bloomberg School of Public Health and other researchers, used data from the Geisinger Health System on over 9,000 pregnant women and their over 10,000 newborns between January 2009 and January 2013. The researchers found that the pregnant women who live near active fracking operations in Pennsylvania were at a 40 percent increased risk of giving birth prematurely. Premature birth is the leading cause of infant death in this country.

So we're talking about data that indicate that fracking operations could put newborn babies at risk of death. This was a study published in the peer review journal, Epidemiology.

Our families should have the benefit of these studies and many more that might be disregarded under the proposed rule. To exclude them would be to weaken the scientific record and

undercut an accuracy and strength of EPA's regulatory process, and to endanger human health.

For that reason, Physicians for Social Responsibility opposes the proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 36, Lyndsay Alexander, and Speaker Number 37, Laura Bender, come up to the speaker's table.

And would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, take your seat at the on-deck chairs.

MS. ALEXANDER: Good morning. My name is Lyndsay Alexander, A-L-E-X-A-N-D-E-R. I direct the National Health Year Campaign at the American Lung Association. I am also the mother of a thriving toddler, who like all children, deserves healthy air to breath, and safe water to drink that won't make him sick or die prematurely.

I am here to ask EPA to withdraw this proposed rule because I'm very concerned that rather than foster transparency in regulatory

science, this rule promotes a callous effort to suppress and censor the science used to inform EPA policy to the detriment of millions of Americans' health and well-being.

EPA's ability to effectively fulfill its mission and protect public health from dangers, such as air pollution, hinges on the ability of its scientists to first evaluate the best available scientific evidence of the health threats of air pollution. Recognizing that scientists' understanding of the relationship between air pollution and public health would continue to evolve, congress wisely required EPA to review the latest evidence and revise air pollution limits for six key pollutants every five years. And then to work with states to reduce pollution to meet the limit.

While more work remains, this basic approach has worked exceedingly well at reducing ambient air pollution, saving lives, and improving health by preventing asthma attacks, heart attacks, and many other negative health outcomes

from air pollution.

This proposed rule would require EPA to exclude many of the best available peer-reviewed and rigorously scrutinized studies from consideration during decision-making, such as its upcoming air quality standard reviews for ozone and particulate matter.

Excluding studies for which raw data are not available due to concerns over patient confidentiality, or which do not meet vague standard of reproducibility because studies were conducted over long periods of time, or connected to real world events beyond the control of researchers, would greatly narrow the body of evidence and the quality of the information that EPA can consider. This would undoubtedly lead to weaker protections and EPA's ability to estimate the true threats of air pollution on human health, and the benefits of reducing pollution, and thus result in weaker air pollution limits.

In 1993, researchers at Harvard University published a landmark air pollution

study, showing that particulate matter air pollution was linked to premature death. The Harvard Six Cities Study, as it is known, tracked the health of 8,111 adults, and 14,000 children in six small cities in the United States, beginning in the 1970s.

This study found that people in cities with cleaner air were living two to three years longer than those living in cities with dirtier air. Residents of Steubenville, Ohio, the city with the dirtiest air, were 26 percent more likely to die prematurely than were citizens of Portage, Wisconsin, the city with the cleanest air.

What surprised researchers was that the culprit was particulate matter, not sulfur-dioxide, as they had thought. This was a very important scientific discovery. This study, and countless others since, have helped EPA to understand that particle pollution in the air we breathe, resulting from activities such as burning coal for electricity, or diesel exhaust from vehicles, harms human health in profound ways in

communities across the nation and has paved the way for stronger air pollution limits designed to protect public health.

But the data for the Harvard Six Cities Study are not publicly available, and the study was conducted over a long period of time that make it very difficult to reproduce. Industry, and their allies in congress previously challenged the findings of this study and other similarly important studies. Instead of blocking the studies, as this proposal would do, EPA took a logical step and referred them to an independent third-party, the Health Effects Institute, for a deep dive review.

There, autonomous reviewers examined the data and developed a report that confirmed their original findings. Other research has since confirmed similar findings, including some studies that use publicly available data sets. Critically important studies, such as the Harvard Six Cities Study would likely be excluded under this proposal to the detriment of health protections. This

proposal would also affect other protections currently in place, such as limits on certain toxic air emissions from tail pipes and smoke stacks, and information on the health effects of many of these; more than 150 chemicals come from older studies built on confidential patient or private business data that cannot be made public.

This could -- this proposal could also cull the use of research that includes confidential business information or older studies that has data stored on older technology that can't be recovered, just to name two other limitations.

Thank you for the opportunity to speak today. The American Lung Association will submit more detailed written comments.

MR. ROBBINS: Thank you.

MS. BENDER: Good morning. My name is Laura Bender, L-A-U-R-A B-E-N-D-E-R, and I'm the National Director of Advocacy of the American Lung Association's Healthy Air Campaign.

The lung association's mission is to save

lives by improving lung health and preventing lung disease. And as you know, we strongly oppose EPA's so-called, "Strengthening Transparency in Regulatory Science," proposal.

Today you've heard from many representatives at the public health and medical community about the ways this proposal would undermine human health. I'd like to take a few minutes to highlight the Lung Association's concerns about the lack of transparency in EPA's work on this rule.

The administration has attempted to rush this rule forward at every turn, consistently sacrificing expert analysis and public health along the way. This is a sweeping proposal that will impact a wide range of public health safeguards, essentially affecting every future decision at EPA based on science. And yet, EPA's process in issuing it has been haphazard, rushed, and anything but transparent.

First, back in April, then Administrator Scott Pruitt, prematurely announced the proposal

while it was still undergoing interagency review at the White House Office of Management and Budget. Then, when media inquired about this discrepancy, OMB actually backdated the clearance by several days. This means that OMB only reviewed the proposal for 48 hours. That's a staggering tight timeline for such a sweeping rule.

In a similar vein, EPA initially only allowed a 30-day comment period with no public hearing. The Lung Association was among the organizations who requested 60 additional days and a hearing. We greatly appreciate the additional time and today's public hearing.

That additional time is crucial, particularly because EPA has failed to complete a regulatory impact analysis that explains the impacts of the proposal, putting the burden on commenters to do so instead.

EPA ignored another important opportunity for review when it failed to consult the Agency's own Science Advisory Board. The SAB, which

includes appointed members from this administration, voted at its May meeting to request to review the proposal.

In a letter to EPA last month, they said that they were only made aware of the rule through the press, and when it was published in the Federal Register. The SAB said unequivocally, quote, "The proposed rule merits review by the Board."

We strongly encourage the Agency to move forward with the SAB review of the proposal. To refuse their request to do so would be unprecedented and in direct contradiction of the Agency's stated claim of wanting the best science to inform its decision-making.

EPA rushed out this proposal after an inadequate review process, and it shows. The proposal falls short in several key ways. First, EPA fails to provide any evidence that the changes outlined in the rule are needed. EPA's existing approach towards science, with its detailed review and deliberation of the research, is already

transparent and has worked well for decades.

First, independent science has revealed that studies prior to publication by recognize journals, then independent and EPA staff scientists reviewed them again and question every aspect of the research in depth. And they do these reviews in wide open processes, including publication, public hearings, and comment periods.

EPA does not acknowledge the rigor of this process in its proposal. Instead, it attempts to justify this rule by claiming that the Agency is following in the footsteps of scientific journals. But last month as other commenters have noted, several scientific journals issued a joint statement highlighting their concerns with EPA's proposal and pointed out that even though many peer-reviewed publications have recently adopted transparency policies, they are still able to assess and use studies for which the underlying data cannot be made public.

Second, EPA fails to define its requirement that studies must be replicable. Does

EPA mean that the Agency couldn't consider a study that looked at health impacts of a one-time event, like a major oil spill?

The SAB also raised questions about EPA's failure to define this and other terms.

Finally, EPA did not explain how the Agency would implement the rule. The proposal offers no process for public hearing, or even consultation with the SAB over implementation. What process would EPA use to review and assess the existing research and revisions? What guidance would the administrator receive to avoid arbitrary decision-making over the fate of this research?

And where would the massive staff time and resources the EPA would need for such a massive additional workload come from? What would have to be sacrificed?

EPA's rushed process, its inadequate review, its false attempt to claim that its policy is supported by scientific journals, and its many unanswered questions about how the proposal would

work, all underscore a core problem with this rule. It would not improve the use of science of EPA. It would not make the Agency's science-based rules more transparent. It would permanently damage EPA's ability to do its job to protect the public.

On behalf of the millions of people with lung disease that we serve who will be hurt by the weaker pollution protections that would result from this proposal, we urge EPA to withdraw this rule to censor science. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, come up to the speaker's table. And Speaker Number 40, Albert Donnay, you're already at your seat. Excellent. Also, if Speaker Number 15, Harvey Fernbach, is in the room, you can take a seat at the on-deck chairs. Last call.

MS. BORKOWSKI: Thank you for the opportunity to present comments. My name is Liz Borkowski, and I'm the Managing Director of the

Jacobs Institute of Women's Health, which is at the Milken Institute School of Public Health at the George Washington University.

The Jacobs Institute is concerned about EPA's proposed rule, "Strengthening Transparency in Regulatory Science," due to the harmful impact it would have on women's health and reproductive justice.

We urge EPA to withdraw it based both on its detrimental impacts, and on the lack of a demonstrated need for such a rule. EPA has failed to demonstrate that its current processes for considering science and regulation are inadequate. It has not provided examples of any instances in which insufficient transparency has resulted in outcomes contrary to its statutory mandates or executive orders.

Given extensive existing procedures used by EPA and the scientific community at large to ensure the quality of research, EPA has failed to make a case that additional public access to data is necessary.

The theoretical, but as yet undemonstrated benefits of EPA's proposed rule, must be weighed against the extensive and unequally distributed costs of such an approach. Failing to consider the best available evidence because the underlying data are not publicly available, would result in regulations that fail to sufficiently protect public health. The consequences would fall most severely on sensitive groups not adequately protected by current rules, which include racial and ethnic minorities, those with low socio-economic status, the elderly, and pregnant individuals and their eventual children.

My comments provide a few examples related to reproductive health. First, neurotoxicants are of particular concern to pregnant people and the parents of young children. In regulatory activities, to reduce exposure to neurotoxicants, such as lead and methyl mercury, EPA has relied on an extensive body of research. This research includes longitudinal studies of individuals who are exposed in utero or as young

children to higher levels of lead or methyl mercury than would typically occur in the U.S. today. It would not be ethical to publicly release data from these studies, and it would not be feasible, particularly for older studies that used incompatible storage media to locate all participants and obtain their permission.

EPA's use of research on lead and methyl mercury also has implications for other agencies that address these substances. For instance, the Department of Housing and Urban Development relies on EPA's renovation, repair, and painting rule in its regulation of renovators working in housing units, receiving HUD housing assistance where lead paint is present.

EPA calculated the reference dose for methyl mercury that EPA and the Food and Drug Administration used to create guidelines on fish consumption, including recommendations for pregnant and breast-feeding women.

It does not appear that EPA has undertaken the required interagency review process

to assess the implications of its rule for other agencies.

Another neurotoxicant of concern for reproductive health is the pesticide, chlorpyrifos. Researchers followed a cohort of children exposed to this pesticide before the current ban on indoor use and found lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.

In a rulemaking process regulating agricultural use of chlorpyrifos, EPA requested the underlying data from the Columbia Center for Children's Environmental Health. The response from Columbia University explained that because of the detailed sociodemographic and health-related elements their data set contains, they did not believe they could submit extensive individual-level data to EPA in a way that would ensure participants' confidentiality.

Such concerns are not uncommon with the kids of longitudinal data sets that allow identification of long-term consequences of

environmental exposures. Often, the combination of variables used in an analysis provides enough information to identify individual participants and may include sensitive information, such as diagnosis of neurodevelopmental delays.

In addition, endocrine disrupting chemicals are of great concern and reproductive health and EPA has regulated some of these, such as PCBs and PBDEs, under the Toxic Substances Control Act.

Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence, but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

If EPA moves forward with the rule it has proposed, it will undermine science and regulatory decision-making by making it difficult and potentially impossible to consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health. The Jacobs Institute of

Women's Health urges EPA to withdraw this rule.

MR. ROBBINS: Thank you.

MS. NOLEN: Hi. Thank you. My name is Janice Nolen. It's J-A-N-I-C-E N-O-L-E-N, and I am the National Assistant Vice President for Policy for the American Lung Association.

The American Lung Association turns 114 years old this year. For more than a century we have fought to save lives for protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago, in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society then. They were looking to create a huge database of ordinary Americans would be willing to provide them with confidential information about their health and medical experiences, and would allow them to track those for years to come.

I was so pleased that two men from my church choir in Nashville agreed to participate.

They completed the forms and other paperwork, and became two of the more than half million participants in the cancer prevention study too.

Fast-forward a decade or so and I learned that their data were now part of a landmark study, the American Cancer Society study that revealed the risks to human health from breathing air pollution that I and my colleagues at the lung association were working hard to clean up.

Their data and private health and medical information, from hundreds of thousands of others were -- from hundreds of thousands of other people, who were pointing the way, the need to clean up emissions from power plants, from diesel engines and fuels, and many other sources. I never dreamed when my mother-in-law made her first request to me that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution.

None of us then would have ever dreamed

that the information these two men provided would have helped to identify and underline the threat to human life posed by microscopic particles in the air we breathe.

Furthermore, that study and the Harvard Six Cities Study became examples, not only of ground-breaking research, but of how questions about that research can be reviewed and resolved without having to lose the entire study.

Unfortunately, that is an example that this proposal clearly fails to understand. These two studies with decades-old patient data and others in the long list of studies that found evidence of harm from industrial emissions are unique events that no one hopes to replicate, like gulf oil spills, clearly appear to be targets of this proposed rule.

Studies that have been -- long been targets of industry polluters and their allies, remains so in this proposal.

Once published, these studies raised alarms in the public health community about the

increased likelihood of premature death from particulate matter, widespread in the nation. The studies raised alarms within industry too, about the increased likelihood that their polluting sources would have to clean up their emissions. Industry kicked in messaging developed by the tobacco industry, to challenge the science using the same arguments we have in this proposal.

I have in my office, a page from a 1999 U.S. News and World Report article on the challenges to these studies that could have been written this year.

Scientists are working to become more transparent in their research. More researchers use publicly available information, but some studies cover populations that are so limited in size or specialized in their characteristics that these data could not be posted on the web for all the world to see. Anyone who has an account on Facebook should have a visceral knowledge of how important keeping confidential data confidential can be.

Meanwhile, EPA could readily review historical data and studies in ways that respect patient confidentiality and the gifts of data from people like my two choir member friends.

So far, EPA has failed to show any reason that these changes are needed in the current system. Failed in its own transparency on this issue, in fact since EPA has not sought SAB review of this, and has not provided sufficient rationale for why EPA needs this change, much less how they would this rule going forward.

We request EPA to withdraw this proposal. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 40, Albert Donnay, come to the speaker's table. And Speaker Number 41, Mona Sarfaty.

MR. DONNAY: Thank you. My name is Albert Donnay. My comments are based on experience gained from 40 years working on regulatory science as an environmental health engineer and toxicologist, as a research

scientist, public health activist, clinician, consultant, peer-reviewer for academic journals, environmental groups and government agencies at all levels, including EPA.

I'm glad I get to follow the last two speakers because I want to highlight that although EPA's proposal to "Strengthen Transparency in Regulatory Science" is needed, did not give any examples of regulations that had been undermined by a lack of such transparency.

I want to remind everyone here what's at stake and what happened the first time EPA, congress, and environmental groups had to decide whether it was okay to base regulatory standards on published scientific studies whose achieves were no longer available for review.

They got the answer right then, and I hope they'll get it right again now. It was May, 1983, 35 years ago, and the EPA was about to publish a new national ambient air quality standard for carbon monoxide based on nine studies by a distinguished cardiologist at the VA, Dr.

Aronow. When the Washington Post reported that he'd been barred by FDA a year earlier for submitting a wave of false medical experiments after he admitted, quote, "fudging his lab reports in human drug studies."

Although EPA's head of the Office of Air Quality Planning and Standards said the Agency had, quote, "No reason to believe anything was wrong with Aronow's CO studies," whose data Aronow claimed at the time, "are excellent and can't be questioned." EPA nevertheless appointed a special team of agency and outside scientists to review his work, quote, "When we read that Aronow had done some kooky things."

A month later, The Post reported the shocking results under the headline, "EPA Probe Criticizes a Study Used in Air-Quality Standard." The team had said, quote, "Could not resolve the issue of possible falsification of data because," quote, "no data were available." Aronow told them he'd discarded the archives of all of his CO studies after first storing them in his garage for

years, and offering it to EPA because they didn't want it.

The investigators noted considerable concerns about the validity of the results reported, quote, "Raw data were lost or discarded. Adequate records were not maintained, available data were of poor quality, and quality control was nonexistent."

And Aronow's published results were consistently too good to be true. They found it, quote, "Rather remarkable that in 10 years of research his papers showed," quote, "not even one missing data point." They concluded that EPA, quote, "Cannot rely on Aronow's data due to the concerns we've noted." And they recommended the Agency commission new research to attempt to replicate Aronow's findings.

Congressional hearings and the GAO investigation followed, after which Administrator Ruckelshaus agreed that EPA would not rely on any of Aronow's studies in future rulemakings, but only on studies whose archives were still

available for review.

In coordination with the California Air Resources Board and the Health Effects Institute, EPA commissioned a series of new controlled human exposure studies on CO, and since 1994, has based the CO NAAQS exclusively on just six of them, all of which published their individual results in deidentified form so they would be available for public review in perpetuity.

And it's a good thing they did since all the larger archives of these studies were eventually discarded by their authors without being offered to EPA. This history shows that EPA can and should base regulations solely on studies whose methods and data are available for review. To base regulations on studies that can't be reanalyzed is not science, and there is no need for it. Even federal rules that are based on older epi studies, like the last particulate NAAQS rule in 2013 that cited just six studies could and should be based on more recent research that better reflects current air quality.

Over 500 studies a year are now published on particulate epidemiology, and many are in high quality journals that require authors at least to make all their deidentified data and methods available to reviewers, if not to all readers from the posting of supplemental material.

Given EPA's interest in basing regulations on more transparent research, EPA should start requiring all the researches it funds, intermural and extramural, to publish their results in such journals. Hopefully this will prompt less rigorous journals that don't require the posting of supplemental material to update their policies.

In conclusion, the Aronow scandal shows EPA cannot rely exclusively on traditional peer review to detect misconduct. Aronow reviewers at 11 leading journals, as well as EPA staff and their scientific advisors on the CASAC, who also review the studies before recommending that nine be cited as the basis for the CO NAAQS. Unfortunately, despite all this publicity, none of

Aronow's studies were retracted, and the EPA has started citing them again, most recently in the 2010 integrated science assessment of the CO literature.

EPA's proposal to strengthen transparency and regulatory science could stop this from happening again, which is why I support it and encourage my colleagues to do so as well. Thank you.

MR. ROBBINS: Thank you.

MS. SARFATY: Can you hear me?

MR. ROBBINS: Yes.

MS. SARFATY: Yeah. Okay. Respected EPA panelists and fellow citizens, my name is Mona Sarfaty. I'm a physician trained in family medicine and public health. I practice primary care medicine and taught medical and public health students in three different academic medical centers for 35 years.

Today I direct a program in climate and health at George Mason University in Fairfax, Virginia. I also direct a consortium of physician

societies called the Medical Society Consortium on Climate and Health, whose 550,000 members are more than half the physicians in the United States.

The Consortium seeks to inform the public and policy makers about the health harms of climate change, and the health benefits of climate solutions. I'm submitting the formal comment of the consortium in written form in a separate document.

The EPA is proposing to change the rules that dictate what evidence must be considered as the basis for protecting the public's health. As a physician who spent a summer in Southern California during college and didn't see Mount Wilson looming in front of me for an entire week because of smog, I am incredulous.

I remember well the pain in my chest when trying to play tennis on those smoggy days. This was the early 70s, when a republican president was creating the EPA. Now, 50 years hence, tremendous evidence has accumulated that validates my symptoms and the negative effect that unhealthy

hair -- air, has on people who must breathe it.

After that summer, as a practicing physician, I took care of people with asthma and chronic lung disease who were at greater risk on bad air days. So it is shocking to me that the EPA would propose putting aside huge amounts of thoroughly reviewed evidence on the causal connections between air pollution and poor health, claiming that the basis for this conclusion was secret.

Today, I lead a consortium comprised of the country's largest medical societies whose doctor members are highly concerned about the health harms of climate change. The similarities between the current EPA willingness to disregard established science about the connection between carbon dioxide and global warming, and the willingness to disregard solid evidence about the impact of air pollution on health, are glaring.

Despite overlapping evidence from every country in the world, and the entire U.S. climate science enterprise, not to mention major federal

agencies like NOAA and NASA, the EPA leadership does not accept or recognize reality.

To all of us whose lives are dedicated to helping people get and stay healthy, there is a secret lurking in the science of air pollution and global warming. It is not what we have long-known about how burning fossil fuels creates waste products that damage and inflame our lungs. This has been validated by voluminous overlapping research studies. The secret is not that carbon emissions from burning fossil fuels are warming our climate, exacerbating the health harms of air pollution, and causing other dangers to our health, from heat waves, wild fires, pollen, and storms.

The secret is hiding in plain sight. Fighting air pollution is the greatest public health opportunity of our time. It's the greatest public health opportunity of our time.

Reducing polluting fumes and emissions from fossil fuels will rapidly improve our health and fight climate change.

When an EPA's not so secret agenda is to promote fossil fuels, two things follow. The fact that fossil fuels are the major contributor to both air pollution and global warming must be undermined or denied. And the research that documents this reality and how it harms our health must be attacked. It's not hard to see that the approach is to mislead people by wrapping these attacks in rhetoric that's alternatively scary as in secret science, and high-minded, as in transparency.

We're told that the rationale for the new proposed strengthening transparency standard is that individual and medical records included in research were secret. In fact, like all medical records, they were confidential and they remain so.

The record shows that the same argument of secrecy against scientific studies has been used by polluting industries going back many years.

Health providers know that the facts may

be scary when our health is threatened. But we also know that denying or ignoring facts blinds us to discovering and acting on the best ways to heal medical problems and protect our health. We can't let that happen. The EPA must live up to its charge and work to face facts and protect our environment and our health. With this proposed regulation, its leadership is pointing in the opposite direction. Thank you.

MR. ROBBINS: Thank you.

Okay. We're going to take a short recess now and we'll resume at noon.

[Morning session adjourned.] [On the record 12:00 p.m., Afternoon session.]

MS. RADZIKOWSKI: Good afternoon. If everyone will please take their seats? Hello, and thank you for coming. My name is Mary Ellen Radzikowski and I am in the EPA's Office of Research and Development and I'm one of the hearing officials. Joining me is Lynn Flowers, also from the Office of Research and Development and we have a number of folks: Nanishka Albaladejo, Lauren Hall and

Lesley Stobert from SC&A Inc., helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science". EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under the authority of 5 U.S.C. 301, in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA receives your comments in an orderly fashion. Although EPA panel members here may ask clarifying questions, the intent of the hearing is to listen to your comments, not to discuss or debate the proposal.

Now I will go through a few housekeeping items and

ground rules: Please refrain from interrupting speakers or asking questions. Shouting, noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies. For everyone's awareness, this hearing is open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing.

There is no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again so please be aware of the time.

If you would like to make an oral comment at today's hearing and did not pre-register to speak, please see the hearing staff at the registration

table located right outside the doors here. If you would like to provide a written comment for the official record, you may hand-submit it to EPA staff today, or mail, fax or email your comments. See the staff at the registration table for instructions on how to do that. There is a comment box at the registration table where you can leave hardcopies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments, it is not necessary for you to give the same comments orally; written comments and oral testimonies will receive equal consideration by EPA in preparing its final rulemaking decision.

EPA has extended the comment period. Written comments must now be received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science", so please refrain from making comments that are not related to this action.

EPA will not be providing responses during the hearing. Rather, EPA will prepare a written summary of the comments received that includes responses.

The summary of the Response to Comments, the document, will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter, who will be preparing a verbatim record of this hearing.

Please speak clearly and slowly into the microphone so that the court reporter can accurately record your comments. A copy of the transcript will be placed in the docket. This hearing is also being audio streamed through Adobe Connect via the telephones.

The hearing is scheduled -- started at 8 AM this morning and is scheduled to go to 8 PM. We're in the second session: 12pm-4pm.

Public restrooms are located down both sides of

the hall. At the doors we have staff that can escort you out and back. Please note the location of the emergency exits. Please take a moment to silence your cell phones.

Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For this session, the speaker sticker color is white, so if you have a white sticker you're registered for this session.

Speakers will be called to the speakers' table (located right over there) in pairs by their speaker number.

When it is your turn to speak, please come to the table, state and slowly spell your name for the record, and if you are appearing on behalf of someone or another organization. If you are not in the room when it is your turn to speak, I will recall you after all other speakers have made their oral comments. Each speaker will be allotted 5 minutes for remarks. Elected and

appointed government officials may be provided additional time, since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system consists of green, yellow, and red lights. When you begin to speak, the green light will come on to indicate you have your 5 minutes. The yellow light indicates that you have 1-minute left and when the red appears, your 5 minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap-up your testimony to give others an opportunity to speak.

At this time, we are going to begin.

MS. STOBERT: If Speakers Numbers 1, Pamela Miller, and 2, Elizabeth Geltman, will come to the speakers table and Speakers 3 and 4, Patricia Koman and Alexis Adiman would go to the on-deck seating located near the stage.

MS. MILLER: Good afternoon, my name is Pamela Miller, P-A-M-E-L-A, M-I-L-L-E-R. I serve as Executive Director and provide these comments on behalf of Alaska Community Action on Toxics.

We're a nonprofit, public interest environmental health, research and advocacy organization, dedicated to protecting public health. I also serve as principle investigator of multiyear research studies involving several universities that investigate exposures and health outcomes concerning endocrine-disrupting chemicals in collaboration with Arctic indigenous communities in Alaska. I traveled the distance to Washington, D.C., from St. Lawrence Island, Alaska, in the Northern Bering Sea, two full days of travel, where we are conducting summer field research and interrupted this because EPA did not make it possible to provide remote testimony.

Through a process known as global distillation, the Arctic has become a hemispheric sink for contaminants that are carried on atmospheric and oceanic currents into the north where they concentrate in the bodies of fish, wildlife and people. Indigenous peoples of the Arctic are among the most highly exposed populations on Earth to persistent bio-cumulative and toxic chemicals

because of their reliance on traditional foods including fish and marine mammals that they use for their spiritual, cultural and physical sustenance. The communities that I work with on St. Lawrence Island also have higher exposures to chemical contaminants from military operations associated with formerly used defense sites. Our research elucidates exposure pathways, body burdens and health outcomes associated with chemicals including PCBs, PBDEs (or polybrominated diphenyl ethers) and other flame retardants and also perfluorinated substances in homes, in air, water, traditional foods and in the blood serum of the Yupik people of St. Lawrence Island. Our studies have shown elevated body burdens as well as disruption of thyroid function associated with these exposures to certain PBDEs and perfluorinated substances. We are now beginning a research study to investigate exposures to PCBs, PBDEs and currently used organophosphate flame retardants in young Yupik children, age 2 to 12, because elders and other community leaders are

concerned about possible adverse effects on children's neurodevelopment. They're concerned that chemical exposures might harm the children's abilities to learn the languages, songs and stories that are so vital for the continuance of the culture of Yupik people. Participation is dependent on the trust of confidentiality that they give to us as researchers. Our research team submits each proposal to rigorous review to the National Institute of Environmental Health Sciences. In the process of the research, we submit also to several institutional review boards for approval to collect sensitive and detailed information on health and behavior as well as spatial and demographic data in an ethical manner that protects human subjects. We have published results of our research in 11 peer-reviewed journal articles after receiving approval from the tribal leadership. These findings help inform interventions and policies to reduce burdens of toxic exposures and prevent further harm to public health. These studies are possible only because

we guarantee to protect the medical privacy of participants, again dependent on trust of the researchers. We gather detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures. If the proposed rule were to go into effect, studies such as these would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic such as decisions to limit the production and use of persistent biocumulative toxics and other chemicals including those regulated under TSCA and FIFRA and in regulations that hold military and industrial polluters responsible for contamination of air, waters and lands under CERCLA, the Clean Air Act and the Clean Water Act. EPA indicates that the proposed rule is intended to strengthen transparency of EPA regulatory science; however, we find this a duplicitous claim. It would favor industry data protected as confidential business information over public peer-reviewed research.

We support the best scientific evidence to inform regulatory decisions. However, this rule would have a dangerous counter effect by limiting the science that should be used to inform decisions about public health. Furthermore, we disagree with the agency's conclusions as stated in the proposed rule document that this action does not have tribal implication as specified in the executive order and requiring government to consult with tribes. This rule would disproportionately affect vulnerable populations including American Indian and Alaska Native People and, therefore, is relevant and requires consultation.

MS. RADZIKOWSKI: Excuse me, your time is up. We need to be fair to others.

MS. MILLER: I'll wrap up to say that we urge EPA to end this rulemaking promptly and we strongly oppose the proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. GELTMAN: Good afternoon. Thank you for the opportunity to comment on EPA's proposal entitled,

"Strengthening Transparency in Regulatory Science." My name is Elizabeth Glass Geltman, G-E-L-T-M-A-N. I am a Professor of Environmental Health Policy at the City University of New York -- the CUNY School of Public Health, located in Harlem. I am the author of 17 books on environmental and natural resources policy, a peer-reviewer of numerous journals and have worked on EPA-regulated matters for over 30 years. I am also the Chair Elect of the Law Section of the American Public Health Association. As a professor, I aim to advance public health by preventing people from getting sick. My efforts address reducing health impacts, and hence controlling health costs, by evaluating chemical and environmental determinants of health. Although EPA's rule aims to establish a clear policy concerning the use of dose-response data and models that underlie pivotal regulatory policy, the rule is, in fact, a continuation of the Trump administration's two for one regulatory reform policy announced in Executive Orders 13771,

13777, and 13783. The rule promises, "to change agency culture and practices regarding data access so that scientific justification for regulatory actions is truly available for validation and analysis." However, the new rule, in fact, creates new regulatory hurdles by discounting and precluding consideration of long-standing, established scientific practice. Rather than promoting the transparency of scientific information used to create environmental regulations, the rule will obscure the democratic process, slow the pace of science and progress, and potentially prevent important health data from being considered by U.S. EPA in outlying important environmental policy. Administrative procedure requires the EPA consider data submitted by the public in evaluating regulations. Let's be clear, scientific studies have always been of uneven quality. EPA has a process in place, including use of Scientific Advisory Board testimony and written and oral public notice and comment, using internal and external peer review to evaluate

data. Depending on context some studies are given greater weight than others. Some studies are disregarded entirely. It is inappropriate, however, and unlikely unlawful -- and likely to be unlawful -- under the Administrative Procedure Act. For EPA to categorically eliminate certain types of studies, and hence certain types of data, without considering context. But, even more important, eliminating studies, unless all underlying data is made public, is hazardous to human health and the environment. Longitudinal medical and epidemiological studies are often conducted over years, if not decades. Many studies require people who are study subjects to share very, very personal information, often on the legal or ethical condition that private medical information provided will be protected from public view. EPA is not, and has never been, in the regular business of replicating studies. Timing and the cuts in EPA funding make replicating studies as a condition of promulgating regulations an impossibility. EPA has presented

no scientific reason to prevent use of human health studies simply because the underlining medical records are not available for public inspection and review. One size fits all rarely works in fashion and it is even more unworkable in science and regulation. It is imperative the EPA allow consideration of all available scientific data pertinent to a proposed environmental rule or regulation including random, controlled human health trials and other epidemiological studies. Eliminating certain classes of human health studies would be like picking NFL players in the draft without allowing any scouting reports or eliminating the minor league in baseball. It doesn't make sense in sports; it makes even less sense when we're safeguarding our nation's air, water and land. For the reasons stated, I respectfully request the EPA withdraw the misleadingly-named rule entitled, "Strengthening Transparency in Regulatory Science." Thank you very much for allowing me to speak. My comments are my own. I'm happy to answer questions and I

will submit more detailed comments for the record.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Number 5 is Alexis Andiman. Also, if Speaker Number 6 could take a seat on the on-deck seating: Sarah Kogel-Smucker. Speaker Number 3, Patricia Koman, and Speaker Number 4, Alexis Andiman.

MS. PATRICIA KOMAN: Thank you. My name is Patricia Koman, K-O-M-A-N. I'm an environmental epidemiologist at The University of Michigan School of Public Health. I'm a member of the American Public Health Association, and in my comments I'm representing myself and my colleagues at the University of California at San Francisco Program for Reproductive Health and the Environment. As a scientist who has formerly served at the U.S. EPA and has been significantly involved in analyzing science to create regulation and programs that protect the public's health from diesel and air pollution, I value the importance of open science which includes appropriate data sharing and full reporting of methods. However,

U.S. EPA's proposed rule is not consistent with the principles of open science, inappropriately codifies how science should be conducted, and codifies science policy decision in direct conflict with consensus reports from the National Academies of Sciences 2009 and often the enabling environmental statutes such as the Clean Air Act and the amended Toxic Substances Control Act. Therefore, EPA should withdraw this proposed rule immediately. Instead, EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies. The proposed rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human subject data. The rule's requirements for specific types of test methods, defaults, dose response models and/or other analyses are not supported by current science and these provisions should be removed. The rule is counter to mandates in the amended Toxic Substances Control Act, to use the best available

science and systematic reviews for chemical evaluations. Specifically, the proposed rule inappropriately codifies particular data analysis approach such as dose response modeling that should be made based on empirical considerations. This proposed rule will lead EPA to utilize inadequate science resulting in inaccurate analysis and, consequently, inadequate public health protections. The proposed rule does not expressly address the issue of how the new procedures will be protective of public health. Alternatively, existing open science guidelines can and should be used to protect public health such as the 2013 memo from the Office of Science and Technology Policy. In addition, protocols and guidelines such as CONSORT, ARRIVE and STROBE do not require public access to all study data and will still improve the scientific basis of evaluating studies and thus promote public health goals.

I want to call your attention to especially troublesome provisions of the proposed rule which

is not consistent with current scientific practice and why this proposal should be withdrawn. For example, it is not appropriate to require the use of standardized test methods, guideline studies or so-called good laboratory practice studies. These types of studies are not designed to address health effects from low-dose exposures, complex and systematic endocrine effects, behavioral or learning effects, or metabolic changes. In addition, the so-called good laboratory practice and guideline studies are not consistently associated with higher quality research, proper study design or correct statistical analysis. Further, by dictating the model choices without empirical basis the proposed rule sets a dangerous precedent of prescribing how science should be conducted without regard to the data, or hypothesis or peer review. This is especially troublesome for dose response models. Simply using a greater number of models as the proposal preference is unlikely to improve results without considering the models' assumptions and whether

they fit the data set, the goals of the analysis, and many other issues. Therefore, giving priority to studies based on the number or range of models used is scientifically inappropriate.

Contrary to the proposed rule's statement about growing evidence of nonlinearity in concentration response functions, the body of empirical evidence points to the opposite, that for most chemicals and pollutants there is likely no safe threshold on a population level because of ongoing exposures and preexisting vulnerabilities. The rule mandates reconsidering using a linear no-threshold dose response but the National Academy of Sciences recommends exactly the opposite in considering low-dose effects. "The committee recommends that cancer and non-cancer responses be assumed to be linear as a default." Regarding other defaults, I oppose provisions that mandate reconsideration of established science-based defaults on a case by case basis. This is in direct contradiction to the National Academy of Sciences recommendations. The rule is counter to the mandates in the amended

Toxic Substances Control Act to use the best available science and systematic reviews for chemical evaluations. In contrast, this proposed rule will have EPA ignore well-conducted, relevant studies simply because all the data are not publically available and/or may not conform to the rule's invalid assumptions about good laboratory practices and guidelines, studies, and dose response modeling. This is inconsistent with modern science and the TSCA statutory mandates. Further, EPA's risk evaluation framework rules under TSCA mandate the use of systematic review methods. Well conducted systematic reviews consider the entire body of scientific evidence and the quality and strength of all relevant individual studies are considered to reach the overall conclusion.

Therefore, for these reasons, and those outlined in my full written comments, I strongly oppose this proposed regulation and recommend that EPA withdraw it immediately. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. ANDIMAN: Good afternoon, my name is Alexis Andiman, A-N-D-I-M-A-N. I am an Associate Attorney at Earthjustice, the nation's original and largest nonprofit environmental law organization. Earthjustice strongly opposes the proposed rule entitled, "Strengthening Transparency in Regulatory Science." If finalized, this rule would drastically undermine the U.S. Environmental Protection Agency's ability to protect public health and the environment through science-based regulations restricting the presence of chemicals and pollutants in our air, drinking water, food and consumer products. Under the guise of increasing transparency, the proposed rule would authorize EPA to ignore scientific studies that incorporate personal data and other information that researchers cannot practically, legally or ethically disclose. Indeed, EPA admits that the rule would preclude it from considering landmark studies assessing the health consequences including risks to children associated with exposure to particulate matter and lead. This is

unnecessary and unacceptable.
The proposed rule raises more issues than I can address during five minutes of testimony. In partnership with other environmental and public health organizations, Earthjustice plans to submit extensive written comments detailing our serious concerns about the rule's procedural and substantive defects. Today, I will focus on three key points.
First, EPA lacks authority to adopt the proposed rule. Second, the rule would directly conflict with laws that EPA is charged with implementing and enforcing. And finally, the proposed rule would harm the communities of color and low-income communities that are most in need of strong, science-based protections.
First, EPA lacks authority to issue the proposed rule: It is axiomatic that administrative agencies may act only pursuant to authority delegated to them by Congress. The Administrative Procedure Act requires that each notice of proposed rulemaking reference the legal authority

under which the rule is proposed. EPA failed to identify any meaningful authority for the proposed rule at issue today. In announcing the rule, EPA cited provisions of numerous environmental laws but virtually every provision cited authorizes or directs EPA to undertake research, not to impose unfounded limitations on the research it will take into account. EPA also cited provisions that authorize it to promulgate rules necessary to achieve the goals of these environmental statutes, but ignoring credible scientific evidence is neither necessary nor consistent with the statutes enacted to protect public health and the environment.

Second, the proposed rule directly conflicts with numerous laws. Multiple statutes require EPA to ground its decisions in credible science. For instance, the Safe Drinking Water Act directs EPA to rely on the best available, peer-reviewed science and the best available public health information. The Toxic Substances Control Act similarly mandates that EPA consider all

reasonably available information and act in a manner consistent with the best available science. At no point do these statutes suggest that the quality of a scientific study depends on the public's ability to access the underlying data. Indeed, as the EPA previously determined, and as the U.S. Court of Appeals for the D.C. Circuit agreed requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.

Finally, the proposed rule would harm the communities that are most in need of strong, science-based protections. Decades of scientific research have established that communities of color and low-income communities are disproportionately likely to experience exposure to chemicals and pollutants. This research is also critical to establishing regulatory safeguards that will protect these communities and their environment. Nonetheless, the proposed rule would preclude EPA from considering this research simply because it incorporates personal health

information and other non-public data. As a result, the rule would eliminate an important means of understanding and beginning to resolve the harms suffered by over-burdened communities and that's what perpetuates the environmental injustices these communities already face. Earthjustice urges EPA to withdraw the proposed rule without delay. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Number 5, Alexis Andiman, is already seated at the table. She's speaking on behalf of Devon Hall. If speaker Number 6, Sarah Kogel-Smucker would come to the speaking table. If we could have Speaker Number 7, John Doherty and Speaker Number 8, Tricia Sheehan, come to the on-deck seating. Speaker 5.

MS. ANDIMAN: Good afternoon. I am reading testimony on behalf of Devon Hall. D-E-V-O-N, H-A-L-L, who was unable to make it today. My name is Devon Hall. I am the Cofounder and Program Manager at the Rural Empowerment Association for Community Health, also known as REACH. On behalf

of REACH and the community we serve, I urge the U.S. Environmental Protection Agency to withdraw its proposed rule entitled, "Strengthening Transparency in Regulatory Science." I cofounded REACH in 2002 to address social, economic and environmental inequities in and around Duplin County, North Carolina. Our primary focus is protecting our community from pollution caused by industrial animal operations. North Carolina is a leading producer of swine and poultry. There are nearly 2-1/2 million hogs and pigs and more than 16 million chickens and turkeys in Duplin County alone. Together, these animals generate well over 2 billion gallons of wet waste and more than 190,000 pounds of dirty litter each year. This waste produces an overpowering odor and pollutes our well water, rivers and streams. REACH uses scientific research as a tool to educate and empower our community. Common sense tells you that it's not healthy to breathe air that smells bad enough to make you gag and that makes your nose run and your eyes water. I began to work as

a citizen scientist in 2004 because I wanted to understand exactly what I was breathing and how it was likely to affect my body so that I could better protect myself and help my neighbors protect themselves. So far, I have coauthored nine published studies documenting the threats that under-regulated industrial animal operations pose to community health. For example, I contributed to a study showing that kids who attend school downwind of industrial hog operations are exposed to relatively high levels of hydrogen sulfide, putting them at greater risk of symptoms like difficulty breathing and impaired lung function. I also worked on a study finding that children of people who work in industrial hog operations are more likely to carry dangerous, antibiotic-resistant bacteria on their bodies, even though those children likely never set foot in industrial hog operations themselves. REACH has no interest in putting anybody out of business, but we believe it is possible for industrial animal operations to be more

environmentally friendly and more community friendly. It is not enough for us to talk about our symptoms and our diminished quality of life. No matter what we say there will always be some people who think we are just complaining or making things up. My neighbors and I want to be part of the science so that we can gather proof about what we're living with on a daily basis. We hope that policy makers will listen to that science which reflects the experiences of real people and begin to make some changes. If adopted the proposed rule would prevent EPA from considering the scientific studies that REACH helps to conduct. We cannot make all of our data publically available because we cannot risk compromising the confidentiality of the people who contribute to our work. Because we live in a rural community it would be relatively easy to identify study participants based on de-identified information like age, sex, occupation and number in households, even if the participants' names were redacted. Simply put, people would not

participate in our studies if they knew that the identifying information they shared could become publically available. Even if EPA were to expand on its vague promise to protect confidentiality, I would not trust the government to deliver. Once, I called the North Carolina Department of Environmental Quality to report a permit violation at an industrial animal operation and, even though I asked to remain anonymous, I received a call back directly from the operator I had complained about. The government apologized to me later, but the damage was done. My anonymity had been violated and I felt violated as a result.

On another occasion, the North Carolina Pork Council tried to obtain the identities of study participants from Dr. Steve Wing, a researcher who worked closely with our community. Dr. Wing worked hard to protect our trust, but I know that the legal problems he experienced deterred other researchers from studying the health effects of industrial animal operations. EPA's proposed rule might also deter researchers from partnering with

communities like ours to study public health impacts because it would dramatically reduce the influence of those studies in agency rulemaking. Contributing to research about a polluting industry is a lot like acting as a police informant. You're providing information that could help to make everyone more safe, but you are putting yourself at risk, too. People who work at industrial animal operations would lose their jobs if their employers knew they were participating in a scientific study. And losing your job is not the only risk. I have been spoken to hard by powerful people who do not like the work I do. And I know people who have been physically and verbally threatened by industry representatives. EPA has investigated this issue and in January 2017, it expressed grave concerns about the intimidation we have experienced.

I'll wrap up quickly. My first priority is to the people I serve. I will never do anything to violate their trust or put them in danger. If EPA cares about keeping people safe, it should

withdraw the proposed rule immediately and instead take steps to support community-based research. Thank you.

MS. KOGEL-SMUCKER: Good afternoon, my name is Sarah Kogel-Smucker, Special Assistant Attorney General at the Office of the Attorney General for the District of Columbia. I am commenting on behalf of Karl A. Racine, the Attorney General for the District of Columbia. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," is a solution in search of a problem. Instead of strengthening ways in which EPA can benefit from advances in scientific studies, the proposed rule limits EPA's access to important studies and hampers the development of regulations needed to protect the public health and welfare of the residents of the District of Columbia and the nation. The proposed rule should be withdrawn. In these comments, I will briefly address why the proposed rule limits the use of valid, peer-reviewed scientific studies, violates several environmental statutes and lacks sufficient

details to be appropriately evaluated and implemented.

First, the proposed rule impedes EPA's decision-making by creating burdensome, and potentially impossible, barriers to the use of certain scientific studies needed to determine the impacts of pollutants and toxic materials on air quality, water quality and human health. The proposed rule requires that EPA's significant regulatory decisions be justified only by studies based on dose response data and models that area available to the public. This requirement limits EPA's ability to rely on otherwise peer-reviewed scientifically valid studies that do not or cannot make their data publically available because of confidentiality concerns. For example, EPA used the landmark Harvard Six Cities study demonstrating a dramatic link between premature mortality and air pollution as part of its justification for key clean air regulation. The study has been rigorously independently peer reviewed but the subjects were promised

confidentiality and the data is not public. Studies with confidential data can still be appropriately peer reviewed through the use of confidentiality agreements and subject to rigorous scientific scrutiny over their methods and conclusions. Where cost-effective and appropriate use of open or publically available data should be encouraged. EPA, however, should not provide blanket limits on the use of studies that cannot be made public because they contain confidential health or business information. Scrubbing studies of such information may be impossible while still keeping the study reproducible. The proposed rule may also have important implications for rules subject to periodic update like the Clean Air Act, NAAQS, if EPA can no longer use the same or similar methods that were used to support the existing rules.

Second, the proposed rule violates several environmental statutes because it hinders EPA's ability to rely on best available science or most up to date information as they require. The Clean

Air Act, Clean Water Act, Safe Drinking Water Act, Toxic Substances Control Act, and Emergency Planning and Community Right-to-Know Act all require certain decisions or regulatory criteria be based on the most up-to-date science. These criteria are described as best available science, latest scientific knowledge and best available public health information. The proposed rule would illegally limit EPA's ability to rely on best available science in violation of these statutes.

The nearly 700,000 residents of the District of Columbia rely on EPA to protect their health and environment. While air quality in the District has improved over the last several decades, many residents who face disproportionate exposure risks because of where they live or work still face risks to their health from air pollution. For example, the American Lung Association's "2018 State of the Air (sic)" report gave the District a failing grade for the period from 2014 to 2016 because of the number of days that the air was

unhealthy for vulnerable populations due to high levels of ozone. The District's vulnerable populations, including the estimated 10,415 children in the District with asthma, are entitled to protection from unhealthy air. Because people of color and children living in poverty disproportionately suffer from childhood asthma, environmental justice demands that EPA continue to use advances in scientific research to improve air quality through appropriate regulation. EPA should not be artificially hampered in this duty just because the data or models from a high-quality, peer-reviewed study are not publically available.

Lastly, the proposed regulations are too vague to be meaningfully evaluated and successfully implemented. For example, it is unclear whether Section 30.7 requires EPA to conduct its own peer review of all pivotal regulatory science and, if so, whether EPA has the capacity or capability to perform those reviews. Likewise, the exemption process does not provide sufficient standards to

ensure that the administrator made consistent determinations. For these reasons, the proposed rule should be withdrawn. Subsequent EPA transparency initiatives, if any, should be based on consultation with the National Academy of Sciences and should not restrict EPA's ability to rely on the universe of best available science when promulgating regulations. Thank you for the opportunity to comment today.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker Number 7, John Doherty, and Speaker Number 8, Trisha Sheehan, would come to the speaker's table. Speaker Number 9, James Duffy, and Speaker Number 10, Erika Rosen, if you'd go to the on-deck seating.

MR. DOHERTY: As a retired EPA toxicologist I know the firsthand frustrations of having to deal with epidemiological reports. However, I believe that epidemiological reports are valuable but more, critical, initial review is needed. Today, I hope to present a path forward. The animal studies that I've reviewed are required to support the

registration of pesticides follow very strict quality assurance, good laboratory practices and ethics and reporting standards. Multiple layers of primary and secondary reviewers are identified and assigned to review documents to assure quality assurance and transparency. Every force, however, has a mixed bag of standards to my experience for QLT, quality assurance ethics in reporting. They are often accepted at their face value without documentation of independent review. There is no way to verify the procedures or results presented and the EPA reviewers are not identified. This is very unfair to the public. Historically, I would like to mention two situations where more critical initial evaluation would have prevented social and medical problems. The first is the report on the Kallikak family published in 1912 by Henry Goddard. The book was the foundation of eugenics and was well received at first, but very serious social consequences resulted. However, closer examination revealed that much of the interviewing reflected the biases of the interviewers. Goddard

later regretted publication of this book. The other is associated with vaccinations and autism that could not be verified. The publisher retracted the original publication; however, within the past two years there is an increase in measles in Minnesota because people feared autism from vaccinations. When the concept of disparity in the views of animal versus epidemiological studies, and the need to provide a more critical initial review the EPA posed, I am proposing an epidemiology peer review consult with the goal of creating a transparent document reflecting a thorough review be established at EPA. The Council will consist of six independent subcommittee and relevant experts as follows: First would be an ethics subcommittee. All aspects of assuring the personal safety and identities of the individuals on the study would be protected. Second is an end-point evaluation. The relevant experts knowledgeable in cancer and rural behavioral, or whatever the condition is, they would discuss the factors like how many

people are really needed in a cohort to make a decision. Identify what is known about that particular condition environmental factors or chemicals are known to cause it. The other -- is self-explanatory. Exposure evaluation, statistic evaluation, analytical chemistry and animal toxicity and structure activity correlations. Each subcommittee will articulate why additional data are or are not needed. The Council will consist of qualified individuals from the EPA, FDA or other agencies' consultants as needed. The Council will have considered the reports of the six independent subcommittees and make their recommendations especially with regard to additional data needed to support a transparent regulatory decision.

The report of the Council -- the final report of the Council, will append each of the six subcommittee reports as well as any dissenting opinions. The Council owns the decisions and since all responsible individuals will be identified, the report is thus transparent. Thus

AP may further review the Council report. In conclusion, controversies associated with epidemiologic reports may not be eliminated by the Council, but the Council should contribute to minimizing these controversies. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. SHEEHAN: Good afternoon, my name is Trisha Sheehan, S-H-E-E-H-A-N, and I'm representing Moms Clean Air Force. I traveled here today from my home in New Jersey. I'm the National Field Manager for Moms Clean Air Force. We are an organization of over 1 million members from across the country who are fighting every day to protect the health and safety of their children from toxic chemicals, air pollution and dangerous climate change. I am also a mom to three young boys and last week my family and I joined Democratic House Leader, Nancy Pelosi, to share our own story of how my family was impacted from a toxic chemical accident and today I'm here to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name

of transparency. Limiting the scientific information the EPA can use to identify public health threats and protect us from pollution is reckless and dangerous. Not only does this proposal compel EPA to subject high-quality research to extreme unnecessary and untenable levels of disclosure, but it also includes loopholes that would allow the administration to exempt industry from having to disclose details of their own studies. American families depend on the EPA and high-quality science to protect families like mine from the impacts of air pollution and toxic chemicals. This proposal puts that protection in jeopardy, placing the health of our children at risk. This proposal is misleading. It would require the EPA to only consider those studies that use public data. This would prevent the EPA from using studies that are based on personal medical data, eliminating some of the most important long-term epidemiological studies that investigate the impacts of pollution on public health. This proposal would

significantly limit the research and data the EPA can use to make informed policy decisions under major public health and environmental laws including the Clean Air Act, the Safe Drinking Water Act and the Toxic Substances Control Act. This proposal means that many studies on populations such as the elderly, children and people of color, groups who often suffer disproportionately from pollution, would be excluded from EPA consideration because making the data public could identify the participating individuals. Excluding this important data from consideration means that implementing the proposal could even further exacerbate negative environmental impacts on these and other vulnerable communities. As a mom who has witnessed her children's health deteriorate due to polluted air they were breathing, I know personally what it's like to rely on scientific studies whose data informed us during that horrifying time. On behalf of my family and Moms Clean Air Force's one million members, I strongly

urge the EPA to withdraw this dangerous proposal for the health and safety of our children. Thank you.

MS. STOBERT: Speaker 9, James Duffy, and Speaker 10, Erika Rosen, if you would come to the speaker's table. Speaker 11, Gretchman Goldman, and Speaker 12, Maggie Flaherty, if you would come to the on-deck seating.

MR. DUFFY: Good afternoon, my name is J. Duffy. I am an Associate Attorney with Clean Air Task Force. CATF seeks to help safeguard against the worst impacts of climate change by working to categorize the rapid global development and deployment of low carbon energy and other climate-protecting technologies through research and analysis and public advocacy leadership. EPA's proposal at best is a solution in search of a problem. The Agency has failed to identify a need for further review of the already extensively peer-reviewed public health and environmental science it uses in its decision-making, nor has it made the case the underlying health data must be

made more public than current statutes and practices allow. The only thing transparent about the proposal is that is an attempt to undermine EPA's ability to use the best available science by placing arbitrary limits on the ability to consider these studies.

As a professor who has cited multiple times the proposal recently stated, if this proposal is finalized, science will be practically eliminated from all decision-making processes so that public health and environmental regulation would then depend on opinion and whim. Banning the use of fully peer-reviewed studies because their underlying data must be kept confidential would eliminate the consideration of vital information in critical public health-making decisions. This is not only unnecessary, it also represents a significant shift in decades-long policy without any justification. As the D.C. Circuit has held when considering this exact question, requiring agencies to obtain and publicize the data underlying the studies on which they rely would be

impractical and it would be unnecessary. Congress has clearly spoken, moreover, mandating that the agencies must consider all relevant science. It is well understood, and it has been for decades, that many of the most important public health studies are those based on actual patient information. Because that information must be kept highly confidential and because making even some of the patients' details public would allow them to be identified, the information must be kept private. But that does not mean that these studies can't be, or haven't been, verified. For example, the Harvard Six Cities Study linking fine particulate matter and mortality has been exhaustively reanalyzed by independent institutions, including by the researchers under the auspices of the Health Effects Institute. This reanalysis confirmed the study's essential findings while keeping confidential the underlying data. There are already several ways in which the public can access the studies that EPA uses and in some cases their underlying data without the

release of confidential information, including through the Freedom of Information Act which provides an avenue to request raw data, including a process to ensure that sensitive data is protected. The proposal puts the EPA in the untenable position of either violating its mandate to consider all relevant science or violating confidentiality laws. Additionally, the proposal is impermissibly scatter-shot, it's vague, it's confusing, it's insufficiently formed to allow for meaningful comment. It seems more like a request for ideas about how to discredit the best available science than for how to make it more accessible. For example, the proposal claims that it is consistent with the Data Quality Act and HIPAA as well as various executive orders, but each of these contain checks on the release of confidential information. In fact, the longstanding OMB guidelines stemming from the Data Quality Act recognizes peer review as the per se marker of objectivity and the Harvard Six Cities Study reanalysis set the gold standard for

reproducibility.
Finally, in violation of Executive Order 12866, the proposal fails to perform any analysis regarding the impact this rulemaking could have on the environment, public health or science generally -- or even on what it would cost to implement. Because the Agency does not have authority to undertake this effort, and because it would undermine the consideration of relevant science in its public health and environmental rulemaking, it should be abandoned. Thank you.
MS. RADZIKOWSKI: Thank you. I'd like to remind speakers to please speak into the microphone.
MS. ROSEN: Good afternoon, this testimony is on behalf of Lynn Goldman. She is a pediatrician and an epidemiologist and has been Dean of the Milken Institute School of Public Health at the George Washington University since 2010 and former Assistant Administrator for Toxic Substances at the US Environmental Protection Agency. My name is Erika Rosen and I am delivering this oral testimony on her behalf. Her full written

comments will be submitted for the record. This proposal suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as similar agencies internationally, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision. making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as

Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking. The proposal ignores the "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences and the National Toxicology Program. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments.

Risk assessment activities at EPA are extensive and its programs are performing more than 1,000 risk assessments per year. The proposal does not consider the costs, the significant time and paperwork burdens, and major regulatory delays that will occur when EPA is waiting for data to be made publically available, which may not ever happen.

For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base underpinning EPA's decisions.

The proposal misrepresents the recommendations of prior expert reviews such as the so.called NAS "Silver Book" and the Bi.Partisan Commission review. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. Single studies are used to inform risk assessors of the possible shape of dose response curves. Instead, EPA evaluates all of the scientific information to gain a biological understanding of the "mode of action". When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens, and certain noncancer effects that have no practically identifiable thresholds.

This proposed rule for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

I strongly urge the EPA administrator: (1) not to use the Agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community. What is at stake is no less than the credibility of the Agency with the American public and public confidence in the integrity of EPA's science and decisions.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 11, Gretchen Goldman, and

Speaker 12, Maggie Flaherty, if you would come to the stage. Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, if you'll come to the on-deck seating.

MS. GOLDMAN: my name is Gretchen Goldman, G-R-E-T-C-H-E-N, G-O-L-D-M-A-N. I'm the Research Director at the Center for Science and Democracy at the Union of Concerned Scientists, and I'm also a mom. As a scientist, I'm deeply troubled by this proposal. As a mom, I'm alarmed by it, and the risks that it poses to my children and others. The EPA's mission is to protect public health but this proposal does the opposite. This proposal needlessly restricts the science that EPA can use to make decisions about all of our families' health. Many crucial scientific studies that rely on public health data, intellectual property, confidential business information and other scientific information that may not be publically acceptable would be unavailable to EPA experts under this proposal. As a result, the EPA will be prevented from making rules that protect people

using the best available science. There is no reason for such a rule. The EPA already follows a rigorous, science-based process for determining when and how studies are used in its decisions. I've seen this first-hand when the EPA contacted me about my own scientific research. The Agency needed to obtain results data from my peer-reviewed studies looking at ambient air pollution exposure in time series' epidemiologic studies. I can attest to the fact that the EPA already ensures it is using reliable and robust scientific information to make decisions. When my son was born he spent five days in the neonatal intensive care unit because of a respiratory problem and when I took him home I knew it would be important for me to make sure that he could breathe clean air. I can't protect him from the air outside always but the EPA can. When my children breathe outside I need to know that the air is healthy. When my children play in the grass I need to know that there aren't harmful pesticides in it. When my children drink from their sippy cups, they need

to know -- I need to know that the water is safe. How can EPA scientists protect my family and others if they can't use the best available science?

I urge you to withdraw this proposal and instead focus on EPA's mission of ensuring safe water, air and land for people across the country. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. FLAHERTY: Good afternoon and thank you for the opportunity to speak today. My name is Maggie Flaherty, F-L-A-H-E-R-T-Y, and I would like to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule. I would first like to emphasize that this rule proposed during Scott Pruitt's time as administrator of the EPA is a purely political decision. It is modeled after past efforts from the tobacco and fossil fuel industries for similar policies that prevent the use of science that reveals the harmful human health impacts of such industries. This proposed rule is not about

legitimate transparency; it is about making it harder for the EPA to make decisions based on the best available science. Under this rule studies that rely on personal health data, confidential business information, intellectual property, or studies whose data is no longer available would be excluded from the EPA's consideration when making decisions regarding regulations. When it comes to regulating things such as air pollution, water pollution and toxic substances, some of the most vital scientific information comes from studies of respiratory illnesses, cardiovascular diseases, and premature deaths, all of which rely on personal health data. If such vital studies are excluded because of this arbitrary rule, the EPA would be lacking critical public health information when making decisions that directly impact our health and environment.

If EPA is truly worried about transparency in science they would listen to the voices of the numerous scientists who have come out in opposition to this proposed rule and who have,

additionally, suggested other ways of introducing transparency. Instead of focusing on disclosure of data that can contain confidential and private information, a rule that truly increased transparency in science would focus on funding disclosure. Despite how strict the peer review process is, people should be able to know who is funding a study. This rule proposed by the EPA does not address the issue of funding transparency at all. According to an article in the Journal of the American Medical Association if all of the EPA's proposed changes to environmental policies since the election of President Trump go into effect, the result would be at least 80,000 unnecessary deaths per decade. This assessment is based on numerous scientific studies that would most likely be excluded by this rule. The EPA should not exclude studies that demonstrate the true health costs of their actions and remember their true mission of protecting our public health and the environment. I therefore urge the EPA to withdraw this proposed rule. Thank you.

MS. RADZIKOWSKI: Thank you.
MS. STOBERT: If Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, will come to the speakers' table. Speaker 15, David Coursen, and Speaker 16, Abigail Omojola would come to the on-deck seating.
MR. FINKEL: Thank you. I appreciate the opportunity to comment as a former chief regulatory official at OSHA and a former member of the EPA Science Advisory Board and Board of Scientific Counselors. I support a wide spectrum of efforts to improve the transparency of the inputs to and the outputs of risk assessment and cost-benefit analysis, especially if they involve a more honest disclosure of uncertainty and variability. I will submit a recent paper I wrote with George Gray in this regard. But this proposal decreases transparency and reliability in three ways: It fails to identify a legitimate problem; it ignores closely related and glaring actual problems with regulatory analysis; and it promotes remedies that add noise while decreasing

signal.

First, the central dogma of regulatory policy since 1993, and most enthusiastically touted by this administration, holds that no regulation can be proposed absent a real problem to be solved, like market failure. Here, there is no failure of the scientific market and hence no need for a disruptive set of hurdles. By its own policies it developed to constrain its own regulatory excess, EPA should demonstrate, and not just with an anecdote or two, the crisis justifying the need for this proposal, or else should scrap it. I note that of the five URLs the EPA provides in Footnote 12 to document its claim that there is a "replication crisis," two of the links are broken and the other three discuss psychology and clinical trials. The end points in epidemiology, toxicology and exposure studies are simply not as subjective as psychology experiments are. There have been some problems found with clinical trials but the unmeasured variability is likely much more important with respect to whether a drug will cure

and weather a pollutant will harm. Most importantly, the EPA has cited no studies giving even guesstimate of what percentage of environmental science studies might be in need of replication or reanalysis and, of course, some of the shrill prior claims of error others have noted in the Six Cities Study have turned out to be fallacious. Surely EPA does not intend that most epi studies or bio-assays need to actually be replicated. Some epi studies can be redone but surely not natural experiments we never want to repeat such as the atomic bomb survivors study or the changes in air pollution during groundings right after 911. Lifetime animal bio-assays already use multiple doses, species and sexes and they are expensive and take years to complete. Why would we waste time and money duplicating them? And so, what if someone did try another species and got a lower potency estimate or didn't get positive results? Would we allow a rat or mouse carcinogen in unlimited quantities because it might not also be an aardvark carcinogen? I

don't think so. So, EPA probably means reanalyze, not replicate, and it should say so. But then EPA presents no evidence that anyone is hindering anyone else from reanalyzing anything. Any bio-acid that the EPA would use would already have individual tumor data and exposures and could be reanalyzed with any model that anyone wanted. Ditto for epi studies. But what would a reanalysis program actually do other than be costly and invite delay? What if someone reanalyzed a health study and got a different answer? One that suggests the first study had exaggerated the harm. In such a case the second study would be right and the first wrong only if both of these conditions were true. First, the difference in the results was not already acknowledged or contained within the uncertainties in each answer. If somebody claimed that banning a chemical would save between 500 and 1000 lives across the country, EPA chose to estimate it at an expected value of 750; another study that said 550 would not be different from the first study at

all. And secondly, the first study would have to be not just different, but wrong. Anybody can take the same data and botch the risk analysis of it making seem like they have a better answer. Just like there are potential problems with an analysis that doesn't control for some variable, it can be a mistake to control for a variable that shouldn't be included.

In short, EPA should never refuse to look at a study just because someone could reanalyze it but hasn't, has done so and gotten a different but not a better answer, or has done so, didn't like what it saw, and suppressed the results while claiming the original study still needs to be reanalyzed. Secondly, there is a crisis in regulatory analysis and EPA is completely ignoring it for reasons that are obvious to me. It's the economists' analysis of the costs of regulation and the values of benefits that are flawed, opaque and in need of reanalysis. Every criticism leveled at this proposal ought to first be applied to regulatory economics. They are obviously as pivotal as

estimates of risk. Regulatory cost estimates are notoriously biased high and they are surrounded by more uncertainty than surrounding risk estimates, but unlike risk estimates, cost estimates are rarely, if ever, presented with uncertainties and are sometimes even of the wrong side. In my written comments I'll give two examples. I have a paper newly published with Brandon Johnson. We looked at more than 1000 estimates, the value of a statistical life, certainly the most pivotal quantity in all of risk regulation derived from hundreds of studies. Only 40% of those studies gave any information about the ranges or standard deviations of the individual VSL values. So, no one can reanalyze that work to see what higher or lower values of the VSL are also compatible with the data. And perhaps the most well-known so-called study of the costs of regulation is the series of reports from Mark and Nichole Crane suggesting that regulations "cost the U.S. nearly two trillion dollars a year."

MS. RADZIKOWSKI: Excuse me, sir, we are out of

time.

MR. FINKEL: I'm sorry?

MS. FLOWERS: We are out of time, in fairness to others.

MR. FINKEL: I'm sorry, I didn't realize. The third one is about defaults and I will submit those, but EPA is a protection Agency, not a prediction Agency. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WILSON: Good afternoon, my name is Augusta Wilson, and I am here representing the Climate Science Legal Defense Fund. The first name is spelled A-U-G-U-S-T-A. I appreciate the opportunity to speak to you today and the Climate Science Legal Defense Fund will file more detailed written comments in the online docket for this proposed rulemaking. CSLDF is a nonprofit organization whose mission is to protect the scientific endeavor. In this capacity, we work closely with scientists at government agencies and at research institutions, so we have particular insight into how attempts to silence science

negatively impact both researchers on an individual level and the conduct of scientific research as a whole. There are numerous reasons why EPA should not proceed with this rule. In the time I have today I will focus on a few of the most important from the perspective of protecting the integrity of the scientific endeavor. First, studies that involve human subjects, particularly those investigating the human health impacts of exposure to environmental pollutants, are among the most relevant to EPA's core mission. In order to conduct such studies, scientists need participants willing to allow researchers access to their confidential health information. If enacted as currently proposed, this rule would make it much more difficult for scientists to credibly promise study subjects that their patient information will remain confidential. This could have deeply concerning, chilling effects on the conduct of important human health studies. Privacy concerns could influence what science gets done and what science does not get done. Lines of

scientific inquiry that would have been pursued may not be. The quality of data may be poorer than it otherwise would have been. Furthermore, the justification for this rule to the extent it exists seems to be based on the false premise that scientific studies cannot be adequately evaluated or reproduced unless all of their underlying data are made public. This is simply not the case. On the contrary, the reviewers can evaluate the merits of studies even when they rely on data that cannot be made publically available. This is because part of a scientist's core, fundamental training is the ability to assess research based on the strength of the experimental design and the precision with which experimental methods and analyses are described. In addition, when necessary and appropriate, reviewers, as well as other researchers seeking to reproduce or extend scientific analysis, can have confidential access to key data in conformity with privacy requirements.

That said, the scientific community has certainly

recognized that recent technological developments allow for significant improvements in data sharing and reproducibility and that such improvements can benefit science. There are numerous scientific societies, journals, and other organizations, as well as individual researchers, who are actively engaged in a dialogue about how to improve transparency while protecting scientists and taking into account issues like patient confidentiality and proprietary business information. If EPA is genuinely concerned about these issues, it should engage deeply in this discussion and with the scientists who are having it and should move forward only in concert with them. As written, this rule which EPA professes is intended to strengthen science will ultimately do significant damage to it and to the United States' ability to lead the world in research. EPA should not promulgate such a rule. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 15, David Coursen, and Speaker 16, Abigail Omojola, would come to the

speakers' table. Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford, if you would come to the on-deck seating.

MR. COURSEN: Good afternoon. My name is David Coursen, C-O-U-R-S-E-N, and I'm here on behalf of the Environmental Protection Network, a nonprofit organization of EPA alums working to protect the Agency's progress toward clean air, water, land and climate protection. There are so many things wrong with this proposal that it's easy to downplay the most important one: The harm it will do to peoples' health and the environment. The proposal hides this in a fog of ambiguous language, meaningless generalities and vague platitudes about the value of transparency. It requires EPA to wear a blindfold when it is developing major rules by ignoring what relevant and reliable science tells us about health risks any time the raw supporting data is not publically available. Transparency is important, but it is not part of the Environmental Protection Agency's mission and certainly cannot be the basis for a

one-size-fits-all litmus test for when the Agency must ignore what science tells us about the risks of pollution.

The laws governing EPA programs require it to consider all of the available scientific information in deciding how to protect peoples' health and the environment. Ignoring such information would be both arbitrary and unlawful. EPA rulemaking has always relied on the best available science, a principal the proposal gives lip service even as it outlines a scheme to prevent the EPA from using even the best available science if it is not "transparent." The proposal would put even the most persuasive and useful science off limits subject only to a vague and standardless exemption process. The proposal does not show that the EPA's existing practices have produced bad environmental outcomes or that increasing so-called transparency will lead to better outcomes. Those are not things the proposal seems to care about. There is no legal or environmental basis for the proposed

restriction and, not surprisingly, the proposal fails to mention that EPA's statutes do not allow the Agency to ignore available information about the risks of pollution. Inevitably, restricting the science EPA considers in rulemaking will produce less informed and less protective decisions. In effect, the proposal sacrifices relevant and reliable scientific information, a cornerstone of effective environmental protection on the altar of so-called transparency. A proposal to ignore science when all of the supporting data is not public would preclude using even recent studies that are subject to confidentiality agreements or legal restrictions on disclosure. It also will certainly and deliberately exclude older studies where the data is no longer available, even if their findings are widely accepted as authoritative and form the basis for EPA regulations that have proven effective in protecting peoples' health for many years.

The proposal is evasive about its targets using

footnote language only a lawyer could understand to identify two seminal air pollution studies that it excludes and says nothing at all about what other important studies it would ban. Written comments via the Environmental Protection network will spell out the policies that proposes many legal and policy defects in detail. The proposal is brief and cursory and provides far too little information to meet the legal requirement to alert the public to its substance and basis. It would prohibit EPA from considering important science in rulemaking even though the laws governing EPA's use of science require it casting a wide net. It sheds little light on how the proposal would work and no light at all on its environmental consequences. Instead of explaining how EPA will implement and interpret the rule, it largely throws these questions to the public. It doesn't show a need for any rule much less an absolute rule that sweeps across eight statutes. It claims its approach is consistent with a host of policies and studies but what Environmental Protection

Agency looked at them it found almost no support for the proposal and in some cases the authors have objected to the use of their studies and it posed the proposal. In sum, there is neither a legal basis nor a need for this rule. It would require the EPA violate explicit statutory provisions and unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of reliability and environmental protection to so-called transparency, a term not found in the relevant EPA statutory provisions. It is too full of undefined or ambiguous terms to create a workable legal frame work. In other words, the proposal is unintelligible, unlawful and unworkable. EPA, I respectfully request that EPA withdraw it.

MS. RADZIKOWSKI: Thank you.

MS. OMOJOLA: Good afternoon, my name is Abigail Omojola, O-M-O-J-O-L-A, and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would not serve to provide the public with greater "confidence in and understanding of" EPA's regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard not to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of

breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule's requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would

provide.
An example of the kind of study this proposed rule could eliminate from the EPA's regulatory process is the National Institute of Environmental Health Sciences' Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.
This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publically available. This is particularly true

for vulnerable marginalized communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research already. There is the competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to prevent this devastating disease. This proposal takes a hard step away from that goal.
Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.
MS. RADZIKOWSKI: Thank you.
MS. STOBERT: If Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford will take seats at the speaking table. If Number 19, Paul Allwood, and Speaker 20, John Stine, would take seats at the on-deck seating.
Mr. LOCKWOOD: Good afternoon, my name is Alan Lockwood, A-L-A-N, L-O-C-K-W-O-O-D. Thank you for this opportunity to speak on behalf of Physicians for Social Responsibility. I am a board-certified neurologist and an elected fellow of the American Neurological Association and the American Academy of Neurology, and Professor Emeritus of Neurology

at the University at Buffalo. PSR is a 501(c)(3) scientific and educational organization headquartered in Washington DC with over 30,000 physicians, medical students, and others across the country. Our mission is to protect human life from the gravest threats to health and survival. We submit this testimony in strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposed rule would change the standards for the inclusion of studies used by the Agency and lead to the abolition or weakening of virtually all protections under the purview of the Agency. Under the misleading veil of "transparency," the proposed rule could force investigators to invade the confidentiality of research participants and make confidential and private data open to all. A similar concern was voiced by the current Scientific Advisory Board, writing, "there are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests ..." The rule could replace evidence-

based decision-making with arbitrary determinations based on political considerations. Peer-reviewed research has led to important gains in health. The Clean Air Act protects us from air pollution and is arguably the most health-protective law in effect. I have written extensively about this in The Silent Epidemic. Peer-reviewed studies link air pollutants with leading causes of death in the United States including heart disease, stroke, and respiratory diseases. Additional studies link particulates to Alzheimer's disease and Type II Diabetes. Seminal studies include the Harvard Six Cities Study that involved 8,111 adults followed for between 14 and 16 years showing a clear link between pollution and mortality. The Women's Health Initiative study involving 65,893 post-menopausal women that demonstrated a link between particulates, and cardiovascular disease and stroke mortality. I attended closely to the study of 1,705 neurologist-confirmed strokes showing that a transient increase in small particles was

associated with a statistically significant increase in strokes even though levels were within limits "generally considered safe" by the EPA. A congressionally mandated report prepared by the EPA projected that by 2020 Clean Air Act provisions would save two trillion dollars per year in adverse health impacts. Many savings will positively impact the budgets of state and federal agencies at a time of ballooning deficits.

EPA rules provide significant protection for the developing brains of children by establishing limits on lead. Lead impairs brain development and has adverse effects on behavior and cognition. Other data link arsenic levels in drinking water to Type II diabetes and cancer.

Natural gas production, particularly "fracking" harms health due to human proximity to wells, pumping stations, and contamination of water supplies and contributes to climate change.

Protecting the privacy of research participants is a keystone of biomedical research and one with which I have had years of personal experience as a

member then chairman of the Buffalo VA Institutional Review Board. Peer-reviewed journals require authors to affirm their adherence to federal privacy protections as a pre-condition for publication. This standard should not be abolished. PSR's mission is to "to protect human life from the gravest threats to health and survival." To protect the scientific integrity of the EPA and protect health, we oppose the deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WOOLFORD: My name is Elizabeth Woolford and I am an undergraduate student at Wesley University and an intern with the National Parks Conservation Association. My comments are my own. Today, I would like to express my strong opposition for the proposed rule titled, “Strengthening Transparency in Regulatory Science.” This rule would have sweeping impacts on the ability for the EPA to consult public health studies, as almost all utilized data from medical records that are

protected from public scrutiny. Their proposal would force the Agency to disregard such studies unless scientists reveal their participants' private medical information. Scientists conducting public health research would then be left with two unacceptable options: To break confidentiality agreements in order to disclose the personal health records of their subjects; or not to have their studies consulted by policy makers at all. As a result, some of the most significant research from the past decade, for example studies linking air pollution to premature deaths and measuring human exposure to pesticides would be left completely unavailable to the Agency. I would like to emphasize that data of a sensitive nature does not imply inherent unreliability, rather this kind of information is essential to achieve an accurate understanding about how human health is impacted by chemicals, chemical compounds and other substances. Such an understanding is necessary for the EPA to fulfill its mission to protect public health and protect

the environment with the creation of effective regulations under the Clean Air Act, Clean Water Act, CERCLA, and other cornerstone environmental laws.

This proposal is based on a false premise about data quality and acceptability. There is no reason why one cannot protect the confidentiality of subjects and at the same time use information about them. This rule questions the integrity of the scientists and doctors conducting public health studies by implying that these professionals may have biased their subjects to achieve a particular outcome. However, it is evident that peer review already protects against for such bias.

For these reasons, one must consider how this proposal fails to achieve the requirements of OMB's Information Quality Act. It is clear that this proposal is overkill and would unnecessarily exclude scientific studies simply because they do not meet an unrealistic transparency standard. This would all be to the detriment of public and

environmental health.
In addition, this rule would create a blatantly political and dangerous double standard by eliminating the use of studies that follow confidential health guidelines while allowing polluting industries to keep their data under wraps. That alarming imbalance would skew regulation inherently favoring polluters over those impacted by their pollution.
Furthermore, this proposed rule would cross Agency lines and interfering with informed policy making and undermining the safeguards that protect millions of people, our public lands, and the space and places we call home. EPA's scientific research and related policies influences the decisions of other agencies charged with protecting our health and environment. For example, the National Parks Service needs access to the best available science to inform decisions that protect parks' air, land, water, wildlife and people. If EPA goes forward in placing unreasonable limits on the scientific record, the

National Parks Service and similar agencies will be unable to protect public health and the environment to the extent they otherwise could. As a young person, this proposal leaves me frightened. Within a decade I will be part of the generation that inherits the responsibility for this nation. If adopted, the negative implications of this rule will not be short-lived and could forever change the safeguards that EPA is supposed to develop to protect public health and our environment. In the many more decades of life I have in front of me, I intend to finish my education in this country, I intend to raise a family in this country, I intend to enjoy public lands and outdoor spaces in this country, and I intend to breathe this country's air and drink this country's water and eat this country's food. I hope to do so knowing that the regulatory body charged with keeping my body and environment safe has made decisions based on nothing less than the best scientific information there is. For these reasons, I urge the EPA to abandon this dangerous

and misguided proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Numbers 19 and 20, Paul Allwood and John Stine, if you would take seats up here. And Speaker Number 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would take seats the on-deck seating.

MR. ALLWOOD: Good afternoon, my name is Paul Allwood. I am Assistant Commissioner of Health Protection at the Minnesota Department of Public Health. Commissioner Stine is with me and we're going to do this joint testimony. Commissioner Stine will go first.

MR. STINE: Thank you. As Commissioner of the Minnesota Department of Health, Mr. Allwood is the Assistant Commissioner there, and as Commissioner of the Minnesota Pollution Control Agency, my name is John Link Stine, S-T-I-N-E. We are appointees of Minnesota's Governor, Mark Dayton. We are deeply disappointed in and troubled by this proposed rule, "Strengthening Transparency in Regulatory Science." We have traveled 1100 miles

from our home in Minnesota to be here today to speak against this rule. On May 15, 2018, our two state agencies commented against this rule in a letter from Commissioner Malcolm of the Health Department and myself. Our testimony today expands upon those comments and provides specific examples from Minnesota that show why this arbitrary and non-ethical rule must not be adopted.

MR. ALLWOOD: The first example is that the State of Minnesota is dealing with a massive area of contamination with PFAS chemicals, otherwise known as PFCs. The contamination came from 3M Manufacturing and disposal sites that contaminated groundwater on a very massive scale impacting over 150,000 residents. Minnesota's Department of Health conducted bio-monitoring studies of over 200 people living in those impacted communities to be able to understand their exposure and their potential health implications. Those studies help Minnesota derive health protected values under state law and furthermore also help the state of

Minnesota reach a settlement with 3M Company of over 890 million dollars. Now, without these studies and without these data we would not have been able to be successful in our litigation with 3M Company and residents of the communities that were impacted by this pollution would have had to foot this bill.

Now, these studies are only possible because we provided absolute guarantees to the participants that their data would be protected and that we would assure its confidentiality. The proposed rule will make it unlikely that public health data such as this -- and you heard it from other testifiers -- would be available for states to use, but even more so for the EPA to use in its decision-making. This is to be avoided.

MR. STINE: Our second example is the 2015 study and report that our agencies jointly released "Life and Breath". We released that report regarding the health impacts of air pollution in the Twin Cities Metropolitan Area of Minneapolis and St. Paul. The study used public health data

and mathematical modeling software developed by the U.S. EPA. EPA's modeling software is based on published, peer-reviewed scientific studies of the relationship between human health and air pollution. The study confirmed air pollution leads to increased disease and death in our population. Every year about 2000 premature deaths, 400 hospitalizations and 600 emergency room visits occur in the Twin Cities Metropolitan Area that are caused by fine particle or ground-level ozone exposure. In fact, the study found that fine particle air pollution and ground-level ozone was a causal factor for some deaths and hospital visits for lung and heart conditions. The implications of the proposed rule are that under this rule's requirement for the use of public data, future public health data on which studies like our "Life and Breath" were based would not be available. Public health data and research relies on citizen confidence in confidentiality of their personal information. We believe the rule would lead to an over-reliance

on animal studies and toxicological data which cannot estimate disease burden as well as population health data and studies. The proposed rule would lead to weaker environmental regulations, more air pollution, greater levels of heart and lung disease and death. As a result, health care costs will increase. Asthma already costs the United States 56 billion dollars annually and the incidence of asthma is increasing. The rule language under Part 30.8 requires that EPA implement the rule in a manner that minimizes cost. Ironically, the rule will lower the cost to EPA and environmental polluters. A fundamental principal of our environmental protection law is that polluters pay. The plain truth is that your rule does not address the increased costs that come with relaxed regulations. In fact, the polluters will pay less and costs will shift onto the public in health insurance. With that I'll kick it to Mr. Allwood.

MR. ALLWOOD: So, to conclude, to say that state as public officials we are responsible for

protecting the health of our state population, it's really important for us to be assured that EPA is going to use the best science in its regulatory decision-making. This rule severely brings that into question and we would like you to know that we are looking at this as an urgent matter that requires the EPA's attention and would urge that time be taken to suspend and slow the process of adopting this rule so that a full and complete review can be done. Thank you.

MR. STINE: Thank you.

MS. RADZIKOWSKI: Thank you both.

MS. STOBERT: Speaker 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would come to the speakers' table. Speaker 23, Steve Milloy, and Speaker 24, Steve Milloy for John Dunn, if you would have seats at the on-deck seating?

MS. RUIZ: Good afternoon, my name is Virginia Ruiz. I am the Director of Occupational and Environmental Health at Farmworker Justice, an organization devoted to working with migrant and seasonal farmworkers to improve their living and

working conditions. On behalf of my colleagues at Farmworker Justice and the farmworkers that we represent, I strongly urge the U.S. EPA to withdraw its proposed rule, "Strengthening Transparency in Regulatory Science." If finalized, this rule would endanger farmworkers and other vulnerable people across the country. We oppose EPA's proposed rule for three reasons: First the rule would prohibit EPA from considering credible scientific evidence about the dangers farmworkers face including exposure to pesticides and other chemicals. Second, the rule would deter farmworkers themselves from participating in future scientific studies. Third, the rule would make it more difficult for Farmworker Justice to obtain the research we need to advance our mission. With respect to the first point, the proposed rule would prohibit EPA from considering credible scientific evidence about the dangers that farmworkers face. As EPA's own Science Advisory Board acknowledged, there are many reasons why researchers and study participants

might choose to keep data confidential, and many of these reasons have no bearing on the credibility of a scientific study. For instance, because farmworkers are often migratory, moving for work across domestic and international borders, researchers may be unable to locate farmworkers they last encountered as study participants years ago, and thus unable to renegotiate privacy agreements struck at the time the research was conducted. Farmworkers themselves may also have legitimate reasons for wanting to preserve their privacy. For example, some research shows that farmworkers face an increased risk of exposure to chemicals that impair fetal development resulting in lower IQ scores, an outcome associated with significant social stigma. We already suffer from the dearth of scientific evidence and information about occupational and environmental health risks that farmworkers face. EPA should base its regulatory decisions on the credibility of scientific evidence and not on arbitrary factors like the

public availability of research data. With respect to the second point, the proposed rule would deter farmworkers from participating in future scientific studies. Farmworkers are extremely vulnerable members of our society and it's unlikely they would agree to participate in scientific research without an iron clad guarantee that their identities would be kept confidential. Farmworkers value their privacy for a number of reasons including an undocumented or other tenuous immigration status and insecure employment. Farmworkers whose identities are exposed would risk retaliation from their employers ranging from termination to deportation. As a result the proposed rule would present farmworkers with a false dilemma. They could choose to participate in research studies that might eventually yield better regulatory protections at great personal risk, or they could choose to protect their privacy by refusing to participate in research studies, thus forgoing badly needed protections, also at great personal cost. EPA should not

present farmworkers with such a choice. Finally, the rule would frustrate Farmworker Justice's ability to achieve our mission. We rely on credible scientific evidence to educate farmworkers, policy makers and the public at large about the risks farmworkers face. Much of this evidence comes in the form of epidemiological studies that the proposed rule would categorically exclude from consideration unless the underlying data were made publically available. If EPA's proposed rule were to result in fewer scientific studies focusing on farmworkers, as seems inevitable, we would lack information we need to carry out this important aspect of our mission. It would severely undercut our ability to effectively advocate for farmworker health and safety.

Accordingly, we urge EPA to protect farmworkers and other vulnerable communities by withdrawing the proposed rule without delay.

MS. RADZIKOWSKI: Thank you.

MS. MONGOVEN: Good afternoon, I'm Karen Mongoven;

K-A-R-E-N, M-O-N-G-O-V-E-N, Senior Staff Assistant at NACAA, National Association of Clean Air Agencies, and I appreciate the opportunity to testify today on behalf of NACAA. NACAA recommends that EPA withdraw this proposed rule. In our view the proposal would likely undermine the very objectives that it's supposed to promote. In particular, we believe it would hinder EPA's use of best available science and environmental regulations and it would likely diminish, rather than improve, public confidence in the integrity of EPA's scientific decision-making. Reliance on best available science is a fundamental requirement of the Clean Air Act and other environmental statutes the EPA administers. Indeed, science-based decision-making is at the very core of our shared mission as air regulators to protect public health and the environment from the harmful effects of air pollution. There is a long-term trend toward increased transparency in science including toward providing greater public access to underlying data and

analytical techniques after scientific studies are published. We think this trend is a laudable one, but complete public access to underlying data is not always possible, especially in the case of the epidemiological studies based on private health data that must remain confidential. Transparency concerns must not override EPA's obligation to consider the full range of peer-reviewed, sound, scientific research that is available and relevant to its regulatory decisions.

Full public access to underlying data and models is not necessary to assure the validity of scientific studies. Rather, the most effective assurance is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all of these components to establish validity. The process of peer review

has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it should explain exactly why it believes the process is inadequate and how this proposal specifically addresses those inadequacies. If adopted, the proposed rule could serve to bar EPA's consideration of relevant scientific literature and the establishment of air regulations to protect public health and the environment resulting in serious adverse effects on the nation's air program.

In a footnote in the proposal, EPA cites two D.C. Circuit cases that upheld the Agency's reliance on confidential data in setting health-based air quality standards for lead and fine particulate matter. In that footnote, EPA states that it is "proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions." The clear implication is that EPA will discard rigorously vetted scientific literature in the service of greater transparency. This would be an

abdication of EPA's legal obligations and stated intention to rely on the best available science. NACAA is also concerned with a provision that would require EPA to conduct its own "independent peer review of scientific studies underlying significant regulatory decisions." The EPA included no details about how this provision would be implemented and moreover the proposal failed to acknowledge the EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts including a Science Advisory Board and its Clean Air Scientific Advisory Committee. EPA does not explain why scientific literature that has already undergone peer review and been vetted by EPA's science advisory panel should be subjected to an additional layer of peer review. We do recognize that the proposal would allow the EPA administrator to grant exemptions to the rule's requirements on a case by case basis if he or she determines that "it is not feasible to make underlying data publically available or to conduct

an independent peer review of scientific studies." However, the rule does not include any criteria for how the administrator would make such a determination. We believe this provision would have the effect of interjecting the appearance of politics into what should be a fair and unbiased assessment. It's an opportunity for arbitrary decision-making and it is insufficient to protect against the exclusion of relevant valid scientific studies.

EPA requested comments on whether the proposal should be applied retroactively or retrospectively should they decide to adopt it. We believe the rule should not be applied retrospectively. To do otherwise would create significant regulatory uncertainty by calling into question existing standards as well as prevent state implementation plans and other decisions that are based on those standards.

In conclusion, NACAA respectfully requests that EPA withdraw the proposed rule. If the Agency does intend to update its approach to transparency

and reproducibility it should do so in consultation with the National Academy of Sciences and in the spirit of cooperative federalism EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation's environmental laws. NACAA appreciates the opportunity to provide the testimony I offered today and we also intent to submit written comments to further elaborate on the concerns I discussed here. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Steve Malloy, Speakers 23 and 24 would come to the speaker's table. Speaker 25, Meredith McCormick, and Speaker 26, Olivia Bartlett if you would go to the on-deck seating.

MR. MILLOY: Good afternoon, my name is Steve Milloy. I publish JunkScience.com.. I am making my comments here on behalf of myself and also Dr. John Dale Dunn, who is an emergency room physician in Texas. We are here to support the proposed transparency initiative. Science transparency in EPA is long past overdue. When I first started

working on EPA issues in 1990, the main controversy with EPA science was the use of science policy and default assumptions, like linear no-threshold model of carcinogenesis. The problem wasn't necessarily the use of science policy default assumptions, the problem was, rather, the EPA's failure to disclose the nature of those default assumptions in regulatory actions. In other words, what part of the regulatory actions was science, what part was guesswork and what was politics? When I first reported on this problem from the Department of Energy in 1994, the Clinton administration tried to censor my report but they failed. But I didn't and many others didn't. So here we are, many years later, making progress on this important issue.

More recently, the major problem with EPA science has been what has become known as secret science. Since the 1990's EPA grantees like Harvard's Doug Dockery and Brigham Young University's Arden Pope, have refused to make available to the public the

raw data used in their epidemiologic studies, and this is true despite the fact that these studies were cited by EPA as the principle scientific basis for major air quality rules like those that constituted the Obama administration's war on coal.

Worse, prior EPA administrations actually aided and abetted Dockery and Pope hiding their data from public review. In 1996 and 1997 the Clinton administration refused a request of Congress. In the 2000's things got so bad Congress actually had to subpoena the Obama EPA for the data and they refused to provide it.

I can only conclude that this is because independent review of the Harvard Six Cities and the American Cancer Society line of studies would prove them to be highly problematic, embarrassing and even fraudulent. Desperate to defend the indefensible, supporters of Dockery and Pope have wrongly maintained that making the data in question public would violate medical and personal privacy rights. Nothing could be further from the

truth. For the most part, data is electronic. Scrubbed files with key data needed for independent review can easily be made available. No one -- no one -- is interested in any personal or medical data. It has no value to anyone. The State of California has made such data files available for use for many years. I know. I have obtained this data -- over 2 million death certificates to be precise -- and with it enabled research to be published that completely debunks the secret science of Dockery and Pope. Fear of exposure of their research as faulty, if not fake, is why Dockery and Pope are so scared of producing their data for independent review. To make these comments current, up to date, efforts have been made this month to obtain the Dockery and Pope data but they continue to keep their data secret. Given that the Dockery and Pope research and related PM2.5 research has been funded by taxpayers to the tune of more than 600 million dollars and then this research is used to regulate the public costing untold billions more dollars

without providing any public health or environmental benefits, the conspiratorial hiding of this secret data is more akin to crime than science.

If EPA wants to regulate, that is fine, but the basis of the regulations and the reason for the regulations must be clearly laid out so there could be full and fair debate. Harvard's Doug Dockery and Brigham Young's Arden Pope don't want independent scientists to check their work for some reason. Dockery and Pope supporters may offer whatever excuses they like but we all know what the reality is: Fear of exposure. Thanks to the Trump administration the days of secret science are coming to an end. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 25 and Speaker 26, Meredith McCormack and Olivia Bartlett are now onstage. If Speaker 27, Dan Byers, and Speaker 28, Antonia Herzog, would come to the on-deck seating.

MS. McCORMACK: Meredith McCormack, M-E-R-E-D-I-T-H, M-c-C-O-R-M-A-C-K. My name is Meredith

McCormack and I'm a pulmonary critical care physician at Johns Hopkins University where I care for patients and I also investigate the effects of air pollution on lung health in cohort studies of children and adults. I serve on the American Thoracic Society Environmental Health Policy Committee and I'm speaking today on behalf of the ATS, the American Thoracic Society.

The ATS is extremely concerned about the proposed EPA policy. In short, we believe this policy is not in the best interests of our profession, the patients that we serve, or the public health. The focus on transparency is highly reminiscent of the rhetoric used by tobacco lawyers decades ago. As revealed in tobacco industry documents, in 1996 a tobacco industry lawyer drafted a plan for tobacco giant, R.J. Reynolds, to combat research that documented the health effects of second-hand smoke. A tobacco industry lawyer described a plan to construct explicit procedural hurdles the Agency must follow. The memo used the same terms of transparency, sound science and calls for

reproducible science, the language that the EPA is now using in its proposed policy. While the guidance provided in that memo was intended to undermine research studies that documented the adverse effects of second-hand smoke, the recommendations provide a road map for any industry seeking to undermine science that could lead to greater regulation. While concerning, it is no accident that EPA is proposing policy once touted by tobacco industry lawyers. By proposing this policy, EPA is literally taking a page out of tobacco industry's playbook to undermine the legitimate role that science plays in public policy formation.

The ATS supports transparency in upholding scientific rigor but the approach proposed in this rule is flawed. The proposed policy would require all science and biomedical research used by the Agency in major regulatory actions to have its raw data and health records made publically available under the guise of allowing third party analysis to confirm the results of the research. This

artificial standard cannot be met without forcing the release of confidential patient information and is in direct conflict with the mandates of our institutional review boards and updated privacy laws.

As a physician, no doctor or medical society would advocate ignoring large portions of the medical literature because the underlying data were not in the public domain. Medical guidelines are based on the best available evidence: Evidence that emerges from multiple peer reviewed publications, not a single study. The medical field is rapidly moving towards increasing transparency but this cannot be applied retroactively. Is the best available science only the subset of studies whose data are available for analysis by the public? That is not the case for medical research studies and is certainly not the case for studies of environmental health effects.

EPA's new transparency standard introduces a more severe standard than the FDA uses to make decisions about the approval of drugs or that

Medicare uses to decide which treatments to cover. As a doctor I would do my patients a disservice if I ignore the best available evidence to guide my clinical decision-making. The proposed rule will allow the EPA to ignore the best scientific evidence in future decision-making about health effects of the air that we breathe and the water that we drink. The Transparency Rule fails to recognize the power of replication, a key criteria for defining the strength of scientific evidence. Replication refers to the fact that consistent findings from studies in different populations in different places strengthens the likelihood of an effect. The proposed rule would create a context for the EPA administrator to have the discretion to disregard studies that have provided the strongest scientific evidence underlying the dramatic health effects and dramatic improvements in air quality in the U.S. -- improvements that have led to measurable health benefits to our children, our patients and the general public. For the EPA to use these studies will patients

forego their confidential information? Or will the EPA now ignore the evidence from dozens of studies that have replicated findings that pollution is associated with increased risks of premature death. The Transparency Rule is unnecessary as there are processes in place to rigorously review the scientific integrity of the studies that are used in regulatory science.

In short, we fully concur with the statement from the editors of several leading scientific journals that the merits of studies relying on data that cannot be made publically available can still be judged. It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them.

In summary, this policy is issued in bad faith, is bad for science and bad for patients and bad for public health. The ATS strongly urges the Agency to withdraw this ill-conceived policy proposal.

Thank you.

MS. RADZIKOWSKI:

MS. BARTLETT: I'm Olivia Bartlett. B-A-R-T-L-E-

T-T. I'm from Bethesda, Maryland and I represent the 1200 members of Do the Most Good, Montgomery County. I am a retired PhD health scientist. For 15 years I conducted research involving human subjects and also served as a peer reviewer for both grant applications and research papers submitted for publication. For the next 30 years I oversaw the scientific peer review of thousands of applications for funding of a wide variety of health science studies including the women's health study that was mentioned by a previous speaker, so I'm very familiar with the scientific research and publication process and the rules regarding protection of human subjects. I also have asthma, as do my son and my grandson, so I am also very familiar with the impact of soot and smog in the air on the ability to breathe. EPA's mission is to protect health and the environment. I strongly oppose EPA's so-called Transparency Rule since it will restrict the scientific studies that EPA can use to carry out that mission and to set safety standards for toxic

chemicals and pollutants in the air we all breathe and the water we all drink. The proposed rule was given an appealing title but it's just a politically motivated attempt to undermine decades of progress in protecting human health from hazards, particularly small particulate pollutants in the environment, while allowing soot-producing industries off the hook. The proposed rule is seriously flawed in several important ways. First, it reflects former EPA Administrator Pruitt's woefully inadequate understanding of scientific research methods, the nature of the long-term large-scale epidemiologic studies necessary to gather the kinds of data needed to determine toxicity of a pollutant and the rigor of peer review of both research grant applications and publications. Peer reviewers carefully scrutinize the methods that will be used to collect and analyze the data before a research study is ever funded. Additional peer reviewers and different ones scrutinize the data collection and analysis methods and whether the data supports

the conclusions, again prior to publication. Studies with flaws in design, data collection or data analysis don't make it into reputable journals. The proposed rule also seriously underestimates the burden and the consequences of making all raw data publically available. Most research funding agencies and journals now have policies that require researchers to make their data available to other scientists for reanalysis, validation and meta-analyses after publication and this has already been mentioned by previous speakers. However, many studies involve sensitive and personal data that could identify individual subjects even if the subject's name and address are redacted, so releasing these data sets to the public would violate patient confidentiality rules. The proposed rule may also violate the requirements of the Clean Air Act and Clean Water Act and other standard acts already mentioned to use criteria that accurately reflect the latest scientific knowledge, the best available science and inclusive analysis of all

available studies in assessing potential effects on public health. Furthermore, the proposed rule would create an unacceptable double standard for industry-sponsored and academic research by allowing companies to shield their confidential business data, thus corporate secret science would be okay but data sets that expose individual subjects' identities would have to be made public or would be excluded from consideration in rulemaking. This ill-conceived proposed rule has been condemned by hundreds of scientists, all but one of the previous speakers today, and numerous scientific societies across health and environmental fields. Editors of prestigious journals have denounced the proposed rule and stated excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes. The bipartisan policy center, the bipartisan environmental protection network represented earlier by a speaker, the Attorney Generals of seven states and D.C. who was here earlier and

EPA's own Science Advisory Board have also denounced the proposed rule. Rather than increasing transparency, the proposed rule will hamstring EPA, eliminate some of the best science available to inform standards under the National Ambient Air Quality Standards program and jeopardize both the environment and public health by making it more difficult to adopt rules that protect public health and the environment in the future. EPA's long-standing process using data from peer-reviewed science, EPA in-house scientists and the EPA Science Advisory Board works well and mirrors the processes of other science-based agencies. The system isn't broken and doesn't need to be fixed. If EPA wants to accomplish its mission, the proposed rule should be withdrawn immediately and should not affect any rulemaking going forward or any of the studies used in periodic reanalysis of existing rules. Thank you for allowing me to comment.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 27, Dan Byers, and Speaker

28, Antonia Herzog, if you would take seats on the stage. Speaker 29, Tess Dermbach, and Speaker 30, Mary Angly, if you would take seats in the on-deck seating.

MR. BYERS: Good afternoon. My name is Dan Byers. The U.S. Chamber of Commerce strongly supports the intent of the proposed rule and applauds EPA for addressing a long-standing problem inherent in much of its regulatory decision-making processes. While the Agency's proposed reforms are clearly controversial they are grounded in a universally-accepted democratic principle: Citizens have a right to the data and information that are used in the development of public policy. This spirit of openness with respect to the regulatory process is found throughout government. It is enshrined in statute and countless federal directives and EPA memos reinforce the principle and detailed guidance for implementing it. It is also supported by experts of all political stripes. In 2012, congressional testimony, President Obama's Science Advisor, Dr. John Holdren, unequivocally

endorsed this idea, stating that: "Absolutely the data on which regulatory decisions and other decisions are based should be made available to the committee and should be made public. The Chair of EPA's Science Advisory Board during the Obama administration subsequently echoed this sentiment. Unfortunately, while this principle is generally accepted, EPA has not followed it consistently in practice. In fact, for many years EPA has relied upon non-public data to justify its aggressive regulatory agenda. The most egregious, but certainly not the only, example of this involves two controversial studies undertaken in the 1980s that suggest a linkage between certain types of particulate matter and health outcomes. The data associated with these decades-old studies has never been made public but EPA nonetheless has used them to monetize regulatory benefit claims that dominate the communications and regulatory marketing associated with nearly all of its major rules. It's also worth pointing out here that, separate from the studies themselves, EPA's

benefit monetization is highly subjective and controversial in and of itself. For example, in 2009 the Agency modified its assumptions in a manner that resulted in a quadrupling of purported benefits without any change to the underlying data and information used to monetize it. We hope that these sorts of subjective and questionable practices will be addressed since the Agency concurrently examines the development of regulatory cost-benefit analyses. The scale of EPA's practice in this respect is mind boggling. Data compiled by the U.S. Chamber found that between 2000 and 2016, EPA issued 62 rules claiming a total of 923 billion dollars in regulatory benefits. Incredibly 898 billion of these benefits, or 97%, were monetized based on the non-public data associated with PM2.5. In fact, these benefits comprise nearly 80% of all regulatory benefits across the entire federal government. Even though the vast majority of these rules were not intended to address PM2.5, and even though the vast majority of their

corresponding claim benefits came from areas of the country already deemed safe and in compliance with the standard, the Agency repeatedly touted these figures to build public support for its regulations. It's one thing to be cavalier about transparency principles when their application has little or no import to public policy. The federal rules that impact millions of people and billions of dollars should be held to a higher standard. For these reasons, we applaud EPA's effort to establish and meet a higher standard and we commend the Agency for doing so through the formal public comment and rulemaking process rather than simply instituting a new policy. As EPA makes clear throughout the rule, these changes will require considerable effort and cooperation, and despite suggestions otherwise, the proposal clearly states that its aim is not to exclude science but rather to ensure: "That over time more of the data and models underlying the science that informs regulatory decisions is available to the public for validation." And, to more broadly

quote: "Change Agency culture and practices regarding data access." The outcome will not just lead to better public policy, it will improve the integrity of the rulemaking process and in doing so increase public trust in, and support for, EPA itself. Whether you agree with the administration's regulatory approach or not, that is a good thing. With that fundamental background in mind I will close by calling attention to six high-level areas that warrant emphasis and attention as the Agency works to finalize the rule. These are elaborated on in my written comments.

1) Protect sensitive information;

2) Formally coordinate with other agencies working to address similar regulatory transparency challenges;

3) Develop further guidance and processes for employing the administrator's exemption authority under the rule;

4) Consider alternative approaches to balancing trade-offs between goals related to

transparency and maximizing the quantity and quality of information relied upon. For example this could include assigning greater decision-making weight to publically available data while still allowing for the consideration of nontransparent data;

5) Where possible, work to protect and de-identify sensitive information to allow for its continued use in regulatory decision-making, and;

6) Ensure that relevant transparency information is incorporated into public communications and marketing materials associated with regulatory initiatives. Thank you for your time and consideration today.

[Substitution of panel members.]

MS. HUBBARD: Thank you.

MS. HERZOG: Hello, my name is Antonia Herzog, H-E-R-Z-O-G, and I am a scientist with a doctorate in Physics. I am particularly concerned about preserving the scientific integrity of the EPA. I work in the Environment and Health Program at Physicians for Social Responsibility, a nonprofit

organization here in D.C. with chapters in multiple states across the country and over thirty thousand members and activists around the country. Our mission is to protect human life from the gravest threats to health and survival; we number environmental pollution among those key threats. PSR would like to express its strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." This proposed rule could arbitrarily exclude many important scientific studies-including thousands of public health and epidemiological studies that the Agency uses to make informed policy decisions regarding major public health and environmental laws. While it pretends to be about "transparency", the policy actually will limit the Agency's ability to use the best available science thereby weakening protections for public health and the environment. In essence it could censor and block much of the peer reviewed scientific research that has allowed us to address many serious environmental health threats over the decades.

EPA's proposed rule would place crippling restrictions on the use of data the Agency would accept in the rulemaking process by ultimately requiring investigators to divulge personal information about the participants in research studies. Scientific studies that failed to meet this criterion would not be acceptable to the Agency. At present, this kind of information must be kept confidential according to the generally accepted rules that govern the conduct of research that must be adhered to by agencies of the federal government and institutions that receive federal funds. A particular example that is concerning to me and is particularly relevant today where it's so hot outside and the air quality is questionable, is the Clean Air Act, a bedrock environmental law that protects us from dangerous air pollutants. It is such a critical health protection that would be endangered under this proposed rule because it relies on a longitudinal epidemiologic study of thousands of individuals. This includes the National Ambient Air Quality

Standards (NAAQS) in the Clean Air Act. These standards address six major classes of common air pollutants, including standards for fine particles {PM2.5), and these are the backbone of the U.S. air quality management system.

The Clean Air Act specifies that new or revised NAAQS be based on scientific criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." EPA has relied largely on community epidemiology and controlled human studies in establishing the specific pollutant levels and averaging times for NAAQS. If these studies were excluded by the EPA restrictions it would greatly reduce the availability of information that has proved to be significant in assessing the consistency and coherence of the evidence upon which the standards are based and would certainly weaken the scientific basis for maintaining or strengthening

those current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.

PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 29, Tess Dernbach, and Speaker 30, Mary Angly. If you come to the speakers' table. Is Mary Angly in the room? Okay, we'll come back to her at the end.

MS. DERNBACH: My name is Tess Dernbach, T-E-S-S,

D-E-R-N-B-A-C-H. I am a third-year law student at Columbia Law School and a legal intern at Earthjustice, speaking on behalf of Earthjustice. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," requires a choice between breaching medical privacy or ignoring data for rulemaking decisions altogether. Breaching a patient's medical confidentiality can have severe and wide-ranging consequences for patients' lives and livelihoods. Various groups have often tried to access patient data for retaliatory purposes. For example, when pork industry associates tried to access the identities of individuals who had participated in a study by the University of North Carolina Professor Steve Wing, about the harmful health impacts of hog farming, or when the Department of Justice tried to access names of women who had late term abortions for use in litigation challenging the Partial Birth Abortion Ban Act. Employees' health information can be and is used against them by employers as an excuse for termination or other poor treatment. Moreover,

when the medical confidentiality of research participants is breached, people are deterred from participating in research altogether. Medical confidentiality is a necessary element of modern medicine. Patients must feel safe telling their doctors the most intimate details of their lives. The expectation of confidentiality fosters openness and trust between doctors and patients and is crucial to the delivery of medicine and conducting clinical research. Courts recognize, too, the importance of medical confidentiality and privacy. In 1928, Justice Brandeis described the right of privacy as: "The most comprehensive of rights and the right most valued by civilized men." At least five circuit courts have recognized an individual's constitutional interest in or right to the privacy of their medical information. In Farnsworth v Procter and Gamble in the 11th Circuit, the court recognized that: "Even without an express guarantee of confidentiality, there is still an expectation, not unjustified, that when highly personal and

potential embarrassing information is given for the sake of medical information it will remain private." This right to medical privacy can extend to beyond publication of medical data to situations where medical information is available to those without a legitimate interest in it. See, for example, Tucson Women's Clinic v Eden in the 9th Circuit, where the court observed that even if safeguards against public disclosure were adequate, the lack of safeguards against release of information to government employees who have no need for the information could create a violation of the right to privacy.

The EPA claims, vaguely, that confidential data will be protected by redaction or de-identification. However, these mechanisms are entirely inadequate to maintain patient confidentiality. Latanya Sweeney, a Harvard Professor of Government and Technology, found in her study simple demographics often identify people uniquely that she was able to identify 87% of people in the United States with only their

gender, zip code and birth date. She has also found particular problems in patient confidentiality de-identification observing that in many healthcare data sets there will be unique data about people that can be used to identify them even when they are not explicitly identified in the data set. Sweeney found that even without identifying data in health data sets: "The remaining data can be used to re-identify individuals by linking or matching the data to other databases or by looking at unique characteristics found in the fields and records of the database itself."

Paul Ohm from the Georgetown Law School found in his pivotal work: Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization, that using traditional, personally identifiable information focused anonymization techniques, any data that is even minutely useful can never be perfectly anonymous. These studies seriously undermine government claims that de-identifying data will provide adequate privacy for

patient data contained within research studies. Because of these reasons and those given before me, I strongly urge EPA to revoke the proposed rule immediately. Thank you.

MS. HUBBARD: Thank you.

MS. ANGLY: Hello, my name is Mary Angly and I'm interning for the organization Physicians for Social Responsibility and I've come to speak against the proposed rule, "Strengthening Transparency in Regulatory Science." Medical studies, clinical reports, and real-world field studies all include data and information that cannot be made public without violating confidentiality in patient protection laws. The proposed rule implies that these studies are not transparent because researchers necessarily suppress names and other identifying information about patients whose health information is relevant to study findings. Releasing individual participants' data to the public would violate confidentiality requirements legally mandated by the IRB and/or by HIPAA. By restricting these

studies, the proposed rule would essentially force the EPA to base many of its regulatory decisions on industry-sponsored studies and this rule could have huge environmental and public health implications. Despite a supposed scientific process, the funding source for a study can have significant implications on study findings. For example, in a review of research into the health effects of EPA an evaluation of 115 relevant studies was conducted in 2009. The review found that 94% of the publically funded studies found that chemicals have harmful effects whereas none of the industry-backed studies found these same findings. This is a huge disparity that cannot have occurred due to chance alone. Successful regulatory policies can have huge and quantifiable effects on exposure levels in human health. Biannually, the CDC collects data recording the blood and urine levels of 265 chemicals in people across the country. Longitudinal data can be used to visualize falling exposure levels and thus not measure the impact of a policy. For instance,

following the 1970's era lead regulations, 2009 blood lead levels were 8% of 1980 levels, which is a compelling example of a successful public benefit that occurred as a result of regulatory efforts. This is especially important when one considers that the detrimental effects of lead exposure are well known and well documented. Lead exposures leading to a blood concentration of 1 mcg/dL are correlated with an IQ loss of about 0.2 points. Each IQ point is estimated to raise worker productivity about 2%. Moral arguments aside, when considered from a population perspective, lead regulation has had huge economic benefits. A review of the EPA's archives shows that much of the original clinical research that formed the EPA's decision to regulate lead would have contained private health information. Under the proposed rule many of these studies would not have been able to be taken into consideration which is why it's so important that these studies are allowed to regulate future chemicals. Although lead specifically, and its health effects

are well known and well documented, my fear is that the future regulation of dangerous chemicals will be prevented due to the restrictive nature of this rule. Barring the use of major health studies under the veil of transparency will have huge and detrimental effects on the breadth and validity of the sources the EPA is able to consider when making regulatory decisions. Dangerous chemicals will not be able to be adequately regulated if the scientific processes are stymied.

I urge you to consider the health of this country when deciding whether or not to implement this rule. If the health implications are not enough to prevent the enactment, please consider the economic implications. The cornerstone of a healthy and productive population is a healthy environment. This rule would pose a serious barrier to the EPA's ability to effectively regulate. The power of landmark laws defined to protect human health such as the Clean Air Act, Safe Drinking Water Act, and Toxic Substances

Control Act, could be significantly undermined if this rule comes to fruition. Thank you for your time.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 31, Brenda Munive, and Speaker 32, George Thurston, if you would come to the speakers' table. Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the on-deck seating.

MS. MUNIVE: Good afternoon. My name is Brenda Munive and I am currently interning with the nonprofit organization called Physicians for Social Responsibility. I am a recent graduate of the University of California, Santa Barbara, with degrees in Environmental Studies and Communication. I am testifying today to voice my opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." I believe that scientific transparency is critical. Scientists, policy makers, and the public alike must all be able to trust and rely upon the scientific evidence that shapes our

society and the extent of human knowledge. However, I believe the EPA's proposed rule instead represents a serious misunderstanding of the institution of science. Furthermore, I believe that the proposed rule risks unnecessarily excluding valid scientific evidence from informing EPA policy, and therefore harms our fellow Americans through the creation of ineffective policies. The nature of the scientific field is unique. While most professions are motivated by political, economic or societal interests, scientists are motivated by seeking truth. Scientists perform research with the sole objective of uncovering the reality of how our world operates and gain status and recognition by succeeding in that goal. Top scientists are granted tenure or the assurance they cannot be fired from their position for whatever reason. Tenure guarantees scientists that they will not lose their position even if their research points to facts that are controversial or at odds with the current political societal climate. For these

reasons, ideally, they are not suspect to the same biases as most of the public. To prove this point it is helpful to look at the four norms of scientists as explained by renowned sociologist, Robert Merton. These are: Universalism, or the idea that truth applies to all regardless of belief; communalism -- the fact that all scientific knowledge belongs to the public; disinterestedness -- the fact that scientists are not concerned with the outcome of the research, only that it is factual; and organized skepticism or the tendency to be doubtful of any research to ensuring the deep truth. These norms describe the ideal foundation on which scientists and their research operate. Because of communalism, we can be confident that scientific research is as open as possible. Being intentionally secretive violates this ideal, so critical data must be accurately presented. This norm does not mean that all data is presented, however. Minute details, such as the identities of the subjects, are usually withheld in research studies of all

types to protect privacy and ensure participation -- or, encourage participation. It is important to emphasize that these omissions do not diminish the quality or the outcome of the research, but are made in the interest of the well-being of the participants. Because of this intrusiveness, the public can be confident that scientific research is virtually free of any bias favoring one agenda, and because of organized skepticism, scientific research is subjected to heavy review and fact checking before it is published in a scientific journal, so the public can be confident that published research is factually sound. Of course, there are exceptions to these ideals. For example, the norm of disinterestedness could be jeopardized if a scientist is hired by an outside party such as a company or noted member of the industry. The outside party introduces a monetary benefit and a desired outcome for the research, putting unconventional pressure on the scientist to fulfill the desires of whoever hires them. If the EPA's proposed rule is enacted, industry

funded research could comprise a disproportionate amount of what informs EPA policies, giving the industry, and not the scientific community, a large degree of input in shaping environmental protections.

Based on this knowledge, the proposed EPA rule is unnecessary. Mandating that underlying data be made public in order for scientific research to be utilized in informing EPA policies, attempts to increase transparency but fails to recognize that scientists already take thorough and exhaustive steps to assure their published research is unbiased, truthful and as transparent as possible. Research that does not meet these standards is rejected by the scientific community. The rule would restrict valid scientific data, particularly within health research where patient confidentiality mandates that identifying information remain anonymous. The result would be ineffective and harmful policies that could allow for practices and chemicals that genuinely harm our nation to remain rampant and unregulated.

This outcome would benefit no one and runs contrary to the EPA's mission of protecting public health and the environment. Furthermore, a healthy economy depends on healthy communities. For these reasons, I implore the EPA to reconsider enacting this rule. Thank you for this opportunity to present my testimony.

MS. HUBBARD: Thank you.

MR. THURSTON: Good afternoon, I'm George Thurston. I'm a professor at the New York University School of Medicine. Today I'm here representing the International Society for Environmental Epidemiology, the ISEE, which includes researchers who study environmental causes of ill health including ambient air pollution subject to the National Ambient Air Quality Standards, or NAAQS, promulgated by the EPA, as well as its standards for heavy metals, pesticides, drinking water and other environmental contaminants. As such, our members have supplied a substantial part of the research that is the basis of those standards. We strongly oppose the

implementation of EPA's proposed changes to the way that studies are considered in setting such standards. Based on an incorrect interpretation of transparency and replication in science, the proposed rule would deprive policy makers of the real-world epidemiological evidence based on real exposures of real people that have been, and will continue to be, vital for future considerations of EPA's health-based standards. I especially want to highlight for you the manuscript that I wrote 20 years ago entitled, "Band-Aiding the Release of Health Research Data: Issues and Implications," and the article is already posted on EPA's SAB web page. This article considered a similar proposal that was made in July of 1997 as an amendment to the U.S. House Appropriations Bill without any hearings. The problems I raised at that time are directly relevant to today's transparency proposal.

First, the increased potential for compromise of medical record confidentiality. As you've heard before today in a time of big data it's all too

easy to crack any de-identification process, especially when lots of publically available spatial and environmental data are matched to people in the study as they are in the studies that EPA considers. The solving of the Golden State Killer case, for example, is one example where a combination of two separate databases allowed de-identification of an individual. Second a loss of researchers' intellectual property. This can involve lost publications and academic career derailment. Third, the imposition of a government unfunded mandate. The USOMB has estimated that a similar law considered in the Congress, but that was never passed by the Senate, could cost the government up to 250 million dollars per year. There would also be the data prep costs to the scientists and their institutions.

Fourth, damage to future scientific research. When people no longer wish to enroll for fear that their medical data will be released, new scientific studies could be inhibited. Fifth, the

proposed rule will allow the EPA to ignore large portions of the scientific literature in decisions that are supposed to protect public health. In cases where key studies are excluded from the evaluation of environmental issue because of an inability to release study participants' private health records, the EPA may then ignore key scientific studies. This would diminish the evidence supporting protective health studies, potentially allowing the EPA to conclude that there's insufficient evidence to support proper health protective standards.

Sixth, the abuse of research data to undermine science credibility. This problem is likely the most dangerous aspect of this proposal. Past documented examples of abuse by consultants to a vested interest resulted when the state of Georgia set up an open records law and the R.J. Reynolds Company used it to obtain research data to attack study findings that the use of cartoon characters, such as Joe Camel, in tobacco advertising influenced children's product recognition. That

research was later validated in other studies but the damage was done and the physician involved left research for private practice. Thus, this data release approach has already been tried in the past and shown to be too easily abused by vested interests. There is also a tobacco connection to today's proposal. Just before the 1997 open data amendment was presented to the House, there was a December 1996 memo from the consultant of the tobacco industry, from Christopher Horner, laying out a similar strategy to address federal agency science with respect to second-hand smoke including a now familiar call for science transparency.

Finally, there's no need for this rule. Independent validation has already been conducted by groups such as the Health Effects Institute for air pollution studies, such as for the ACS and the Six Cities studies. Indeed, these are the studies mentioned by an earlier speaker, I believe it was Steven (sic) Milloy, and he incorrectly said that they were never released, they would never release

their data, and in fact they did release it. So, his testimony was incorrect. And whoever it was, I think it was Steven (sic) Milloy, but anyway, earlier speaker who said that Pope and Dockery had not released their data. They have done so and, in fact, it's an excellent example of how the system works. So, finally just to say such independent evaluations could easily be applied again to any new cases of concern for data validation without the above-noted risks. Thus, this dangerous rule seeks to needlessly solve a purported problem that just doesn't exist. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the speakers' table. Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you would come to the on-deck seating.

MS. MEYER: Hi. My name is Brittany Meyer and I am the Associate Director of Public Policy at the Michael J. Fox Foundation for Parkinson's

Research. I am here on behalf of the nearly one million people with Parkinson's disease in the United States who rely on the Environmental Protection Agency to safeguard their health and inform them about potential hazards in the environment.

For over the past ten years, we've learned a lot about the mechanisms of Parkinson's disease and now know that the condition is caused by both genetic and environmental factors. It is now very clear that when coupled with a genetic risk factor, exposure to several chemicals, most notably solvents and certain pesticides, can trigger the disease. Just eight weeks ago, a study out of Canada suggested that low-level exposure to pesticides disrupts cells in a way that mimics the effects of mutations known to cause Parkinson's. More research is needed to fully understand the mechanisms at work and how to prevent them.

Many of the studies used to identify risk factors for Parkinson's disease are investigated via large population-based epidemiology studies and will be

impacted by EPA's proposal. I am going to highlight one clear example- though along with my health and science colleagues here today, we can provide hundreds of examples of studies that could be impacted.

A 2009 study used GPS to estimate participants' well-water contamination exposure from agricultural pesticides. The results showed that consuming well water from a private well located in an area with historical pesticide use resulted in an increased risk of Parkinson's disease. Due to the nature of wells - typically serving a relatively limited number of people within a very small radius - the detail needed to perform the study renders proper de-identification impossible. All one needs to know is that a certain person lives near a particular well along with a demographic detail such as their age, gender, race, etc., and privacy is at great risk. Data from studies like this cannot be de-identified to the degree needed to protect patient's identification while still providing the

amount of specificity needed to help a scientist trying to replicate the results. Obtaining consent is not a solution. Some people make the choice to not disclose their Parkinson's diagnosis for a variety of reasons including privacy concerns, fear of prejudice or retaliation at work, and others. It is simply unreasonable to put people in the position of outing their diagnosis or to decline to participate in a study that could someday find a cure for their condition. Additionally, people who are willing to sign away their privacy and those who are not are different in ways we cannot predict or control for in study analysis.

The Michael J. Fox Foundation believes in open, reliable, and replicable science. We fund approximately 90 million dollars in research per year and hold our funded scientists to the highest standards. Our contracts require science studies to be peer reviewed and most require data to be as available as possible while protecting precious health data. We echo the call of our fellow public

health groups here today and the nearly seventy public health, science, academic, and medical groups who signed on to a joint statement calling for the rule to be abandoned for the sake of science and for our health. Thank you.

MS. HUBBARD: Thank you.

MR. SPANIER: Good afternoon, my name is Adam Spanier, S-P-A-N-I-E-R. I am a pediatrician and Associate Professor in the Department of Pediatrics at the University of Maryland School of Medicine. I'm also a member of the American Academy of Pediatrics, Council on Environmental Health Executive Committee. I'm here today on behalf of the American Academy of Pediatrics. The AAP strongly objects to EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposal will require EPA to ignore the best available, peer-reviewed scientific evidence on pediatric and reproductive environmental health, may violate patient confidentiality, and could dampen scientific processes by creating barriers to the use of

quality research in EPA science. Children and pregnant women are disproportionately affected by environmental pollutants and changes. Between 1990 and 2010, the Clean Air Act prevented over 160,000 premature deaths, 54,000 cases of chronic bronchitis, 130,000 acute myocardial infarctions, 1.7 million asthma exacerbations, 3.2 million lost school days and 13 million lost work days. Landmark academic studies guided EPA to implement policies leading to these dramatically positive outcomes. However, EPA's proposed rule will no longer allow EPA scientists to use much of the scientific evidence that's brought on these life-saving regulatory changes.

Scientific studies used by EPA to make regulatory changes are already rigorously examined prior to being published in peer-reviewed scientific journals. Scientists not associated with the research study must review the study design to ensure that it is scientifically sound before the study can be published. Many of the studies that inform EPA policy to protect the health of

children and pregnant women are based on IRB approved studies of the health of human subjects that require data confidentiality. Such studies involve observing the longitudinal effects on reproductive and child health from exposures to lead, particulate matter and other toxic substances. Replicating such investigations for the purpose of providing open access data for EPA to use would be morally unacceptable as it would require exposing children to lead, ozone and other damaging pollution. It would also not be ethical to exempt the study participants from data confidentiality protections. By requiring reproducibility the rule may also exclude many landmark public health studies that were so scientifically rigorous and resource-intensive that they could not be reproduced, such as the Framingham Heart Study, a 70-year-long cardiovascular epidemiologic study. Requiring reproducibility may also exclude studies done after landmark ecologic events such as oil spills and natural disasters. This rule does not improve

the scientific merit of the studies used for EPA policies, and, instead, creates significant barriers to EPA's assessment of past, current and future scientific work. This proposed rule contravenes EPA's mission to ensure that American pregnant women, children and families have clean air, land and water, and the AAP strongly urges you to not move forward with it. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you'll come to the speakers table. Before they speak I wanted to note that the time is now 2:39 and Speakers 35 and 36 are the last two speakers here to speak during the afternoon session. So, at this time if there's any speakers currently registered for the evening session but would like to speak now, if you would go to the registration desk we can get you a speaker number. Go ahead.

MR. MOULTON: Good afternoon, my name is Sean Moulton, Senior Policy Analyst at the Project On Government Oversight, a national nonprofit,

nonpartisan, government accountability organization. Thank you for the opportunity to speak this afternoon. I'm here to express my organization's strong objections to the proposed rule, "Strengthening Transparency in Regulatory Science," and urge the Agency to withdraw it. In the proposed rule the Agency notes that the best available science must serve as the foundation for EPA's regulatory actions. It is hard to argue with that fundamental principle, but this policy won't make scientific information better, nor more available. Instead, the new rule will often mean the best available science is off limits to the Agency, create delays in rulemaking and result in greater litigation.

I'd like to focus primarily on the rulemaking process and first raise serious concerns about the insufficient development process that produced this rule, a rule that fundamentally changes what information can and cannot be used in future rulemakings is a major undertaking and requires a great deal of certainty and evidence, yet this

proposal offers no clear explanation of the precise problem, no supporting evidence, no studies establishing that EPA has an information problem, nor citations that the proposed standard has been successfully used before or that EPA understands what its impact will be on the regulatory process when implemented. Even if the Agency truly believes there is some deficiency in its information policies and procedures, this proposed rule is premature. The starting point should be conducting studies of the issue to better understand the scope of the problem, if there is one, and the best way to improve transparency of regulatory science. The Agency should allow the Science Advisory Board to fully investigate and offer specific recommendations before moving forward with any proposed rule. There are any number of steps that the EPA should be completing before rushing into a formal rulemaking. The incomplete foundations for this rule reveal themselves in the vague language and unclear standards. The rule does not specify how

the new standards will be implemented, what mechanisms will be made available to allow publishing of more detailed data. More importantly the rule doesn't address how it will fit into the legal requirements the Agency has under the Administrative Procedure Act or other environmental laws.

The proposed rule is being done at EPA's discretion with no statutory authority backing it up. So, should this policy come into conflict with statutory requirements under existing law, those laws take precedent, and laws governing rulemaking have a number of requirements that this proposed rule would be in conflict with. The Administrative Procedure Act makes clear that an Agency cannot engage in arbitrary, capricious actions or decisions in its rulemaking; while the Agency has authority in its given area, that authority is not absolute. The Agency must have clear and strong justifications for its actions. Given the lack of supporting evidence for this policy or a statutory requirement from Congress,

EPA will be hard pressed to prove that this untested standard is not arbitrary. Even if the rule isn't immediately dismissed under the APA, the EPA's requirements under other laws, such as the Clean Air Act, that it consider all available, or best available, science in rulemaking and this policy would be in direct conflict with those. If the Agency seeks to apply this new standard in areas ungoverned by such statutory requirements, it will result in a confusing patchwork of standards where a study may be available for consideration under a Clean Air Act rule or a TSCA rule, but that same study would not be considerable in another rule.

I wanted to note in a case before the U.S. Court of Appeals for D.C. around the availability of air quality data study information, the court addressed this very issue, stating that, "If the EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant

scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment." Placing large portions of scientific research off limits simply goes against common sense. EPA should be able to use any and all available information to produce the best, most up-to-date rules. If a study is unreliable or flawed in some way, then the Agency can decide that based solely on that study's merits, and sometimes even flawed or partial studies can offer important insights that the EPA should benefit from.

We strongly urge EPA to withdraw this rule. Thank you very much for your time.

MS. HUBBARD: Thank you.

MR. BERGMAN: I'm Andrew Bergman, and I'm speaking today as the Special Environmental Advisor at the Project On Government Oversight, but I'm also currently a Ph.D. student in applied physics at Harvard University.

While the proposed "Strengthening Transparency in Regulatory Science" rule uses the words

"transparency" and "reproducibility" to project lofty goals, it's real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process. I'm here today to urge EPA to withdraw this rule. My colleague, Sean Moulton, has just addressed how the proposed rule conflicts with the EPA's regulatory process, and the statutory requirements underlying that process, but the rule will also have a direct impact on how the EPA approaches science.

The rule fails to properly address its two key considerations that will have a major impact on how it is implemented. First, the rule states that data relied on in making regulations must be made publically available, but it doesn't suggest a mechanism for how personally identifiable information or confidential business information would be handled.

This is an incredibly important issue, as so many studies that EPA uses rely on this type of confidential data. Yet it's reasonable to conclude

from the rule that, if it goes into effect, the EPA will no longer be able to use most longitudinal human health studies to craft public safeguards, even though those studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity. Instead, they will be left with industry studies that more often use animal test subjects, which don't have any personal privacy concerns.

Second, while the rule refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' reproducibility, which has a wholly different meaning in a scientific context. But because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule intends the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings.

The Agency uses many studies, however, such as

those that link leaded gasoline to brain damage in children or a study that found a link between fine particulate air pollution and premature deaths, that examine dangerous real-world exposures and cannot, of course, be safely repeated. Just because they can't, or shouldn't, be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future. Without knowing the details of how these two provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. We can conclude that the result will be that large swaths of studies will be arbitrarily ruled out for use in future rulemakings.

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially. The CBO found that a policy very similar to the proposed rule,

when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding--a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary." The three-judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying

them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all. Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation?

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made

in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed, "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule. Thank you for your time and for the opportunity to comment on this important proposal.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 37a, Emma Glidesgame, and Speaker 38a, Jyotsna Pandey if you would come to the speakers' table. Speaker 39a, Patricia Cohen speaking on behalf of Tracy Woodruff, if you would come to the on-deck seating.

MS. GLIDESGAME: Good afternoon. My name is Emma

Gildesgame, G-I-L-D-E-S-G-A-M-E. I'm a Master of Environmental Management student at the Yale School of Forestry and Environmental Studies, and an intern with the National Parks Conservation Association. My comments today are my own. I'm here to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule, that would censor science and threaten the health of all Americans. Last week, many of us in D.C. awoke to alerts warning of potential contamination in our water system. We were told to boil water before drinking or brushing our teeth or to avoid tap water altogether. For those few days, stores sold out of bottle water, Starbucks stopped selling coffee, and public pool splash pads and water fountains went dry. In the face of an urgent public health risk we did not censor the science that told us that contamination in our water is a threat. To know that clean water is important we didn't need the health records of every person who participated in landmark studies that helped us

understand the effects of contaminated water on our bodies and brains. The science is real. It's not secret, it's been repeated. It's been peer reviewed, analyzed and reaffirmed by generations of experts.

Just as the residents of D.C. took precautionary actions to protect ourselves and our loved ones in the face of a potential public health threat, the EPA must be allowed to use the best available scientific data to accurately assess environmental and public health threats to protect all Americans. The Clean Air Act, Clean Water Act, Safe Drinking Water Act and other historic laws that helped the United States become a leader in environmental protection recognized something that we forget far too often: Human health is environmental health. They are one in the same. Pollutants in the air travel hundreds of miles to become pollutants in our lungs. Contaminated soils grow contaminated food. Toxic river water becomes toxic drinking water. At the same time, clean air builds stronger kids. Healthy rivers,

lakes and watersheds build healthy communities. Good environmental and public health policies rely on a strong backbone of good science. The proposed rule would eliminate many credible, respected, long-standing, peer-reviewed, scientific studies from EPA consideration because they rely on confidential health information which cannot be made public. This proposal allows politically appointed regulators to pick and choose which studies they want to consider and would force scientists to choose between their ethical obligation to protect their subjects' privacy and the obligation to contribute knowledge to apply to regulatory science. Using good science to make strong policy has made America great for decades. The EPA and other agencies have kept countless Americans healthier, safer and more prosperous by using science to inform conservative, proactive protections for human health and the environment. We have protected historic and cultural monuments like the Jefferson Memorial, Statue of Liberty and even the Capitol

Building from the corrosive power of acid rain. We have reduced smog and air pollution in national parks like Great Smoky Mountains, Joshua Tree and Yosemite. We have improved water quality from the Great Lakes to the Everglades. Thanks to the EPA, my peers and I were born into an era of healthier air, cleaner rivers, and safer drinking water than our parents. I hope that someday my children can say the same, and that is why today I am joining thousands of scientists and public health professionals all over the country in speaking out against this rule and asking you to stop it in its tracks. We are all counting on you to listen to the sound and transparent science the EPA has used for decades and we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MS. HUBBARD: Thank you.

MS. PANDEY: Good afternoon, my name is Jyotsna Pandey, and I'm the Quality Manager for the American Institute of Biological Sciences. My

organization appreciates the opportunity to comment on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." We thank EPA for extending the initial 30-day public comment period and scheduling this public hearing on the proposed rule. We support the objective of increased transparency in the rulemaking process. But, the proposed rule is inadequately defined and thus itself lacks transparency and appropriate public protections. We request the EPA rescind the proposed rule and initiate an open process for gathering the information required to more thoroughly articulate the proposed rule. Any proposal to increase transparency in the regulatory process must not arbitrarily exclude important scientific information from the decision-making process, nor can personal information about individuals, such as genetic information or health status be sacrificed. A failure to protect these data will hinder future scientific investigations of people who refuse to participate in recent studies if they are not

confident that their most personal information is protected. Importantly, scientific journals take steps to protect personal information. They are not aware of any secure way to mask or protect personally identifiable information in the public domain and therefore think that any rule requiring this information be made public is needlessly risky. These data are important, however, to informing the decision-making process and should not be excluded for rulemaking processes because they are not publically disclosed.

As far as this request for comment, EPA has solicited input and measures to "provide protected access to identifiable and sensitive data." This is a significant issue and one that EPA should fully understand prior to moving forward with any new rule. Time and expertise are required to identify and properly evaluate the feasibility, cost and effectiveness of potential actions. It is unlikely that EPA can effectively gather and evaluate this information in the time prescribed by the proposed rule. We recommend that EPA

initiate a formal request for public comment on this issue alone and use what it learns to help inform and guide any potential future rule on transparency.

High-quality, curated and vetted mega data are generally required for someone else to appropriately reanalyze or use data such as those that could be made available by the proposed rule. The proposal is silent on meta data standards and practices. This is a significant challenge and another major problem with the proposed rule. We support EPA's goal of conducting independent peer reviews of the science and data used to inform regulatory decisions but thinks the section lacks adequate specificity. Who will conduct and manage the peer review process? Will these reviews be managed by the Office of Research and Development or by the various regulatory offices within EPA? Does EPA have appropriate staffing, expertise and resources to manage these peer reviews? We recommend that EPA partner with scientific organizations and professional communities to

administer and manage these reviews. Such outsourcing and partnerships will help to ensure that EPA gains access to independent and highly qualified experts and to promote greater public confidence in the independence of these peer reviews. This kind of process for managing peer review will also allow EPA to more cost effectively, nimbly and rapidly conduct reviews as it will not require EPA to substantially increase staffing for the remaining reviews. Such a process would also provide EPA with greater capacity to conduct reviews on time skills that do not needlessly delay regulatory and rulemaking schedules. After reviewing this proposed rule the AIBS respectfully urges EPA to rescind the current proposal. We ask that EPA initiate a new transparent and interactive process with the scientific, public health and environmental management communities, as well as other appropriate stakeholders, to identify responsible and viable approaches for promoting greater understanding of the science and data used to

inform EPA decision-making. Thank you for your consideration of our request.

MS. HUBBARD: Thank you.

MS. STOBERT: Patricia Koman, if you'd come to the speakers' table.

MS. KOMAN: Good afternoon. My name is Patricia Koman, spelled K-O-M-A-N. I am speaking on behalf of Dr. Tracy Woodruff, W-O-O-D-R-U-F-F. Dr. Woodruff is a professor in the Department of OB/GYN and the Director of the Program on Reproductive Health and the Environment at the University of California, San Francisco. Dr. Woodruff is a PI, or Principle Investigator, for a Children's Environmental Health Center and she, along with 15 other principle investigators of other Children's Centers, have submitted comments to the EPA about this proposed rule in writing. They are concerned that the proposed rule will adversely affect EPA's ability to use science in decision-making and ultimately negatively influence protections for children's health. Research from Children's Centers contribute

significantly to the foundation of science that informs and supports the Agency's ability to protect the public health. The National Academy of Sciences highlighted that Children's Centers have led to an improved understanding of the environmental impacts on child health and development. Children's Centers research identified the critical contributions of environmental exposures to asthma, obesity, ADHD, cancer, autism and other childhood illnesses. This research has led to new direction, treatment and prevention strategies for these diseases including informing EPA standards for cleaner air which has improved the quality of life for children. Collectively, we have research data from thousands of participants across the country, including some of our most vulnerable populations, children and women in communities of color. To not use or consider studies that do not comply with the proposed rule is inconsistent with scientific principles and evidence-based policy and this would put the public's health at risk

from toxic chemicals. Institutional review boards require that we protect the privacy and confidentiality of our participants, but institutional review boards' requirements conflict with this rule's mandate to publically reveal individual level data. Data masking, coding and de-identification techniques have limitations, because re-identification of participants is still possible. We are especially concerned that the rule inappropriately codifies specific data analysis approaches such as dose response modeling and other scientific decisions that should be made on the basis of scientific judgment and empirical considerations. This will hinder scientific inquiry and lead to inaccurate results. As scientists, we value open science but the mandates laid out in this rule will not improve data sharing, replicability or transparency. Instead, implementation of this rule, especially retroactively, could lead to EPA excluding numerous relevant studies from policy decisions to the ultimate detriment of children's health. We

urge EPA not to move forward with this proposed rule.

Finally, I want to comment about this public hearing and its lack of access to all stakeholders. By not providing the ability to make comments remotely or virtually, EPA limits the public comments to those that have the financial resources to travel to Washington D.C. and limits the participation of populations that are going to be most affected by this rulemaking. This undermines civic engagement and conflicts with the principles of a fair democracy. This is not a technical issue, as U.S. EPA has made virtual public comment in the past.

Finally, we urge EPA not to move forward with this proposed rule. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: It's now 3:02 p.m. This was our last speaker for this session that we know of. We are going to repeat the request that if there is any speaker that has registered but is registered for the evening session, if you'd like to speak

now go to the registration desk and you will receive a speaker number for this session. We're going to wait a few minutes and see if there's anybody that decides to speak now. Otherwise, we will break until the 4:00 session starts.

MS. HUBBARD: And if I could just make a quick announcement, we do have a member of Congress who is on his way to speak who should be here shortly, so we won't go into recess quite yet, so if everyone could just remain in their seats if you're interested in hearing him speak, otherwise feel free to go on and head on out and then we'll go into recess after that.

MS. STOBERT: Sorry, Peter Ferrara, speaker 40a, if you would come to the speakers' table?

MR. FERRARA: Good afternoon. My name is Peter Ferrara, that's F-as in Frank, E-R-R-A-R-A. I'm the Senior Fellow for Legal Affairs at the Heartland Institute. We submitted our comments during the comment period online in response to the notice for public comment in rulemaking posted on April 30, 2018. EPA proposes the rule I am

commenting on intending the strengthen the transparency and integrity of EPA regulatory science. The proposed rule provides that EPA should ensure that the data and models underlying scientific studies pivotal to EPA regulations are publically available in a manner sufficient for independent validation, especially concerning regulations for which the public is likely to bear the cost of compliance. We applaud this proposed rule and find that governing statutes and executive orders, not to mention the basics of the scientific method, authorize the proposed rule and indeed have long required it. In not following the proposed rule in the past, EPA has been flouting the governing statutes and executive orders, departing from the scientific method and abusing its authority. The proposed rule provides that for science pivotal to significant regulatory action, EPA will ensure that the data and models underlying the science are publically available in a manner sufficient for validation and analysis. This new policy is needed because EPA admits to

having not previously implemented these policies and guidance in a world-best, robust and consistent manner.

Examples where EPA previously has fallen short include the public health research used to implement and defend the PM2.5 particulate matter standards, the corporate average fuel economy standards, the ozone standards and carbon dioxide standards. EPA's admitted reliance on secret science occurs at a time when the publications Nature, PLoS, Science, The Economist and other report half or more of published research on public health issues cannot be replicated. This replication crisis is genuine and even more broad and critical than the sources cited by the EPA for this proposed rule are willing to admit. A scientific publishing industry has been created by lavish government funding of politically directed research. Examples of this include supposedly scientific studies finding human impact on the climate or an association between ozone and climate. It may take generations before the

effects of this corruption can be overcome. The root cause of EPA science malfunction has been corruption of EPA's peer review process. Peer review for the EPA has become power review with insiders typically armed with millions of dollars in government funding acting to censor and exclude scientists who disagree with the reigning political agenda. That perverts the whole point of peer review, turning it into a tool used to shut out anyone who disagrees, instead of a process forcing scientists to defend their work against critics. The more widespread replication crisis is proof that this disease has affected most of the world's leading science journals and even its National Academies of Sciences. One scientific finding that has been suppressed by the corruption of peer review was just singled out by EPA in its call for comments, is evidence of non-linearity in the concentration response function for many pollutants. The entire regulatory model is precariously perched on an invalid assumption of linearity and the resulting scientific crisis

continuing to build must now be openly faced, removed and regulations based on such science malfunction, or even outright corruption, must be revised and repealed entirely. EPA's new policy of scientific integrity and transparency should be applied to computer climate models that currently prevail in EPA's funded published and cited climate science. The continued use of default models, not consideration of alternatives or model uncertainty create a false scientific justification for EPA actions, policies and regulatory burdens.

So, we applaud this new proposed rule and encourage the EPA to implement it rapidly.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 41a, Liz Hitchcock, and Speaker 42a, Benjamin Kirby, if you would come to the speakers' table.

MS. HITCHCOCK: Good afternoon, my name is Liz Hitchcock, and I direct Safer Chemicals Healthy Families. We lead a coalition of hundreds of local, state and national groups. This variety of

groups of labor, consumer, parents, educators, scientists, health care providers, health-affected and others shares the concern about the growing recognition of the links between our exposures to toxic chemicals and the increases in cancers and other chronic illnesses and in learning and developmental disabilities, and we share a commitment to reducing and eliminating exposures to toxic chemicals in our homes, our places of work, and the products that we use every day. I thank the Agency for responding to the large number of public comments that objected to the length of the initial comment period by extending it and for scheduling this hearing.

Safer Chemicals Healthy Families joins a long day of voices in opposition to this proposal. Many of our coalition partners and a number of respected scientists have offered strong cases for withdrawing the proposal already today and I thank those speakers for their comments and will try to keep my own comments brief.

The proposed rule is irreparably flawed and

misconceived. In the name of transparency it will prove needlessly burdensome, requiring unnecessary and costly procedures of EPA scientists that are counter to the Agency's longstanding application to base public health decisions on the best available science. Under this proposal without a guarantee of full public access, the study will be considered unreliable and will play no role in assessing a chemical's health effects on human health. This ignores the many ways in which the scientific community, regulators and the public have traditionally determined the quality and relevance of study results. It also disregards the way that hard-working EPA science professionals have taken seriously their charge to use the best available science in their decision-making. Safer Chemicals Healthy Families played a key role in the reform of the Toxic Substances Control Act which requires that EPA use the best available science in the review and management of toxic chemicals. As EPA begins to review the tens of thousands of chemicals already on the market we

are concerned that they be able to take into consideration all information that is reasonably available. For the fence line communities that have been harmed by their exposures to chemicals, for the families who have lost loved ones to asbestos-related diseases, for the firefighters exposed to a soup of toxics as they protect our communities, and to children who are born pre-polluted by a range of industrial chemicals, the stakes are high for these evaluations. EPA scientists working on risk and hazard assessments collect and review thousands of studies. Published reports of these studies typically do not include all the underlying data. This proposal would add the burdensome requirement in such cases that EPA contact the researcher, determine the nature and extent of the underlying data, and put in place a mechanism for the public to access the data. Many before me have called this proposal a solution in search of a problem, but it bears repeating. In proposing this rule EPA leaders have painted a stark picture of EPA

reliance on so-called secret science developed behind closed doors, but is this really so? EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record, even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review and members of the regulatory community are free at any time to replicate studies they deem flawed or to independently seek access to underlying data and reanalyze them. In short, the so-called problem that the proposed rule seeks to fix is largely fiction.

In conclusion, EPA should withdraw this proposed rule. The public health stakes are just too high. Thank you.

MS. HUBBARD: Thank you.

MR. KIRBY: My name is Ben Kirby. I'm an environmental engineer with a doctorate and

master's degree in environmental engineering from Virginia Tech and George Mason University respectively. I'm representing Hall and Associates, and environmental consulting firm in Washington D.C. We support the application of this rule to EPA's environmental impact analyses, particularly TMDLs, or Total Maximum Daily Loads, and NPDES or National Pollutant and Discharge Elimination permits under the Clean Water Act. These legally binding permits include ethylene limits for wastewater treatment facilities for pollutants such as lead, mercury or phosphorus. Slight alterations in these permit limits can cost a single wastewater facility tens of millions of dollars, the cost of which is passed on to individual local rate bearers. These permit limits are supposed to be derived in a manner similar to dose-response relationships as mentioned in the rule where, for example, a lower level of the pollutant in the discharge will result in a measurable increase in receiving water quality working with health. However, we have

dealt with instances throughout the country where environmental agencies have based regulations on publically unavailable data, outdated science or faulty science, even in the face of data or studies which indicate stringent permit limits imposed by these agencies are not anticipated to result in any quantifiable environmental or human health benefit despite the cost. We hope that this rule would remedy these shortcomings. We also strongly support the use of independent expert peer reviews as an additional level of review for fiscal regulatory science. Our firm has been involved in independent peer reviews of various Clean Water Act related EPA regulations which have concluded that the technical basis for EPA's regulations and permit limits were scientifically indefensible. Had no peer reviews occurred, these regulations would have imposed hundreds of millions of dollars of wastewater treatment costs to rate bearers with no anticipated benefit. As a science-based Agency applying science-based statutes it is critical to

both receiving water quality and rate payers throughout the country that these permits and regulations are based on sound science and not speculation.

In this regard, we support application of EPA's proposed rule to Clean Water Act regulations.

Thank you for the opportunity to come.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker A, Dan Lipinski, you are now invited to speak at either the table or the podium.

MR. LIPINSKI: Good afternoon, I'm Congressman Dan Lipinski of the Third District of Illinois. I'm here to ask the EPA to rescind the proposed rule. The origins of the rule are in the 2014 House Bill called, the Secret Science Reform Act, which I voted against in that year and again in 2015, and when it was reintroduced as the Honest Act in 2017. The goal of these bills and of the proposed rule, contrary to its name, is to limit availability of science to inform regulatory decision-making. I'm disappointed to see the

Trump administration circumventing the will of Congress, attempting to administratively implement policies that cannot pass through the Legislature. On June 7th of this year, I joined 102 of my colleagues from both political parties in sending a letter to then Administrator Pruitt urging him to withdraw the proposed rule. My comments today build on that earlier commentary and expand on my opposition to this misguided policy.

EPA's admission, as it appears on the Agency website, is to protect public health and the environment and to ensure that national efforts to reduce environmental risks are based on the best available scientific information. The proposed rule works in direct opposition to that mission by requiring that the data underlying the scientific studies used in informed regulatory actions are available to the public. The proposed rule will exclude vast quantities of valuable research including that based on personal health data, confidential business information, and even older studies whose authors or data sets are no longer

available. In some cases, the rule will require the exclusion of the best available scientific information. To make matters worse, this rule would grant the administrator wide latitude to exclude studies from its provisions, enabling him or her to cherry pick studies in order to affect the outcome on the rulemaking process. There is no basis in any of the statutes under which EPA operates for giving an administrator such broad authority to choose which science is used in rulemaking.

Let me give an example of how the proposed rule could affect a future EPA rulemaking. EPA is planning to update its lead and copper rule in the near future the rule that limits the levels of these metals in drinking water. This update cannot come soon enough. We all know about the drinking water crisis in Flint, Michigan. Chicago and Washington D.C., as well as many other cities around the country, are finding troubling levels of lead in drinking water right now. Most of what we know about the health effects of lead exposure

comes from older studies of children with high levels of lead in their blood. Yet these studies may be excluded from consideration, both because their data are not publically available and because it would be unethical to replicate them. As a result, it is possible that an Agency could conclude that there is no evidence that lead is bad for you and, therefore, does not need to be updated. This would be a tremendous mistake. I have spent my career in Congress working to enable science-based decision-making in government. The proposed rule represents a significant step backward and I urge the Agency, in the strongest terms possible, to rescind it. Thank you.

MS. STOBERT: Speaker 43a, Mahealani Daniels. If you'd come to the speakers table.

MS. DANIELS: Good afternoon. My name is Mahealani Daniels and I'll spell that M-A-H-E-A-L-A-N-I, D-A-N-I-E-L-S. I would just like to thank you for allowing me the opportunity to share my comments in opposition to the EPA's new policy on so-called transparency. The EPA must utilize

the best available science to inform its actions in the creation of environmental and public health laws. Judicial precedents establish that the best available science is all existing scientist evidence relevant to the decision. In further supporting these precedents, the EPA's own regulations state that the best available science would be information that the EPA possesses or could reasonably generate, obtain or synthesize, whether or not that be information that is confidential business information that is protected from public discourse. While increasing transparency and ending an era of secrete science are two statements that publically resonate as appealing advances, when digging deeper it is clear that the EPA's implementation of these standards would do just the opposite and would actually violate judicial precedent as well as the Agency's own regulations. A majority of confidential health data can't be used with the EPA's new standards of transparency, thus limiting the scientific evidence they could use to inform

studies and standards. Since personal health data informs the production of environmental laws that protect public health, it's exceptionally important that the EPA continues to use it. For example, a recent study released by MIT demonstrates that 200,000 early deaths occur every year in the United States as a result of air pollution. Utilizing data on patients' health is not only necessary to establish the aforementioned research, but is also necessary when the EPA goes to set standards on environmental and pollution regulations that affect the lives and health of millions of Americans. I am hopeful that just as a majority of Americans are guided by their own personal values to abide by the laws established by our government, the EPA will too decide to function under judicial precedents and be guided by its principle to utilize the best available science. And with that, I thank you so much for your time.

MS. STOBERT: Thank you. I believe that was the last speaker for this session, so we will recess

now and resume the hearing at 4:00 p.m. Thank you.

[Off the record 3:26 p.m.]

[On the record 4:00 p.m., Evening session. Substitution of panel members.]

MR. RODAN: Okay, so welcome back at 4:00. Let us commence session three of this public hearing. Hello and thank you for coming. This public hearing is now in session. My name is Bruce Rodan and I am in EPA's Office of Research and Development. I will be one of the hearing officials of this two-hour period. Lou D'Amico, also from the Office of Research and Development will be joining me. We also have Nanishka, Lauren and Lesley from SC&A Incorporated helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of

the administrative record on which EPA will base its decision. Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under authority of 5 U.S. Code 301 in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA received your comments in an orderly fashion. Although EPA panel members may ask clarifying questions the intent of this hearing is to listen to your comments, not to discuss or debate the proposal.

Now for a few housekeeping items and ground rules. Please refrain from interrupting speakers or asking questions. Shouting and noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies.

For everyone's awareness, this hearing is open to

the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing. There was no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again, so please be aware of time and the rain outside. If you'd like to make an oral comment in today's hearing and did not pre-register to speak, please see the hearing staff at the registration table positioned at the entrance of the room. If you would like to provide a written comment to the official record, you may hand submit it to the EPA staff today or mail, fax or email your comment. See staff at the registration table for instructions on how to submit written comments. There is a comment box at the registration table where you can leave hard copies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments

it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision. EPA has extended the comment period. Written comments must have been received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making comments that are not related to this action. EPA will not provide responses during the hearing, rather EPA will prepare a written summary of the comments received that includes responses. The Response to Comments, RTC, document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered. The hearing is being recorded by a court reporter who will be preparing a verbatim record of the hearing. Please speak clearly and slowly into the microphone so that the court reporter can record

your comments accurately. A copy of the transcript will be placed in the docket. The hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier, and is divided into three sessions: 8:00 a.m. to 12:00 p.m., 12:00 p.m. to 4:00 p.m., and this session 4:00 p.m. to 8:00 p.m. Public restrooms are located down both sides of the hall and we have staff to escort you. Please note the location of the emergency exits.

Please take a moment to silence your cell phone (I've done that). Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For the current 4:00 p.m. to 8:00 p.m. session, the speaker sticker collar is blue. Speakers will be called to the speakers' table located directly across from the EPA panel

members' table in pairs by their speaker number. When it is your turn to speak, please come up to the table and watch your step. State and slowly spell your name for the record, and if you are appearing on behalf of someone or an organization. If you are not in the room when it is your turn to speak I will recall you after all other speakers have made their oral comments. Each speaker will be allotted five minutes for remarks. Elected and appointed government officials may be provided additional time since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system or speaker timer consists of green, yellow and red lights. When you begin to speak, the green light will come on to indicate you have five minutes to speak. The yellow light indicates that you have one-minute left to speak. When the red light appears your five minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap up your testimony. So, let's begin.

Speakers Numbers 1 and 2 in the afternoon session, please come forward and take a seat at the speakers' table. We will start with Speaker Number 1. Again, please speak directly into the microphone and state and spell your name for the record.

MR. SHIPPS: Thank you for this opportunity to provide public comments on EPA's proposed rule, "Strengthening Transparency in Regulatory Science." My name is Karl Shipps. That's spelled K-A-R-L, S-H-I-P-P-S. I live in New Carleton, Maryland, and I'm speaking as an individual. I am not employed by EPA or an EPA contractor, I am simply a very concerned person. I am a Navy submarine veteran, a grandfather, and have a master's degree in applied physics from the Johns Hopkins University. Because my time is limited I will confine my remarks today to three observations about the proposed rule and two recommendations.

My first observation is this: The proposed rule is based on a faulty premise, namely that only

studies whose underlying data are publically available sufficient to support replication should be considered by EPA as it develops regulations governing clean air, clean water and exposure to toxic substances and pesticides. The rule's premise, which was also the premise of the Secret Science Reform Act and the Honest Act, cannot stand. There are valid peer-reviewed studies that should be included in EPA's regulatory work even though their underlying data sets cannot be released to the public. Two of the most widely known are the Harvard School of Health's Six Cities Study, and the American Cancer Society's Cancer Prevention Study II. Those studies were revalidated by the Health Effects Institute in July of 2000 using an independent oversight board and a competitively selected analysis team. They remain valuable today. Since the proposed rule is based on a faulty premise, I recommend that it be withdrawn. A new rule addressing concerns about reproducibility and replicability should be developed in public with participation by the

scientific community, the environmental community and industry. The rule developers should avail themselves of the results of the ongoing reproducibility and replicability study being conducted by the National Academies of Sciences. That study will report in December 2018. Perhaps the EPA will not take my recommendation to withdraw the proposed rule. In that event, my second observation is germane. My second observation is that the EPA administrator is given extraordinary powers under Section 30.9 of the proposed rule for new EPA regulations or for regulations undergoing periodic update, the administrator could waive or not waive the provisions of the rule. This puts potentially thousands of studies underpinning EPA's regulations at risk of being discarded out of hand at the administrator's whim. The result would not be the best science and it would reduce public confidence in EPA rulemaking, not increase it. Based on that prospect, I recommend what the Texas Commission on Environmental Quality recommended,

namely to give governing authority for granting exceptions to the proposed data Transparency Rule, as well as the oversight of raw data collection, storage and access, to an external entity or entities to ensure independence and objectivity. You can see Docket comment EPA-HQ-OA-2018-0259-2426.

My final observation is that the scientific community was not consulted as the proposed rule was prepared. Even EPA's own Science Advisory Board was not consulted, learning about the rule only through press accounts and publication in the Federal Register. The joint statement on the EPA proposed rule and public availability of data in the 30 April edition of Science disagrees with the proposed rule. EPA should heed the concerns being voiced by the scientific community. Thank you for your attention.

MS. WHITE: Good afternoon. My name is Dr. White, W-H-I-T-E, on behalf of the American Chemistry Council's Formaldehyde Panel. I appreciate the opportunity to provide feedback on EPA's proposed

rulemaking. Utilization of transparent, objective and modern scientific approaches to draw conclusions regarding human health risks is critical to developing sound regulatory decisions. Throughout the EPA the application of scientific information to underpin regulatory activities has often been inconsistent and unclear, leading to concerns regarding how the Agency incorporates the best available science, evaluates the quality of that science, and applies 21st century knowledge concerning cause and effect. The panel has regularly met with EPA scientists related to the IRIS program regarding its subjective use of available science and resistance to moving away from default linear low-dose extrapolations, even when published scientific data support other modeling alternatives, including threshold-based approaches. This stance has often led to the generation of EPA values that are below natural background levels and not indicative of human health risks associated with real world exposures. Perhaps the most telling example can be found in

the case of formaldehyde, where a draft IRIS assessment sets values suggesting that human breath could pose a cancer risk. Formaldehyde has been the subject of scientific study for years and large bodies of evidence show that the levels of formaldehyde most people encounter on a daily basis do not cause adverse health effects, a conclusion reached by several international agencies using alternative models other than a default linear modeling approach. The evidence demonstrates the biological implausibility of any relationship between formaldehyde and leukemia, a threshold mode of action for any potential adverse health effects, and the importance of mode of action information for understanding potential impacts. We are encouraged by the Agency's proposed rule's recognition that there is growing empirical evidence of nonlinearity and that the use of default models without consideration of alternatives can obscure the scientific justification for EPA actions. This acknowledgement by EPA is especially relevant to

formaldehyde given the several decades of published literature illustrating preserved thresholds for both noncancerous and cancerous status.

In addition to the significant research and the development of a biologically-based dose response model for formaldehyde that also integrates the available science and provides results inconsistent with default linear dose response modeling approaches typically apply for carcinogenic end points. The importance of using nonlinear and biologically based dose response modeling, when the published data supports it, cannot be overstated. In this review of a 2010 draft IRIS formaldehyde assessment, the National Academy of Sciences noted the development of several models to evaluate the risks associated with formaldehyde exposure and recommended that alternatives to EPA's default linear low-dose extrapolation approach be considered.

In addition to incorporating modern scientific knowledge, we also recognize the importance of

adequate transparency in data access and ensuring regulatory decisions are based on high quality and reproducible data. For more than a decade, the panel has conducted scientific research engaged directly with EPA's IRIS program to understand the scientific information being relied on to draw conclusions regarding potential for health effects. The panel has experienced considerable difficulty in understanding what data is being relied on and how the Agency has ensured the highest quality and most relevant science is informing its decisions. Importantly, in multiple instances, sometimes after years of requests, once the underlying data was made available, it was found to have significant methodological and quality issues. In several cases, the findings, when reevaluated, did not support the original study's conclusions. The issues identified were not minor and highlight the need for greater transparency and for EPA to have a mechanism in place to evaluate the quality and reproducibility of the data being relied upon for decisions.

One notable example involved over six years of repeated requests to access all the relevant data from a National Cancer Institute study which was relied upon by the IRIS program to draw conclusions regarding formaldehyde and leukemia. The data were requested from NCI for the purpose of validating the author's conclusions and the evaluation of that underlying data found that changes reported by the study authors were not exposure dependent and they did not follow their own stated protocol. As demonstrated by formaldehyde example, when the data access is limited and modern scientific approaches aren't used to move away from default assumptions, the results can be conclusions that lack scientific rigor and potentially provide the public with an inaccurate picture about everyday chemicals which have been used safely for years.

I hope that you find these comments useful and I will provide a detailed set of comments by the August deadline.

MR. RODAN: Thank you. I believe we have another

speaker.
MS. HALL: Right, I don't have any details on that yet.
MR. RODAN: What?
MS. HALL: I don't have any details on who it is or -- standby. Speaker 3, Walter Tsou, please come up to the speakers' table.
MR. RODAN: Around the far side. Take care of the wire. I think you provided a copy at the front desk, we'll take it here. Watch out for the cord there, we don't want you falling over. Okay, so, we went through some long instructions. You have five minutes.
MR. TSOU: Okay. I'll be less. My name is Dr. Walter Tsou. I serve as Executive Director of Philadelphia Physicians for Social Responsibility and a past president of the American Public Health Association. Thank you for this opportunity to testify on "Strengthening Transparency in Regulatory Science". As many of my colleagues have noted today, while the goal of transparency in how studies are conducted, and the ability to

reproduce scientific results are important, it can offer a politically motivated administration a convenient excuse for eliminating or ignoring scientific studies that may go against the wishes of a powerful industry group. All one has to do is demand that the data sets be handed over for "further scrutiny" or demand that the study be repeated before basing a regulation on the study in question.

The very nature of longitudinal public health studies where health and toxins intersect are, by design, large, expensive and require years or sometimes decades before results are found. Sample sizes can often number in the tens of thousands to millions of data points and may need to be collected over many years before a statistically significant finding is identified. For example, Curry, et al studied in Pennsylvania babies who lived within 1 kilometer of active fracking wells. She had to review over 1.1 million birth records before demonstrating the relationship between living close to gas wells and low birth weight

babies. Because these studies are so big, they are often too expensive to repeat. In our state of Pennsylvania, scientific research on fracking is actively stymied or suppressed. In a state where billions are made on gas drilling, only one part time contractor at the Health Department collects data on health complaints from fracking. Those who do have health complaints have to sign non-disclosure agreements and not cooperate with any research in order to get lifesaving water to drink. This I consider extortion and this practice is common in the industry in order to suppress any health studies on the dangers of fracking. If the transparency regulation was in place, all health studies on fracking would be simply not considered because the research could not be conducted due to non-disclosure agreements.

Today there is no reputable scientist that doesn't believe in the harmful effects of smoking. The health studies on smoking were 15 years in the making before the Surgeon General released his landmark 1964 report and except for a handful of

EPA administrators, there is no reputable scientist who doesn't believe that climate change is real and is man-made. The studies on climate change and health have been known since Exxon wrote about it in 1977. If these transparency rules were in place when the EPA was founded, smoking would still be in airplanes and no one would have heard of "greenhouse gases" or "global warming", the greatest threat to our planet's existence.

Since the founding of the EPA, independent scientific research has been the foundational basis of your mission. Science is the cross before the corporate devil. This Transparency Rule would destroy the confidential nature of research and make the burden of conducting research more difficult and expensive. Finally, the real purpose of these rules is to reverse regulations on industries who have been harmful to public health. We should let science speak for itself and speak the truth and the EPA should hear from all scientific studies, not just the ones the industry

wants you to listen to. Thank you for your time.
MR. RODAN: Thank you very much. So, do we have any other registered speakers waiting? So we'll have a short recess and we have a one hour clock ticking. The time now is 4:22.
[Off the record 4:22 p.m.]
[On the record 4:40 p.m.]
MR. RODAN: We are hereby reconvening this public hearing. Come up to the -- go to the right there, there's some steps.
MS. HALL: Speaker Number 4, Mark Mitchell.
MR. BRUCE RODAN: Thank you, you'll have five minutes of time and you'll get a green light for the first four, an orange light and then a red light when the five minutes is up.
MR. MITCHELL: Okay, thank you. Thank you for this hearing. My name is Mark Mitchell. I'm a public health trained environmental health physician. I am testifying on behalf of the National Medical Association which represents the interests of more than 30,000 African-American physicians and our patients. We are a member

society of the Medical Society Consortium on Climate and Health.

I got into environmental health because I was concerned about the health effects of environment on public health. As a public health official, I saw that a lot of the diseases that are common, particularly those that are common in communities of color, are associated with the environment. We are opposed to the misnamed proposed new rule on "Strengthening Transparency in Regulatory Science." The proposed rule prohibits the Agency from setting regulations that are supported in part or in whole by data that is not publically available for reanalysis or that cannot be replicated. This rule, if enacted would limit the consideration of perfectly good science in the EPA regulatory process. What's more, it's retroactive so the current regulations that are based on previous studies that can no longer be replicated for ethical or other reasons, could then be voided. As physicians, we are particularly concerned about our legal and ethical obligation

to protect patient privacy under the Health Insurance Portability and Accountability Act of 1996, otherwise known as HIPAA. We believe that patient health data should be considered in EPA regulations because it's necessary to consider the health effects of environmental exposures in order to protect human health, and that we should also be able to guarantee patient privacy that should be protected.

Currently, we do this in research publications through the peer review process. The peer review process has worked well to ensure an adequate level of transparency while allowing science to advance unencumbered. We do not need to reduce the health protection that environmental regulations provide in the name of so-called "transparency." Thank you for this opportunity to testify.

MR. RODAN: Thank you. So, we'll go into another short recess, or maybe an hour, at 4:44. Thank you.

[Off the record 4:44 p.m.]

[Off the record 5:44 p.m.]

MR. RODAN: It's 5:44. I'll read the closing statement. Thank you for taking the time today to share your comments on the EPA proposed rule. The time is now 5:45 p.m. No additional members of the public have registered or are waiting to speak. Therefore, this hearing is now officially closed. Thank you.

[Off the record 5:45 p.m.]

Whereupon, the above-entitled matter is concluded.

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, NaCorey Nichols, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.

My commission expires:

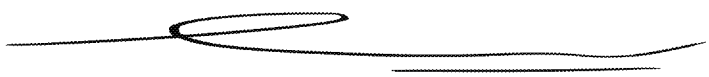
October 14, 2021

NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Gary Euell, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.



My commission expires:

March 14, 2023

NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

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U.S. Environmental Protection Agency

Public Hearing on

Strengthening Transparency in Regulatory Science

9:00 a.m. to 5:45 p.m.

Tuesday, July 17, 2018

U.S. Environmental Protection Agency

1201 Constitution Avenue N.W.

Washington, DC 20460

US EPA Panel Members:

MS. JENNIFER ORME-ZAVALETA (Hearing Official)

MR. CHRIS ROBBINS (Hearing Official)

MS. MARY ELLEN RADZIKOWSKI (Hearing Official)

MS. CAROLYN HUBBARD (Hearing Official)

MR. BRUCE RODAN (Hearing Official)

MR. KEVIN TEICHMAN

MS. MARIA DOA

MS. LYNN FLOWERS

MS. SUSAN BURDEN

MR. LOU D'AMICO

Non-EPA Panel Members:

Ms. LAUREN HALL, SC&A INC.

Ms. LESLEY STOBERT, SC&A INC.

P R O C E E D I N G S

MS. ORME-ZAVALETA: So I want to say hello, and I want to thank you all for coming. We are now calling this public hearing into session. My name is Jennifer Orme-Zevaleta, and I'm with EPA's Office of Research and Development, and I'll be one of the hearing officials today.

Kevin Teichman is also with me from the Office of Research and Development, and we also have some contract staff, Nanishka , Lauren, and Lesley from SC&A Incorporated, who will be helping with the logistics.

The purpose of today's hearing is to accept public comments on EPA's proposed rule, "Strengthening the Transparency in Regulatory Science."

EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding, and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was

published in the Federal Register on April 30, 2018 (83 FR 18768), and EPA is proposing this rule under the authority of 5 U.S.C 301, in addition to the authorities that were listed in the proposed rule document dated April 30th of 2018.

So my role today is to ensure that EPA receives your comments in an orderly fashion, and then -- although EPA panel members here may ask clarifying questions, the intent of this hearing is to hear from you and to listen to your comments and not to discuss or debate the proposal.

So now, for a few housekeeping and ground rules. Please refrain from interrupting speakers or asking questions, shouting, noise making, or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately, and listeners on the phone can hear the oral testimonies.

For everyone's awareness, the hearing is

open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio, and photos. We ask that you not cause any disruption to those who are testifying or observing the hearing.

There is no formal lunch break, so you may leave for lunch and return to the hearing, but just be advised that you'll need to clear security again if you do that.

If you would like to make an oral comment on today's hearing and did not preregister to speak, please see the hearing staff just outside here at the door at the registration table, and they'll be able to sign you up.

If you would like to provide written comments to the official record, you may hand-submit it to EPA staff today, or mail it, fax it, or e-mail it, your comment. So see the staff at the registration table for instructions on how to submit written comments.

There is a comment box at the

registration table where you can leave hard copies of your oral testimony, or written copies. All comments received will be included in the official docket.

If you submit written comments, it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision.

EPA has extended the comment period and written comments must now be received on or before August 16th of 2018. So EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making any other comments that are not related to this action.

EPA will not provide responses during the hearing, rather EPA will prepare a written summary of comments received that include responses. The Response to Comments document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments

submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter who will be preparing a verbatim record of this hearing, so please speak clearly and slowly into the microphone so that the court reporter can record your comments accurately. A copy of the transcript will be placed in the docket. And this hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier. And it's divided into three sessions. 8:00 a.m. to 12:00 p.m., 12:00 to 4:00, and 4:00 to 8:00.

Public restrooms are located on both sides down the hall, men's to the left, women's to the right, and we will have staff escort you so that you're able to get through the security point and be able to come back. And please note the

location of emergency exits, primarily as you come in and you know, out where you entered this morning will be the main emergency exit for you.

So please take a moment to silence your cell phones. Speakers should have been given a sticker on entry that lists your assigned session, and if you plan to speak and have not received a sticker, please go back to the registration table so they can give you one.

For this session, the 8:00 a.m. to 12:00 p.m. session, the speaker sticker color is neon green so we can see you. Speakers will be called to the speaker's table, which is located right across from us, and will be coming up in pairs to that speaker's table. When it's your turn to speak, please come up to the table. Watch your step as you come up the steps over there, and state and spell your name slowly so that we can have that for the record. And if you are appearing on behalf of someone else or some organization, be sure to clear that -- make that clear as well. If you are not in the room when

it's your turn to speak, I will call you after all other speakers have made their oral arguments.

Each speaker is allotted five minutes for remarks, elected and appointed government officials may be provided additional time since they are representing large groups of constituents. Speakers will be notified when their time is ended. We have a time keeping system just over here. It runs by the yellow -- green, yellow, and red-light system. So when you begin to speak the green light will come on and you have five minutes. When you have one-minute left to speak you'll see a yellow light. And then when the red light appears, your time is up. At that moment I will ask you to wrap up your comments so that we can make room for the next speaker to come forward.

Speakers Numbers 1 and 2, if you could go ahead and please come on up and take your seat at the speaker's table. We will start with Speaker Number 1. And again, if I could ask you to please speak directly into the microphone and state and

spell your name for the record.

And if I could ask, Speakers 3 and 4, if you could just stand at the steps so that you'll be ready, and we'll be able to keep this moving. So, Speaker Number 1.

MR. STEICHEN: Good morning. My name is Ted Steichen, and it's S-T-E-I-C-H-E-N, and I am representing the American Petroleum Industry.

API is the only national trade association -- boy, it's not very bright here. Sorry. The American Petroleum Institute is the only national trade association with all facets of the oil and natural gas industry which supports 10.3 million U.S. speakers (sic).

Sorry. I'm having a little trouble this morning.

All right. So, supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. Our 620 corporate members from large integrative oil companies to small independent companies comprise all segments of the industry. API members are producers, refiners, suppliers,

retailers, pipe line operators, and marine transporters as well as service supply companies supporting most of the national energy.

The members of API are dedicated to continuous improvement in compatibility with their operations with the environment, while environmentally, economically developing energy resources, supplying high-quality products and services to consumers.

Our members recognize the responsibility to work with the public, the government, and others to develop and use natural resources in an environmentally sound manner that protects the health and safety of employees and the public.

API supports the use of sound science for a critical component of public policy, to the extent possible and consistent with the protections of other compelling interests, such as privacy, trade secrets, intellectual property, and other confidentiality protections, data and analysis used in establishing or evaluating environmental health, welfare and economic impacts

should be transparent and reproducible and available as early as possible in the rulemaking process.

Transparency and reproducibility should be able to underly -- also be underlying data and information such as environmental and economic impact data and models that are utilized in protecting and predicting the costs, benefits, market impacts, and environmental effects of specific regulations.

API members are aware that there are obstacles to full transparency and reproducibility, and are committed to working with other stakeholders in developing practices and maximize science transparency while preserving existing confidential strictures.

The EPA -- as the EPA goes forward with this rulemaking, API recommends the following principles be followed. Openness to science and related findings underpinning the laws, regulations, standards, and guidance documents. Reproducibility of research and associated

findings, including fully annotated data, methodologies, model inputs, code and other critical information that support the conclusions of research. All of these should be available to the public.

The inclusion of clear requirements to ensure that the data underline the decision-making are publicly available in a manner sufficient for independent validation as much as practicable. Privacy concerns are important, but advances in encryption technology and blinding of data may make it possible to enhance transparency while ensure privacy as necessary to comply with the law.

Protection for confidential business information used in the regulatory process and supporting actions should also be taken into account, explicitly addressing and highlighting uncertainties in data, models, and analysis when utilizing those studies in decision-making. Broad application of these principles to inform the use of policy for setting scientific, economic, and

environment impact requirements and models that are designed to protect health and environment, engaging stakeholders as early as possible in the decision-making process to ensure application of data transparency principles for studies to be included, and to address how those studies have not been reproduced or are not reproducible will be considered in the process, application of these principles as early as possible in the pre-rule making stage, as technical support documents are prepared.

In closing, as described above, API supports the use of sound transparent science and public policy making, and we plan to submit written comments to the docket.

MS. ORME-ZAVALETA: Thank you.

MS. FELD: Good morning. My name is Jodi Feld, J-O-D-I F-E-L-D, and I'm the Chief Scientist in the New York City office of the New York State Attorney General's Environmental Protection Bureau.

On behalf of New York Attorney General,

Barbara Underwood, I thank you for the opportunity to speak before you today. The Office strongly opposes EPA's proposed rule to limit the use of science in agency rulemakings. The proposed rule was developed without any input from the scientific community and has been widely criticized by the scientific and public health communities. It is vague, poorly reasoned, and violates fundamental legal requirements for a valid rulemaking.

Most importantly, while the proposed rule has the stated purpose of strengthening the foundation of EPA's regulatory actions, it would have the opposite effect. It would exclude relevant probative scientific studies, models, and other information from EPA decision-making that have been validated by peer review, simply because the underlying data are not available to the public. The proposed rule broadly and squarely conflicts with core EPA statutory duties. It violates the very federal laws that EPA is required to uphold by limiting EPA's access to the

most current, best available, and generally accepted science that these laws mandate be used by EPA in developing new rules and standards. Quite simply, it is bad science.

It departs abruptly from the best practices of the scientific community and disregards both well-established reasons why public sharing of all study data is not possible or necessary, and why studies relying on such data demand consideration in agency decision-making.

The result of the proposed rule would be to profoundly weaken EPA's science-based regulatory decision-making, and ultimately its protection of public health in the environment in New York and elsewhere across the nation. We urge EPA to abandon this damaging and misguided effort. It appears that the proposed rule was developed with a total absence of independent scientific input. The proposal offers no rationale for the premise that only studies for which the underlying data are publicly available can be used for decision-making, nor any evidence that EPA's

current approach to selecting studies for decision-making is resulting in scientifically unsound decision-making, or is somehow overly protective of public health and the environment. Hence, at its core, the proposed rule is a solution in search of a problem.

Requiring that study data be publicly available as a prerequisite to its consideration by EPA would be an abrupt and unprecedented break from well-established best practices of the scientific community. The scientific community recognizes what the proposed rule ignores, that there are often very good reasons why some research data simply cannot be fully available to the public, such as the protection of personal privacy and confidentiality.

Within the scientific community the validity of research is judged on multiple grounds, including how well studies are designed, how clearly data are collected, how carefully analysis are performed and described, and how thoroughly findings of related studies are cited.

In other words, within the scientific community studies are validated through rigorous expert peer review. They are not summarily judged and valid and discarded simply because all underlying data cannot be fully shared.

Perhaps the strongest indicator that the proposed rule is flawed as a matter of science is the overwhelmingly negative reception it has received from the scientific community. We are not aware of a single major independent scientific organization that has expressed support for the proposed rule, while many have urged EPA to stop and reconsider the proposal.

Contrary to EPA's position, the proposed rule would certainly hurt states. EPA standards and regulations are a fundamental important to states and actions that affect these standards and regulations directly affect us. In fact, many states, environmental laws, and regulations explicitly adopt EPA standards. By undermining the basis of EPA standards and regulations, the proposed rule would likely have direct damaging

impacts on New York and other states' abilities to protect the health and environment of their residents. These impacts will be felt most historically by our most vulnerable populations, the young, the elderly, and the sick, and those living in communities that have borne a disproportionate share of environmental hazards, including communities of color and low-income communities.

From a legal perspective, the proposed rule fails to meet the most fundamental requirements for a valid rulemaking. It is exceedingly vague, creating many more questions than it answers. For example, exactly how, when, and to what the rule will be applied is entirely unclear. And critical information such as its actual cost is entirely missing.

In May, the New York Attorney General, joined by seven other attorneys general, wrote to then, Administrator Pruitt, expressing strong opposition to the proposed rule and calling for it to be withdrawn. Today, the State of New York

renews our call to Acting Administrator Wheeler to withdraw the proposed rule.

I thank you for your time and for providing me with an opportunity to speak on this important matter.

MS. LAUREN HALL: Thank you. If we could have Speakers 3 and 4 come to the table, and then 5 and 6 on-deck?

MR. SUSSMAN: Good morning. My name is Bob Sussman, and I am a former EPA official in the Clinton and Obama --

MS. HALL: Could you bring your microphone --

MR. SUSSMAN: -- administrations --

MS. HALL: Yes, thank you.

MR. SUSSMAN: -- and now a consultant and an attorney.

I'm here today representing Safer Chemicals, Healthy Families, which leads a coalition of 450 organizations and businesses united by a common concern about toxic chemicals in our homes, places of work, and products we use

every day.

I believe that the EPA proposal we are discussing today is flawed and misconceived. In the name of transparency, it will burden EPA scientists with unnecessary and costly procedures that run counter to the Agency's long-standing obligation to base public health decisions on the best available science.

The premise of the proposal is that unless EPA can guarantee full public access to a study's underlying data, the study must be deemed unreliable and should play no role in assessing a pollutant or chemical's effects on public health. This premise ignores the many ways in which the scientific community, regulators, and the public have traditionally determined the quality and relevance of scientific evidence.

Study reports typically explain the protocols use to gather data, the methods used for data analysis, the doses or exposure concentrations at which effects were and were not observed, the nature, severity, and incidence of

such effects, and any unusual occurrences that may affect interpretation of the results.

This information plays an important role in the peer review process, informing the judgment of independent reviewers as to whether a study is worthy of publication in the scientific literature. Agency reviewers likewise consider these indicators of reliability in deciding how much weight a study deserves in making judgments about hazard and risk.

In principle, no one disputes the benefits of improving access to underlying data. The goals of open science have received support from several organizations in leading scientific journals and research institutions. These voluntary efforts, however, do not justify the unprecedented step of requiring EPA to guarantee access to the underlying data for every study it may use for decision-making, and to forfeit the ability to consider a study if this requirement has not been met.

EPA scientists working on risk and hazard

assessments collect and review thousands of studies. Published reports of these studies typically do not include all underlying data. In such cases, EPA would need to contact the researcher, ascertain the nature and extent of underlying data, and put in place a mechanism for the public to access the data.

Even with diligent efforts by EPA, there are many reasons why disclosure of data sufficient to replicate a study may be impossible. The EPA proposal duly notes these obstacles to study replication and provides that exemptions may be granted on a case-by-case basis. But an exemption process will add to the considerable cost and effort required to implement the proposed rule and will undoubtedly result in disputes and even litigation over whether exemptions are justified. Is the damage it will inflict on the quality and timeliness of EPA scientists justified by the benefits of the proposed rule?

EPA leaders have painted a bleak picture of EPA reliance on quote, "secret science"

developed behind, quote, "closed doors," based on data that has, quote, "been withheld from the American people."

This is not the reality that I experienced in my several years at EPA. I saw a very different reality. I saw EPA science assessments providing an exhaustive and critical review of relevant studies, and a full explanation of how they're being interpreted. I saw extensive information about each study being placed in the public record. I saw public comment and peer review of all EPA assessments. And of course, as part of public comment, members of the regulatory community had an opportunity at any time to replicate studies they deemed flawed.

In short, the problem that the proposed rule seeks to fix is imaginary. In conclusion, the Agency's leadership needs to fundamentally rethink the proposed rule. The stakes for EPA science and the protection of public health are simply too high to finalize a proposal which is deeply problematic and unnecessary. Thank you.

MS. ORME-ZAVALETA: Thank you.

DR. ROSENBERG: Good morning. I am Dr. Andrew Rosenberg, R-O-S-E-N-B-E-R-G. I'm the Director of the Center for Science and Democracy at the Union of Concerned Scientists. And we advocate for the role of science and public policy.

I'm here today to ask that you rescind this proposed rule because it would only restrict EPA's ability to use the best available science to fulfill its mission of protecting public health and the environment, while doing nothing to improve transparency and decision-making.

First and foremost, the proposal is fatally flawed because it provides almost no justification of analysis of the impacts of the proposed change in policy. There is no cost-benefit analysis of the rule with respect to the agency, and external researches, nor how it would affect EPA's mission and critical work.

Additionally, the proposal would affect -- effectively prevent the EPA from using many

kinds of scientific studies vital to its decision-making. This includes, but it is not limited to studies that rely on personal health data, confidential business information, intellectual property, or older studies where authors and data sources may not be accessible.

Without the ability to use this scientific information EPA would be unable to meet its mission and statutory obligations. This proposal would make it significantly harder for EPA to use the best available science to protect the public, including from harmful emissions of hazardous air pollutants, particulate matter and ozone, exposure to dangerous chemicals and commerce, drinking water contaminated with toxic chemicals, such as PFAS or lead.

Further, CBO has calculated that such restrictions would substantially increase costs and burdens to an agency that is already experiencing budget cuts, reorganizations and understaffing, thus undermining the ability of EPA to make decisions based on science.

The proposed rule could also prevent the Agency from addressing the impacts of dangerous chemicals at low concentrations where direct measurements are very difficult. This would have the effect of leaving Americans unprotected, even when there was clear indication of harm to human health.

I have over 30 years of experience in government service, academia, and non-profit leadership. I've offered -- authored or reviewed hundreds of peer-reviewed scientific papers. As part of my government service I worked as a scientist and in a policy position at a regulatory agency, and universities as a faculty member and dean. I understand how agencies use science in policy making, how research at universities is conducted, and how these entities incorporate best practices of transparency into their scientific work. As a frequent peer reviewer, I do not review the raw data for studies, since that would tell me little. I review the research questions, the methods that summarize data, the results and

conclusions in order to assess the quality of the work. EPA's proposed rule would do nothing to improve transparency for scientists, policy makers, or the public.

Crafting the rule without consulting with the scientific community is a fatal error for this proposal. Even the Agency's own Science Advisory Board has noted the need to consult with scientists in any further development of this proposal.

A further fatal flaw is that the proposed rule would replace scientific evidence with political judgment. The rule would grant the EPA administrator broad authority to exclude individual studies or entire decisions from being subject to its provisions. Decisions on which science is to rely on should be made by the Agency's scientific experts based on established criteria for best available science.

Five minutes is not enough time to cover all the problems with this proposal. At best, this proposed rule is a misguided attempt at

transparency. At worst, it is a back-door attempt to prevent EPA from protecting public health. UCS supports real transparency reforms. We support scientific integrity policies that prevent political interference in scientific analysis and reporting. We do not believe researchers should be put in the absurd position of choosing between protecting study participant privacy or informing the EPA's effort to protect public health and safety.

On behalf of the Union of Concerned Scientists, and I have 500,000 supporters, I urge the EPA not to move forward with this rulemaking and to continue to allow agency scientists and policy analysts to use the best science available to inform their work. Thank you very much.

MS. HALL: Thank you. Would Paul Tonko and Suzanne Bonamici please approach the speaker's table. Speakers A and B, respectively. And Speakers 5, Daniel Greenbaum, and 6, Jennifer McPartland, please take your seats at the on-deck circle.

MR. TONKO: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. TONKO: Can I begin? Okay. Thank you. Good morning and thank you for the opportunity to address the panel.

I am Congressman Paul Tonko. I represent the 20th Congressional District of New York State, more specifically the Capital Region and Mohawk Valley, an area rich in environmental stewardship.

As the Energy and Commerce, Environment Subcommittee ranking member, I have come here today to express grave concerns about the Environment Protection Agency's proposed rule published on April 30th of 2018, entitled "Strengthening Transparency in Regulatory Science."

This proposal would severely limit the types of research that EPA could take into account when developing policies. It has been cloaked in arguments about transparency. But let's all admit here that this emperor has no clothes. This has nothing to do with transparency. It is a thinly

veiled campaign to limit serious and highly credible scientific research that supports critical regulatory action.

This administration has used this bad faith argument about transparency to say that the many studies, including many epidemiological studies that rely on private, personal, medical data should be excluded entirely from EPA rulemaking. Why would a science-driver public agency undertake such a radical departure from existing and widely accepted scientific standards? I have yet to hear a credible answer to this question that is not rooted in favors to industry polluters.

The current political leadership at EPA has shown a pattern of bad faith in pushing policies that undermine this Agency's -- EPA's mission, and the public trust.

Today's proposal and its false claims about transparency are consistent with that pattern; a fact that was put on full display when the administration realized its broad approach

would hurt regulated industries too, since many EPA chemical reviews rely upon confidential business information. To get around this, the rule would give the EPA administrator complete discretion to exempt studies, especially or essentially guaranteeing that political interests will always matter more than science. That's why I refer to this policy as selective science.

This proposed rule would be used to erode landmark achievements in public health and environmental safety. For example, we know the Clean Power Plan would have led to reductions in pollution that were predicted to prevent some 3,600 premature deaths, 19,000 asthma attacks in children, and 300,000 missed school and work days each year. Many of these health benefits were partially determined by landmark clean air studies like the Harvard Six Cities Study.

Opponents of Clean Air Act protections would like nothing more than to see such landmark public health findings excluded from EPA reviews. I'm not here speaking alone. Nearly 1,000

scientists in many leading scientific organizations are united in vocally opposing this policy. Countless everyday Americans stand with us too, with many more listening in and watching for news to see if anyone in a position to do something about this will finally admit the obvious; this is not about transparency. This is not about protecting human health or our environment. This emperor, again, has no clothes.

This rule would limit the scientific research available to EPA policy makers as they draft public protections and environmental guidelines. I implore EPA to put science and public interest ahead of political and special interests, and withdraw this rule, ill-conceived, that's based on -- its negative impacts on science and public health. A very discouraging and concerning proposal. And I just felt compelled to come here today and vehemently speak against it.

MS. ORME-ZAVALETA: Thank you, sir.

MS. BONAMICI: Thank you. Good morning.

MS. ORME-ZAVALETA: Good morning.

MS. BONAMICI: And thank you to Acting Administrator Wheeler and Director Sinks. I am Suzanne Bonamici. I represent the First Congressional District of the State of Oregon. I serve on the House Committee on Science, Space, and Technology, where I am the ranking Democrat on the Subcommittee on Environment. I appreciate the opportunity to testify before you today.

I am opposed to the Environmental Protection Agency's proposed rule titled, "Strengthening Transparency in Regulatory Science." The proposed rule would impede, if not eradicate the EPA's ability to protect Americans from significant risks to human health and to the environment by limiting the scope of research that the EPA could consider in making decisions.

The proposed rule perpetuates the incorrect notion that the science the EPA relies on is somehow hidden. It is not. This misconception is based on conflating the meaning of secret and confidential. None of the information used by the EPA is secret. Some of

the information may be confidential if, for example, it includes the personal health information of individuals who participated in a study.

As a cornerstone of its regulatory process, the EPA relies on peer-reviewed science. The EPA already publicly discloses studies that support regulatory action. The proposed rule simply attempts to block access to good science. Much of the science that is used to inform regulatory actions is developed outside of the agency. Scientific studies often include personal information and other confidential data. Because this data is legally protected from disclosure, the EPA would be forced to ignore valuable information discovered during their research, because it contains confidential information. This would have chilling consequences for the EPA and for every person who benefits from clean air and clean water.

It is also deeply troubling that the proposed rule is inconsistent with the Agency's

statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, and Clean Water Act. The proposed rule would preclude the use of a range of scientific research that has long been used to safeguard the public.

There is also tremendous uncertainty whether the proposed rule would retroactively apply to existing standards and regulations. Retroactive application would severely undermine existing public health and environmental protections that keep the public safe and healthy.

Transparency is a laudable goal, and it could be accomplished through collaboration with, and input from the scientific community. It is noteworthy that thousands of scientists and many leading scientific originations also propose this proposed rule. If the proposed rule is implemented it is possible, or even likely, that scientists, organizations, and research institutions will be less inclined to participate in EPA funded research because of the risk of

improperly disclosing personal information. It may also be more challenging for researchers to recruit participants for their studies because of the fear that personal data could be shared.

Over the last few years, the House Committee on Science, Space, and Technology has considered several iterations of legislation that have many similarities to the proposed rule. I have been a vocal opponent of these bills for the reasons I just stated.

I also want to note that despite repeated efforts by the majority, the so-called secret science legislation has not passed both chambers. Congress has the sole constitutional authority to legislate, and this proposed rule is an administrative attempt to circumvent the legislative process. I strongly urge you to withdraw this proposed rule. It will undermine scientific integrity, jeopardize bedrock public health and environmental standards, and endanger the EPA's ability to protect the American people, which is its mission.

Thank you for the consideration of my testimony.

MS. ORME-ZAVALETA: Thank you both for coming.

MR. TONKO: Our pleasure.

MS. HALL: Would Daniel Greenbaum, Speaker Number 5 and Speaker Number 6, Jennifer McPartland, please approach the speaker's table. And would Speaker Number 7, David Michaels and Speaker Number 8, Paul Billings, please take a seat in the on-deck circle.

MR. GREENBAUM: Let there be light. And there was light.

My name is Daniel Greenbaum. That's green, like the color, B-A-U-M. I'm the President of the Health Effects Institute, and I'm very pleased on behalf of the Health Effects Institute to provide these brief oral comments today. We are preparing and will submit much more detailed written comments.

As many in this audience know, HEI has a longstanding commitment to the principles being --

attempting to be addressed by this proposal, producing science of the highest integrity and quality with special attention to issues of reproducibility and transparency.

This includes rigorous research and statistical design, subject to competition, continuous oversight, data quality assurance audits, and more, extensive efforts that test all findings against a wide range of different statistical techniques and assumptions, intensive and independent peer review with all results published, and an active data access policy which for nearly 20 years has been working to ensure access to underlying data for all HEI funded studies.

In our view, reproducibility is a critical challenge for science. Can the results of an important study be reproduced? However, in our view the most effective way to test reproducibility and the validity of science is not necessarily to simply reproduce the same results in the same data sets. Rather it is most

important to answer the question, "Are the results consistent when tested in other independent studies?" For example, studies that use new and different data sets not affiliated with the original studies. Studies that have different investigators applying the same and/or alternative statistical techniques. And studies that test the sensitivity of the results against a wide range of possible other explanations like smoking or socioeconomic status.

In a limited number of cases where there are not comparable studies, it may be useful to gain access to the original study data and analytic codes to allow for independent evaluation. Can the original results be replicated, and are they robust to a wide range of alternative assumptions, models, and potential confounders? This is, of course, exactly what the Health Effects Institute did when we conduced an independent rigorous reanalysis of the Harvard Six Cities and American Cancer Society studies. And I've attached and will submit the summary

description of that reanalysis from HEI's final report.

This approach can and did provide comprehensive assurance of the quality, integrity, and validity of the original results. However, this is a highly cost-intensive and time-consuming endeavor, which should only be applied in cases where there are only one or just a few studies in a particular arena.

HEI also agrees with the continued need to enhance transparency and data access, but would note that these issues are not new. We've had our own data access policy for over 20 years, and have been -- and they've been addressed now for over 15 yeas by administrations from both parties, and by the scientific community. This is -- it included guidelines for the Information Quality Act adopted by OIRA in 2002, numerous actions by the scientific community and journals to enhance access, and most recently the requirements for enhanced data access across the federal government promulgated by OSTP in February 2013.

We would strongly urge EPA to review the progress already made under these several major initiatives and to carefully consider whether or not there are additional efforts that could further enhance transparency and to do so before proceeding with a final ruling.

Finally, access to private medical information is essential to conducting high quality and reproducible air quality and health research. There are of course longstanding federal rules for protecting the privacy of individual medical information of the subjects of studies. And gaining access to data from older studies may be difficult, but given the privacy commitments that were made to study subjects in the past.

However, there are today, several means to make such data available to investigators with appropriate privacy protections. Medicare makes it available, federal research data centers make it available, and many investigators already have been taking advantage of these.

Although it is possible, as some have suggested, to create a depersonalized data set by stripping all personal identifiers, such as address, date of birth, et cetera, it's not possible to conduct a high-quality air pollution and health study without knowing the location of those being studied. I.e., Where do they live and what are the sources and levels of their air pollution exposure? So it can't be simply put on a disk and handed out.

Thank you for this opportunity to testify. We look forward to submitting our detailed written comments, and would welcome the opportunity to further assist EPA in these efforts to ensure that the widest array of science is available for decisions.

MS. ORME-ZAVALETA: Thank you.

MS. McPARTLAND: Good morning. My name is Jennifer McPartland, M-C-P-A-R-T-L-A-N-D, and I'm a Senior Scientist at Environment Defense Fund.

EPA's proposed rule represents a

disregard for the Agency's core mission, protection of human health and the environment. Under the guise of transparency, EPA's proposal handcuffs the Agency's use of best available science in violation of many of its statutes. If finalized, the rule will erode critical public health protections, and with them, the scientific integrity and public trust of the agency.

EPA's censored science proposal would prohibit EPA's use of critical scientific studies in developing regulatory requirements unless all the data underlying the studies have been made public. As the authors of this proposal know well, this unnecessary and unworkable standard would effectively bar the Agency from using high-quality scientific research in studying public health safeguards.

The data underlying many scientific studies are not publicly available and cannot be made publicly available. For example, research involving human subjects often rely on medical or other personal information; information that

researchers cannot make public.

Additionally, advances in data science have made it increasingly more challenging to effectively deidentify study subjects and protect their privacy. In other instances, studies may have been published decades ago and the underlying data are no longer available. It is exactly these types of studies that EPA and other authorities use to protect people from harmful environmental exposures like lead, formaldehyde, methylene chloride, benzyne, arsenic, and perchlorate, just to name a few. It is the science generated by our most prestigious scientific institutions. It is the knowledge we rely on to ensure our water is safe to drink, our air is safe to breath, and our land is safe for our children to play.

Beyond jeopardizing critical public health protections, the proposed rule completely disregards established effectiveness mechanisms used to vet scientific research including peer-review, data sharing agreements, and consensus in findings across multiple studies. Indeed, EPA

provides no explanation or justification, showing that this proposal would improve upon these established mechanisms.

The proposed rule also raises several troubling concepts that are contrary to scientific best practices and chemical assessment, as discussed extensively in the Seminole National Academy's report, *Science and Decisions*.

Specifically, the proposed rule ignores the report's conclusions that thresholds of effect for chemical exposures are the exception rather than the rule, given by a logical and exposure variability across the population. The rule also seeks to demote the use of health protective defaults and risk assessment, again at odds with the recommendations of the National Academies.

Additionally, the proposal gives more value to studies in employ of a variety of dose response models, an approach that can be misleading. Multiple bad analysis does not make a study more credible.

More broadly, the proposed rule seeks to

codify scientific practices and irregulation. It is a consistently frowned upon approach given the continuously evolving nature of science. EPA's development of the proposal also represents a total disregard for process. The Agency sidestepped review by its external Scientific Advisory Board, which has now voiced serious concerns about the proposal and has recommended that it undergo full SAB review before possible finalization.

The White House OMB review of the proposal was also quite dubious, involving a revision to the original date its review had been completed to seemingly align with the fact that former Administrator Pruitt had signed the proposed rule a day prior. The final OMB review process took course over just a few days, an impossible amount of time for any legitimate interagency review of the complex scientific issues at stake in this rulemaking, even though they have implications for all other federal agencies that rely on sound science.

Not surprisingly, the proposed rule does not grapple with the challenging steps necessary for legitimate effort to support greater data availability. It does not consider the digital infrastructure that would be required to make underlying study data publicly available in a secure manner, nor the resources needed for researchers in the Agency to use and maintain such a system.

Indeed, the congressional budget office estimated that a similar piece of legislation would cost millions of dollars. Americans need and expect the EPA to use the best available science. Right now, Americans across the country are drinking water contaminated with per- and polyfluoroalkyl substances, or PFASs.

In May, EPA publicly committed to initiating steps to regulate two of the most well-studied, PFOA and PFOS, toxic substances linked to cancer, thyroid effects, and reproductive harm. Some of the best available data on PFOA comes from the C8 Health Project, which involved a community-

wide assessment of 69,000 residents living around Parkersburg, West Virginia, who had been exposed to PFOA for decades. Studies resulting from the project will be critical to EPA as it takes steps to address PFOA and PFOS, yet the censored science proposal would make it difficult, if not impossible for EPA to rely on those studies.

EPA's censored science proposal serves the interest of polluters, not the public. It is designed to undermine EPA's use of critical research, EDF supports, meaning full transparency and science, and the ongoing efforts in the scientific community provide that transparency. But this proposal is not about transparency. It is about rolling back public health protections and environmental protections.

EDF strongly recommends that EPA withdraw the proposed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 7, David Michaels, and Speaker Number 8, Paul Billings, please approach the speaker's table. And Speaker Number 9, Gary Timm, and

Speaker Number 10, Tyler Smith, please take a seat in the on-deck chairs.

MR. MICHAELS: Good morning. My name is David Michaels, M-I-C-H-A-E-L-S. I'm an epidemiologist and Professor of Environmental and Occupational Health at the George Washington University School of Public Health. I'm also submitting a longer set of comments, copies of which I have available.

From 2009 to January 2017, I served as Assistant Secretary of Labor for OSHA, the longest serving in OSHA's history. From 1998 to 2001, I was Assistant Secretary of Energy for Environment, Safety, and Health, charged with protecting the workers, community, residents, and environment in and around the nation's nuclear weapons complex.

As a scientist who has been deeply involved in promulgating regulations that protect the public's safety, health, and environment, I recognize the importance of open science and using the best available science. However, the proposed rule does not accomplish these goals. Instead, it

would make it more difficult for EPA to use scientific findings to protect public health. I have no doubt it would result in more people made sick by pollution or toxic chemicals that would have been prevented in the absence of this new regulation.

This cynical approach proposed by EPA can be best described as weaponized transparency. Decades ago, when studies started to show that smoking killed not only smokers, but also their non-smoking spouses, the tobacco industry recognized the government would use this evidence to reduce smoking. In response, the tobacco industry demanded access to the raw data of these studies.

Big tobacco turned transparency, an important scientific principal, into a weapon. The strategy worked for tobacco for years, helping to delay regulation and increase the death toll from smoking related illness. Since then, polluters and manufacturers of deadly products have followed big tobacco's playbook. First

supporting legislation, and then when that was unsuccessful, this proposed rule.

If promulgated, this regulation would permit the EPA administrator to deny the Agency use of findings of any study unless the raw data and other related materials are provided to the Agency and posted on the Agency's website. There are no constraints on the administrator. She or he is not required to provide any rationale for rejecting a study because the underlying information is not publicly available.

The underlying justification for this quote/unquote, "transparency proposal," is a caricature of how science really works. It is not sound science. It is something that sounds like science, but isn't.

While in theory, most studies could be reproduced, they rarely are because it's a waste of resources. The scientific enterprise involves approaching the same question in different ways to determine if the results support each other. Reanalyzing the same study over and over is little

different from checking on a surprising newspaper article by buying additional copies of the same newspaper to see if it says the same thing.

Under the provisions of the Administrative Procedures Act, the EPA administrator does not have the authority to refuse to consider any comments submitted to the agency. If he or she thinks it's not valid, inaccurate, or inapplicable, she or he must explain why. Under the EPA submissions, including scientific studies, cannot arbitrarily or capriciously be discarded because the underlying data are not provided.

When I was an OSHA administrator, we wanted to protect the integrity of the science used in setting regulations, so we explored asking for conflict of interest disclosures, similar to those requested by every leading scientific and medical journal.

Our legal experts determined that we could request this disclosure, but we could not reject submissions that failed to include them.

This is a comparable situation; rejecting submitted studies because the underlying data are not available is prohibited under the EPA.

Furthermore, many of the EPA's authorizing laws require the Agency to use the best science. For example, the Clean Air Act mandates that air quality criteria accurately reflect the latest scientific knowledge. In the past the EPA has considered all available studies in issuing these criteria without consideration of the availability of the underlying data. Promulgation of this proposed rule would be a violation of these provisions of the Clean Air Act.

When the loss similar to this NPRM was first considered by congress, the EPA told the Congressional Budget Office that it estimated the cost of gathering, redacting, and posting the data on the public website, at $250,000,000 annually. The cost estimate made by the current administration for a substantially similar law dropped to $1 million a year from $250,000,000 a

year, because in the candid shocking words of the CBO, EPA officials explained this approach would significantly reduce the number of studies the Agency relies on when issuing or proposing covered actions.

In summary, by turning scientific transparency into a virtual weapon, the EPA will inflict severe damage to the nation's scientific enterprise. It will undermine the credibility and application of scientific evidence and impose costs and impediments that will discourage scientists from undertaking studies of great importance. Limiting the EPA's use of scientific evidence in the name of increased transparency will impede its ability to protect the health, safety, and environment of the nation. This proposal must be withdrawn.

MS. ORME-ZAVALETA: Thank you.

MR. BILLINGS: Good morning. I am Paul Billings, B-I-L-L-I-N-G-S, National Senior Vice President Public Policy at the American Lung Association. The American Lung Association is the

nation's oldest voluntary health agency. Our volunteer leaders take great pride in that our work is always grounded in the best available science. The American Lung Association opposes this rule and we urge the EPA to withdraw it.

Make no mistake, this proposal is not an effort to strengthen transparency or improve regulatory science. As I will discuss, this proposal is an effort to exclude important studies whose conclusions, especially studies that shows particulate air pollution causes premature death, are inconvenient. Together with the efforts to discount or exclude benefits from pollution reductions, this is a coordinated effort to ignore the science that is inconvenient to EPA's agenda to roll back regulations that reduce air pollution and save lives.

The EPA Science Advisory Board has asked to review the rule under the authority vested in it by the Environmental Research, Development and Demonstration Authorization Act. The SAB sent a letter to the EPA administrator, raising many of

the same scientific issues of confidentiality, feasibility, and the need for a clearer definition of crucial concepts, such as replication and validation. We urge the EPA to fully consult with the SAB before moving forward with this rule.

After the SAB review is complete, EPA should either withdraw the proposal, or provide an additional opportunity for public comment based on that SAB review.

We are disappointed that the EPA has made this proposal. This is not a new fight. It started in the early 1990s, when the tobacco industry tried to undermine the science that supported EPA's landmark risk assessment that showed that second-hand smoke kills. The tobacco industry and its allies lost a decade-long fight about whether or not second-hand smoke causes lung cancer, heart disease, asthma attacks, and other adverse health effects.

We know many of the details the tobacco industry's efforts, because -- as a result of the landmark tobacco litigation, nearly 90 million

pages of tobacco industry documents are housed at the University of California, San Francisco, Truth Tobacco Industry Documents library. Now we know the truth.

Within this archive are documents that show how PR firms, lawyers, and front groups attempted to undermine the credibility of EPA science. The documents show the tobacco industry launched this effort in the name of sound science that not only attacked the second-hand smoke risk assessment, but EPA's efforts to protect the public from ozone air pollution, radon, pesticides, and more. Remember, in 2006, the big tobacco companies were found guilty of civil racketeering for their decades-long conspiracy to defraud the public about the health risks associated with smoking.

The attack on science continued throughout the 90s, when EPA set the first standard for fine particulate matter. The PM2.5 standard. That national ambient air quality standard has saved thousands of lives. This was a

concerted effort by industry and the tobacco industry and their allies, and make no mistake, tobacco industry did not only focus on second-hand smoke. They attacked all of EPA's science. The other polluters came along for the ride and now we're leading that effort.

There was a concerted effort to undermine the Six Cities Study, and the American Cancer Society study. To address the questions being raised, and we just heard from the Health Effects Institute, the HEI, while protecting patient confidentiality, conducted an independent review of the data and these studies. The HEI reaffirmed the results from those studies. These landmark studies were key to informing the rules that cut PM2.5 pollution over the past two decades. Thousands of people are alive, and millions are breathing easier because of those efforts.

These studies depend on patient participation. Protecting patient confidentiality must be paramount and is key to recruiting study participants. This proposal will censor science,

will exclude important well-done peer-reviewed studies that are informing EPA actions, or will threaten that patient confidentiality. This is an unacceptable choice. EPA must use the best science, with within established frameworks, and not limit access to the best science to inform regulatory decisions. We urge the EPA to withdraw this proposal. Thank you very much.

MS. HALL: Thank you, both.

Would Speaker Number 9, Gary Timm, and Speaker Number 10, Tyler Smith, please come up to the speaker's table. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, please take your seat in the on-deck chairs.

MR. TIMM: Good morning. My name is Gary Timm, G-A-R-Y T-I-M-M. I worked at EPA for 38 years and retired in 2011.

I was Chief of the Chemical Testing Branch in the Office of Pollution, Prevention, and Toxics for 10 of those years. The Chemical Testing Branch is responsible for implementing the

testing provisions of Section 4 of the Toxic Substances Control Act.

Today, my remarks will focus on three things. Our studies traditionally used in support of regulation, and vis-à-vis, the proposed transparency policy, it's interaction with TSCA Section 4, and its interaction with our obligations to accept studies conducted in accordance with OECD test guidelines.

Let us be clear, if EPA had adopted this data transparency limitation and past risk assessments, EPA would not have been able to take many of its historic actions to protect children, families, and the environment. No reduction or elimination of the exposure to children to lead and paint, gasoline and drinking water, no air quality standards for particulate matter and other air pollutants, and the list goes on and on.

The proposed policy would affect assessments that will soon be carried out under TSCA Section 6. TSCA gives EPA the authority to regulate the manufacture, processing, distribution

and commerce, use, and disposal of chemicals. The problem formulation documents, which set forth EPA's approach for assessing the first 10 chemicals under the amended TSCA are open for public comment now.

How these chemicals are assessed will be the model for future assessments. The proposed policy would in fact make it impossible for EPA to consider the full array of well-conducted and peer reviewed scientific studies of the health and environmental effects of pollution. It would bias the body of information in favor of industry supplied studies, since they would all have the means to provide the underlying data.

Assessment of all relevant scientific information is essential in making sound judgments about protecting human health and the environment. And it is a legal requirement in all major environmental legislation.

TSCA also contains provisions to require chemical manufactures to test the chemicals that they manufacture and process. To require industry

to test chemicals under Section 4, EPA must make a set of legal findings. It is the data inadequacy finding that we are interested in today, for it is the nexus between TSCA Section 4, and the proposed transparency policy.

To make this finding, EPA conducts a thorough literature search and usually issues a rule to require studies that have not been published to be submitted to the agency. Typically, the bulk of information considered, however, is studies published in the peer reviewed scientific journals. Despite being accepted by the scientific community, these studies do not meet the transparency requirements of the published rule, since it requires that all raw underlying data and the models used to analyze the data supporting their study are available for public review.

Thus, if the Transparency Rule were in effect, under TSCA Section 4's second finding, EPA would have to judge studies from peer reviewed journals as inadequate. Ignoring this large

category of information would cost industry hundreds of millions of dollars to repeat perfectly good scientifically acceptable studies, which the public would ultimately pay for through higher prices. And it would significant delay, or in some cases preclude assessment and regulation of risks to human health and environment.

Another aspect not discussed in the proposed transparency policy is the obligation of the U.S. to accept data generated in accordance with the Mutual Acceptance of Data treaty. The U.S. and other Organizations for Economic Co-operation and Development member countries realize that differences in testing requirements on countries, meant that companies would in some cases have to retest a chemical in order to market it in other areas. This was needlessly costly and resulted in a delay in obtaining information needed for regulatory assessment.

As a result, the OECD member nations agreed to accept, for regulatory purposes, data generated in accordance with the OECD test

guidelines. Submission of underlying data is not a requirement of the Mutual Acceptance of Data treaty. Therefore, the proposed policy which requires underlying data to be made available to be used for risk assessments would run counter to our obligations under the Mutual Acceptance of Data treaty.

In short, the proposed policy is a trojan horse. I can only conclude that this proposal constitutes fraud, as it is deceptive. Waste, rejecting perfectly valid studies and abuse, for it is arbitrary and capricious.

Thank you for giving me the opportunity to provide comments this morning.

MS. ORME-ZAVALETA: Thank you.

MR. SMITH: Good morning. My name is Tyler Smith. I'm a staff scientist at Earthjustice. We are the largest non-profit environmental law organization in the country.

EPA's proposed rule is an attack on the science used to protect children's health. Simply put, it would weaken risk assessments for

chemicals that harm kids. These chemicals include organophosphate pesticides like chlorpyrifos, which EPA scientists long ago concluded present grave risks to children.

Earthjustice therefore urges the Agency to reconsider its approach and withdraw the proposal immediate. Under the Food Quality Protection Act, EPA is required to abide by an additional safety factor of 10 when setting the level of exposure to a pesticide that may harm infants and children. It is well established that children are more susceptible to the toxicity caused by pesticide exposure than adults. The law therefore requires that EPA take this into account and ensure that the most vulnerable among us are protected.

Under the statute, EPA may decide to apply a different safety factor if, and only if it concludes on the basis of reliable data that such margin will be safe for infants and children. The most reliable data, including epidemiological studies conducted in three different perspective

cohorts clearly establish that prenatal exposure to chlorpyrifos and other organophosphates, harms the developing nervous system. This exposure reduces IQ, and it increases the risk of developmental disorders, such as ADHD.

All of this science was peer reviewed prior to publication, and EPA scientists and the independent experts who serve on the FIFRA Scientific Advisory Panel reviewed it extensively and repeatedly over many years. Accordingly, chlorpyrifos risk assessments conducted in 2014, and again in 2016, included the required safety factor, and both assessments found that exposures exceeded the identified levels of concern.

Accordingly, the EPA proposed banning all uses of chlorpyrifos on food in 2015. But last year, political appointees at the Agency disregarded this science and announced that the Agency would not finalize the proposed ban. EPA now may wait years to reconsider. And it appears that the same political appointees who disregarded the science, now want to weaken the chlorpyrifos

risk assessments in advance of their next review.

Indeed, the pesticide industry responded to EPA's conclusions on chlorpyrifos by proposing novel requirements that are strikingly similar to what the Agency now proposes to do for all science. CropLife America, an industry trade association, asked EPA to quote, "Require access to raw data as a prerequisite to relying on any study to support regulatory decisions," unquote. And Dow AgroSciences, which manufactures chlorpyrifos, also complained in comments that the Agency is not quote, "Secured and shared the raw data underlying the epidemiology studies," unquote.

Now EPA did seek a study -- or, I'm sorry, did seek data from a study conducted at Columbia University. However, Columbia determined that it could not provide all of the requested data without violating its obligations to the mothers and children who had participated in the research.

Notably, EPA did not respond to these

concerns by refusing to consider the Columbia study. Rather, scientists from the Agency and Columbia met to discuss the study in greater detail, and the University produced extensive supplemental analysis in response to agency questions.

Furthermore, Columbia offered to make all of the data available to agency scientists for analysis in a secured facility on Columbia's campus. Now these efforts suggest there are numerous alternatives to the rigid requirements the proposed rule would impose on the use of science and agency rulemaking.

As epidemiologic studies of chlorpyrifos support retaining the safety factor to protect infants and children, EPA may believe that such studies fall within the vague definition of dose response data and models contained in the rule. If so, EPA may believe that the continued efforts by Columbia to protect the hundreds of mothers and children who participated in its research preclude the use of these data because they cannot be made

publicly available.

EPA may believe this precludes the use of other epidemiologic studies as well. As a result, this proposal could be used to avoid protecting infants, children, and others from exposure to chlorpyrifos and more than two dozen other organophosphate pesticides. It is simply outrageous that EPA, an agency charged with utilizing science to protect public health, would do the bidding of the pesticide industry it regulates, and try to circumvent its own scientific conclusions by choosing to ignore the best available science.

I urge the Agency to reconsider this proposal and withdraw this deeply flawed rule. Thank you.

MS. HALL: Thank you. Would Speaker Number 11, Eugenia Economos, and Speaker Number 12, Anne LeHuray, approach the speaker's table. And Speaker Number 13, Diana Van Vleet and Speaker Number 14, John Auerbach, please take a seat in the on-deck chairs.

The speakers are reminded to please speak into the mic, and also state who you're speaking for. Thank you.

MS. ECONOMOS: Hi. I am Eugenia Economos, E-U-G-E-N-I-A E-C-O-N-O-M-O-S. I am with the Farmworker Association of Florida. We are a grassroots farmworker organization that's over 35 years old. I say that because it's important to understand that our organization was co-founded by a man who was a farmworker himself. Our staff are almost all former farmworkers. Our board of directors are farmworkers. They're from farmworker families. And I'm here on behalf of our communities who are mostly African/American, Hattian, and Hispanic farmworkers who harvest the food that feed all the rest of us, the food that we eat is harvested by farmworkers in the field who are exposed regularly to pesticides. And I'm here on their behalf.

Our organization is very involved in pesticide health and safety, and in doing that we have participated in community based participatory

research projects, including a four-year project with Emory University that we did. It was funded by NIOSH, and in that study, we looked at farmworkers and in the nursery industry that did ornamental plants in Central Florida, and farmworkers in the fernery industry, which are also ornamental plants.

And we looked at the reproductive health effects of occupational exposures, including occupational exposure to pesticides. We are well-trusted in the community because we are based in our communities and because we are of, by, and for the farmworker communities. And we're able to do these studies because we have the trust of our community members.

In that study with Emory University, we did surveys with 260 women of reproductive age. One of the things we looked at was -- we additionally did urine samples on 100 women, including women that were pregnant, looking at levels of organophosphate pesticides and the pesticide, mancozeb, in their urine.

One of the reasons we chose mancozeb, because that is a fungicide that was implicated in birth defects that happened in Omokollee, Florida in 2004 and 2015, and we wanted to look at the levels of the pesticide in the urine of the women that we studied.

The results of that study showed very high levels of organophosphate pesticides and mancozeb in the urine of the women that we studied, much higher than the NHANES national averages.

We used that information in order to both develop a training for the women about how to protect themselves from pesticides. But we also used that information to write up a paper about -- because mancozeb is coming up for re-review, and we think it's very important to understand the levels that we found of the mancozeb in the urine.

I say that because we would not be able to do that study if we did not have the trust of the people. And we had that trust because we ensured their confidentiality. We would not be

able to do this if there was any sense at all that their confidentiality could be compromised. You're talking about people who are minorities. Many of them are immigrants. They're already under attack in their communities for many other reasons, and if we could not assure their confidentiality, we would not have participation.

I have people come to me all the time with different complaints from their work environments. And it's heartbreaking to me when people come to me and talk about being exposed to pesticides, and then they're afraid to make a report because they're afraid of losing their job, or they're afraid of retaliation.

We would -- we cannot, we would not, we would never engage in studies if we could not ensure that our people, our community would be protected from any kind of revelation of their identities or of their information. So that's why we are opposed to this proposed rule. We're also concerned about that epidemiological data is really important to look at synergistic and

cumulative effects of pesticide exposure, and you cannot find that without doing epidemiological studies. So we are also concerned that we're -- I'm sorry. We're also looking at the body burden of pesticides in the farmworkers that we study, and farmworkers are exposed to multiple different kinds of pesticides. And if you're not looking at epidemiological studies to look at that, then you are ignoring an important role of science in the farmworker community.

I am saying that, I am sitting here, and I just want you to know that even though I'm sitting here, behind me are tens of thousands of farmworkers in Florida and around the country, and I'm here on their behalf. And on their behalf, I'm asking you to reject this rule. Thank you.

MS. ORME-ZAVALETA: Thank you.

MS. LeHURAY: Good morning. My name is Anne LeHuray, L-E-H-U-R-A-Y. And that's Anne, with an E. And I am here as the Executive Director of the Pavement Coatings Technology Council, also I'll call it PCTC.

PCTC, their members manufacture products that are used in pavement maintenance programs to extend the useful life of an asphalt parking lot, for example. Airport surfaces, and the like.

Our members are almost exclusively small family-owned businesses, and their customers, who we also represent, are virtually 100 percent small family -- small and maybe even say micro family owned businesses.

So at PCTC, we strongly support the concept of what EPA is proposing in the "Strengthening Transparency in Regulatory Science" rule, however we urge EPA to go beyond what it has proposed with a goal of improving on EPA's current procedures which lack any meaningful remedies when the Agency relies on science that has been shown to be unreproducible.

The Council supports the efforts of the Agency to ensure that scientific studies, data, and models on which it relies in developing regulations, guidance, and policies are sufficiently transparent. Doing so helps ensure

that others can attempt to reproduce the results in which the Agency bases its regulation, guidance, and policies.

However, the council believes the proposed rule does not go far enough. PCTC has witnessed first-hand the distortions and bad public policy that can result from what has been called in other venues, secret science, by which we mean, science that has been shown not to be reproducible.

And EPA has contributed to this problem. They were not the source of the unproducible science, but they've contributed to the problem by using that unreproducible science, because to use the Agency's words, it is fit for purpose. Meaning, we suppose, that it suits the Agency's desire to regulate, even if the science says that the regulation is unwarranted.

So PCTC's experience causes it to be concerned that the Agency proposes to restrict its increased focus on transparency to only dose response data and models, to only final

regulations, and to only pivotal studies as narrowly defined the proposed rule.

We would note that worldwide scientists and science organizations have recognized the crucial rule of transparency to the very crux of the scientific enterprise, which is, science has to be falsifiable. That means that it has to be reproducible.

At a minimum, the Agency should be as concerned as the publishers of peer reviewed science journals, that all the science it considers is possibly key or pivotal to a right to a regulatory purpose, any regulatory purpose meets the standard of transparency.

EPA's role is to translate and distill research results into regulations, guidance, and policies that have significant impacts in the real world. It is therefore the obligation of EPA to ensure that it uses the best available science, which by definition includes science that has been shown to be reproducible on any issue of any important EPA policy making.

Now to promote the idea of use of reproducible science and transparency, and an understanding in all agency actions, PCTC has two specific recommendations. One is that it gives preference to studies, not just when industry submits a study as part of let's say registering a pesticide, this requires that that study has to follow GLP, Good Laboratory Procedures -- Good Laboratory Practices.

GLP is a formal program. It relies on, like OECD, guidance, methods, test methods. But there's also a thing called the Spirit of OECD, which simply means following good standard scientific practice.

So we recommend and go into detail in our written comments about that the GLP should be given preference in all science that all -- that EPA considers in any of its policy making decisions. And we also have a specific recommendation about how the Office of the Science Advisor should consider combining the roles of the information quality function at EPA, and the

Office of Scientific Integrity, and I thank you very much for your attention and we expand on this in our written comments.

MS. HALL: Thank you very much.

Would Speaker Number 13, Diana Van Vleet, and Speaker Number 14, John Auerbach, please come up to the speaker's table. And Speaker Numbers 15, Harvey Fernbach, and 16, Joseph Stanko, please take a seat on the on-deck chairs.

MS. VAN VLEET: Hello. My name is Diana Van Vleet, D-I-A-N-A, Van Vleet, V-A-N V-L-E-E-T. I work for the American Lung Association, but I am sharing comments on behalf of Health Care Without Harm today.

As the organization leading the global movement for sustainable healthcare, Health Care Without Harm strongly opposes the proposed rule, "Strengthening Transparency in Regulatory Science." The rule would impede the Agency from upholding its mission to protect human health and the environment by limiting the use of scientific research.

It was the EPA's conclusions regarding the human health impacts of dioxin that lead the formation of our organization in 1996. Since then, we have led the charge to transition the U.S. healthcare sector away from medical waste incineration, the leading source of dioxin pollution.

In the United Sates, more than 5,000 medical waste incinerators were in operation in the mid-90s. Today, fewer than 16 medical waste incinerators remain. This work would not have been possible without the EPA relying on sound science to make determinations about the toxicity of dioxin pollution for human health.

Currently, Health Care Without Harm works with hospitals and health systems to transition to renewable energy and to prepare for the impacts of climate change. We look to the EPA to heed the science regarding the human health effects of fossil fuels and climate change when making decisions so that our hospitals are in the best position to protect their patients.

By artificially limiting the research it considers when making decisions, the EPA would endanger health and put lives at risk. We urge the EPA not to adopt this proposed rule.

MS. ORME-ZAVALETA: Thank you.

MR. AUERBACH: Good morning.

MS. ORME-ZAVALETA: Good morning.

MR. AUERBACH: My name is John, that's spelled A-U-E-R-B-A-C-H.

I am a public health practitioner. I've been a leader in the public health field for about 30 years. I was a city health commissioner, a state health commissioner, and an official at the Centers for Disease Control, and currently I am the President and Chief Executive Officer of Trust for America's Health, or TFAH.

TFAH is a non-profit, non-partisan public health and science-based organization that promotes optimal health for every person and community, and makes the prevention of illness and injury a national priority.

TFAH has been focused on issues like

clean air and clean water, because they are fundamental to ensuring that all Americans have the opportunity to live long and healthy lives. This is particularly crucial since we know that unhealthy air or contaminated drinking water disproportionately affect some of our more vulnerable subpopulations, including children, older adults, and lower income Americans who are more likely to include racial and ethnic minorities.

As a component of our mission to promote health we issue a series of reports every year that examine some of our nation's most pressing health issues, and we rely heavily on all available research and evidence to develop recommendations for decision makers on how they can most effectively respond to improve health.

For example, in 2011, TFAH and the Environmental Defense Fund released a report that analyzed the savings and health care spending associated with four different EPA regulations. In so doing, we relied on the EPA's own regulatory

impact analysis that measured reduced mortality, reduced incident of chronic bronchitis, reduced incident of heart attack, and decreased hospital emissions and emergency room visits. These studies estimated that nearly half a million lives could be saved by these four EPA standards alone.

Because of the importance of having access to such scientific data in order to protect the public's health, we oppose the "Strengthening Transparency and Regulatory Science" proposed rule. Research and evidence is the foundation of EPA's policies and has been necessary for success of laws like the Clean Air Act and improving and in saving lives from the dangers of air pollution.

Congress intentionally directed EPA to consider peer reviewed research under the Clean Air Act, and mandates regular reviews of the science to ensure that EPA is reviewing and considering the most up to date science. We believe that the proposal would prevent EPA from using the best science to inform decision-making, and the result would be weaker standards at the

expense of American's health. For example, the proposal would exclude several landmark air quality studies from the evidence base that EPA is permitted to consider, largely on the basis that these studies include confidential patient information that would make them less transparent under the constructs of the proposed rule.

The practical result would be weaker air pollution standards, despite the fact that the science behind these studies is pointing us in the opposite direction. The current methodology and system for review is sound, reliable, and has operated effectively for years. And that's why we have joined with the American Lung Association, the American Academy of Pediatrics, the American Public Health Association, and over 70 additional public health, medical, and academic organizations in opposing this regulation, this proposal.

As a long-term public health practitioner and the President of TFAH, I remain committed to ensuring that federal health policy and practices are guided by the evidence in a transparent and

accountable manner. EPA and other federal agencies should be no exception. We at TFAH look forward to working with congress, with the EPA and others, as we continue to advocate for policies and practices that uphold these principles and protect and promote the health of every American. Thank you very much.

MS. HALL: Thank you very much. If I could ask those that are in the room to please refrain from talking. There's a lot of whispering and it's distracting. If you do need to have a conversation, please step outside the room. Thank you.

Would Speaker Number 15, Harvey Fernbach and Speaker Number 16, Joseph Stanko, please approach the speaker's table. And Speaker Number 17, Peter Lurie and Speaker Number 18, Jamie Wells, please take a seat in the on-deck chairs.

What speaker number are you?

MR. STANKO: Sixteen.

MS. HALL: So, do we have Speaker Number 15? Harvey Fernbach?

[No audible response.]

MS. HALL: Okay, so we'll move ahead.

[Discussion off the record.]

MS. HALL: Number 17, Peter Lurie, would you like to take a seat up here? And then Speaker Number 19, Ami Zota, please take a seat in the on-deck chairs. Thank you.

MR. STANKO: Thank you. My name is Joseph Stanko, S-T-A-N-K-O. Thank you for the opportunity to address EPA's proposal entitled, "Strengthening Transparency in Regulatory Science." My name is Joseph Stanko, and I am counsel to the NAAQS Implementation Coalition.

The Coalition is comprised of trade associations, companies, and other entities who confront challenges in permitting and operating manufacturing and other facilities under increasingly stringent National Ambient Air Quality Standards.

Our members --

MS. ORME-ZAVALETA: If we could ask you to move the microphone a little bit more in front.

MR. STANKO: Sure.

MS. ORME-ZAVALETA: No, the other way. There you go.

MR. STANKO: All right.

MS. ORME-ZAVALETA: Thank you.

MR. STANKO: Our members, and the companies they represent have a proven record of working with states and regional EPA offices on implementing emissions reduction strategies to attain NAAQS.

However, increasingly more stringent NAAQS have caused demonstration requirements for Clean Air Act permits to exceed the limits of current tools and policies for NAAQS implementation. This makes it increasingly more difficult for companies to attain the approvals needed for new state of the art projects that create jobs and bring much-needed tax revenue to local communities.

Without a transparent NAAQS process, underlying studies lack robust external review, leading to standards that may not provide

objective public benefit. In certain cases, increasingly stringent standards have pushed NAAQS to concentrations at or near background levels, beyond the feasible limits of implementation. While inaccurate assumptions in both setting and implementing NAAQS could be more readily absorbed under prior less stringent NAAQS levels, recent more stringent standards have eroded such tolerances.

Addressing this new reality starts with an inherently forward-looking NAAQS review process that assesses science and policy in a rigorous and holistic manner. The transparency proposal fosters such an open-source approach to pivotal regulatory science, one that enables the public to more meaningfully comment on the science underlying NAAQS review. This can foster a more effective NAAQS implementation that still meets the Clean Air Act's mandate to protect public health.

While we support the principles behind the transparency proposal, its sound policy goals

should be balanced with legal and ethical obligations to protect private, sensitive, and confidential information. As the transparency proposal is implemented, efforts must be made to address protected health information under the Health Insurance Portability and Accountability Act, or HIPAA.

Disclosure limitations also exist for proprietary information and trade secrets. We agree with EPA that dose response data and models should be exempt from public review as necessary to protect private, sensitive, and confidential information. However, we believe that EPA can protect such information while still seeking maximum possible transparency.

As the transparency proposal notes, many generally acceptable techniques exist to deidentify personally identifiable information. Where such deidentification is not possible, EPA could facilitate review of sensitive data sets by a diverse group of experts subject to HIPAA compliant nondisclosure agreements.

If all other options to expand review have been exhausted, EPA could decide that a study could not be subject to outside review and verification, and consider the study accordingly without excluding it from a rulemaking proceeding.

Administrations -- administrators pardon me, have regularly taken similar methodological considerations into account when assessing studies in past NAAQS reviews. EPA could further balance transparency and privacy by appropriately tailoring the transparency proposal according to the type and scope of the regulatory decision involved. For this reason, we agree with EPA that the transparency proposal should be limited to pivotal regulatory science that is involved in significant regulatory actions that result in substantial costs.

To that end we note that because Clean Air Act regulations have accounted for the vast majority of costs and benefits cited in rules over the last decade across the entire federal government, such regulations are particularly well

suited for the transparency proposal's high standard of robustness.

As this process moves forward, we encourage EPA to further detail how the transparency proposal will protect private, sensitive, and confidential information, be it personally identifiable or proprietary information, trade secrets, or other similar information. To that end, EPA should explicitly state that any final regulations arising from the transparency proposal do not support or assert authorization under the law to disclose such currently protected information, and that any claim to do so must be independently based on a statutory grant of authority from congress.

In conclusion, the transparency proposal would increase replicability and verification in the scientific process, thereby testing critical methodological assumptions and mitigating biases in key studies upon which the Agency relies in developing regulations. It recognizes that transparency can go beyond simply maximizing

disclosure to better contextualizing studies through replicability and verification.

In doing so, the public can more meaningfully take part in EPA notice and comment rulemaking processes. As EPA advances the transparency proposal, it can and should implement these sound policy goals in concert with obligations to protect private, sensitive, and confidential information.

The NAAQS Implementation Coalition appreciates EPA's efforts on the transparency proposal, as well as the opportunity to present its view on the topic.

MS. ORME-ZAVALETA: Thank you.

MR. LURIE: Hear me? Good morning. My name is Dr. Peter Lurie. I'm a physician, an epidemiologist, and now the President for Center for Science in the Public Interest. We are an independent science-based health advocacy organization with over 500,000 members.

Before I joined CSPI, I served at the FDA as an associate commissioner and in fact, for

several years I led the Agency's transparency initiative. Over the course of my career I've authored close to a dozen academic articles on the topic of transparency, and nobody ever asked me for the underlying data for any of those studies.

We at CSPI are firm advocates of scientific transparency and have had a number of projects along those lines over the years. But EPA's proposed rule is not about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep's clothing of transparency in science. Proposal should be withdrawn.

Transparency is not about restricting the use of sound science, as this proposal would do. Suddenly, the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be the grounds for the summary exclusion of data that were rigorously gathered and reported.

The surest tests of any scientific transparency policy are two. One, was it generated in a transparent fashion? And two, will it actually promote the transparent rigorous science-based decision-making that it claims to? This proposal fails on both counts. Let's start with the procedural matter.

This proposal violates fundamental tenents of transparency rulemaking. EPA failed to consult with relevant stakeholders, such as science, research, or health professional associations, did not consult with other federal agencies who would be affected by this, and did not even make the proposed rule available to its own Scientific Advisory Board for review.

In addition, the proposal lacks critical citations and documentation, or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the Agency has merely adopted a legislative initiative that failed to (indiscernible) despite support from the energy,

chemical, manufacturing, and other key industries.

Moreover, despite its professed (indiscernible) to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply blithely asserts that, quote, "EPA believes the benefits of this proposed rule justify the costs." I wish we could have gotten away with that at FDA.

But the rule would be costly indeed. Analysis of an earlier version of the legislation predicted costs of $250 million over the next few years. But even more important, the proposal does not meet its purported scientific goals and will instead undermine the scientific basis for decision-making at EPA.

Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA's greatest public health accomplishments, such as eliminating lead and gasoline, classifying second-hand smoke as a

cause of cancer were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. And I can say, at FDA, we would not have had the rules that we ultimately developed or proposed on mercury in fish, on arsenic in rice, on dental amalgam, or in sodium targets from a nutritional perspective. None of those could have been done if data of these kinds were eliminated.

In particular, it's also especially troubling that the proposal also opens the door to a reconsideration of past rules which would be utterly inappropriate under prevailing principles of administrative law. In fact, the proposal would have an effect opposite to its claimed purpose. It would address -- it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry.

Further evidence of the pro-industry orientation of this proposal is its discussion of the dose response function and the assault on linearity. Quite aside from the merits of that discussion, which I think are few, the real question is, what is this discussion doing in this proposal in the first place. It has nothing to do with transparency whatsoever, and it's simply there as a marker, in my view, of the pro-industry bias that this entire enterprise represents.

Let me close with a question with which EPA should have started. What exactly is the problem that this proposed rule seeks to fix? Where indeed is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard?

To the contrary, the record is replete with studies that form the basis of health and life saving regulations that would now be precluded from use, and that might even provide a basis for the revocation of rules enacted in the

distant past. Thank you.

MS. HALL: Thank you. Would Speaker Number 18, Jamie Wells, and Speaker Number 19, Ami Zota, please come up to the speaker's table. And Speaker Number 20, Surbhi Sarang and Speaker Number 21, Laura Bloomer, please take a seat in the on-deck chairs. Thank you.

Please, quick reminder to speak into the mic and state your organization.

MS. WELLS: My name is Dr. Jamie Wells, J-A-M-I-E W-E-L-L-S, and I'm the Director of Medicine for the American Council on Science and Health, and I'm here on behalf of our president, Hank Campbell.

In the past, peer-reviewed journal publication ha been considered authoritative, but that has inherent weakness if they can't be replicated. Knowing the potential for error, and even misuse, replication is vital, but we recognize that that's not always possible. A safety valve for that is a higher level of scrutiny when it is not possible. Studies that

can't be replicated should at least make sense within the pattern of available data, which in the case of EPA will often include hundreds of other studies done according to federal guidelines.

However, there are also occasions where replication is not possible and new claims or outliers from the consensus of many other studies. And in those cases, they should still absolutely be used if EPA risk scientists, without breaking confidentiality, can obtain the additional information needed in order to conduct their own analysis.

EPA risk scientists are charged with protecting public health, and the American Council on Science and Health has argued since 1978 that the judgment over which epidemiology and/or toxicology data to use for risk or safety assessment should always include risk scientists. The public's interest is best served when science is replicable and consistent with other information.

On occasions, when studies cannot be

replicated, or when such studies are not consistent with other information, use of those studies depends on having access to the underlying data for independent analysis. When the underlying data are not provided, it is difficult to make a credible risk assessment, much less national rulemaking, as you know. So risk experts should be involved.

You should have received a more extensive written document as well.

MS. ORME-ZAVALETA: Thank you.

MS. ZOTA: I'm Dr. Ami Zota, that's A-M-I, last name Z-O-T-A. I am a health scientist and Professor of Environmental and Occupational Health at the George Washington University Milken Institute School of Public Health. I am also speaking as part of Project Tender. We are an alliance of scientists, health professionals, and advocates with expertise in protecting children from exposure to toxic chemicals that can contribute to neurodevelopmental problems, such as ADHD and learning disabilities.

I oppose EPA's proposed rule. The proposed rule prohibits the Agency from setting regulations that are support in part or whole that is for data that is publicly available for reanalysis or cannot be replicated.

Since the proposed rule is retroactive, it could lead to the dismantling of many important existing EPA regulations that safeguard our children and families -- children and families from toxic chemicals.

I would like to spend my time identifying some of the major problems with this rule that warrant consideration before the Agency moves forward. The scientific sources cited for the basis of this rule do not support the proposed rule. EPA did not consult with critical stakeholders in the development of this proposed rule, including scientists, health professionals, and affected communities.

EPA does not present any analysis of benefit-cost, children's environmental health risk, or environmental justice in support of the

rule which are required under executive orders 12291, 13045, and 12898. The terms, pivotal regulatory science, replication, reproducible, and research data are not defined or are problematic. The rule's requirements for specific types of defaults, test methods, dose response models, and/or analysis are not supported by current science.

The rule is counter to the mandates in the reformed Toxic Substances Control Act, or TSCA, to use the best available science and systematic reviews for chemical evaluations.

Data deidentification and masking techniques cannot ensure confidentiality and can degrade the accuracy of data for further analysis. The rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human data.

For example, in many cases individuals' participant data cannot be made public because of confidential requirements legally mandated by institutional review boards and/or the Health

Insurance Portability and Accountability Act of 1996, or HIPAA.

In conclusion, EPA should withdraw this proposed rule immediately. EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at the federal government. Thank you.

MS. HALL: Thank you.

Would Speaker Number 20, Surbhi Sarang, and Speaker Number 21, Laura Bloomer, please come up to the speaker's table. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please take a seat in the on-deck chairs. Thank you.

Speakers, please remember to speak into the mic and state your organization.

MS. SARANG: My name is Surbhi Sarang, spelled S-U-R-B-H-I S-A-R-A-N-G, and I'm a legal fellow at the Environmental Defense Fund.

I appreciate this opportunity to provide public testimony on the proposal and hope that everyone who wises receives an opportunity to be

heard. We urge EPA to hold hearings in additional locations to allow affected Americans in other communities who cannot travel to be here today, an opportunity to provide input as well. I'm testifying here today to raise our serious concerns of the proposed rule and to ask that the EPA withdraw the proposed rule immediate.

Communities across America rely on EPA safeguards to protect their health and wellbeing. But this rule would greatly restrict the body of scientific information that EPA draws on when setting these safeguards. Instead of being informed by all available science, in many cases EPA would be forced to operate in the dark. By obliging EPA to disregard scientific research that would otherwise alert the Agency to taking strong protective actions, this rule endangers the health of all families and communities. Had this rule been place previously, we would likely currently be facing greater exposures to air pollutants, water contaminants and toxic chemicals.

In the proposal, EPA completely ignores

the practical effects of the proposed rule and how it fundamentally conflicts with EPA's mandate to use the best available science as it develops safeguards.

Agency decisions must be informed using the best available science. Public deserves nothing less when health and safety are on the line. This value is core to EPA's mission and should be placed at the forefront.

But the proposal takes an unsupported and unprecedented leap by suggesting that this mission allows EPA to only use science where the underlying data and models can be made and are made publicly available for independent validation. Much of the data underlying scientific studies concerning human health cannot be made publicly available for legitimate privacy and confidentiality reasons. In many cases, it is impossible even to redact information in a manner that allows independent validation while respecting privacy and confidentiality.

Thus, the proposal would seriously

restrict EPA's ability to use the best available science as it sets critical safeguards. Nor does EPA explain why such restrictions on the use of science are necessary. EPA does not point to any instance in which a failure to disclose data resulted in an EPA decision or standard that lacks scientific integrity.

EPA does not explain why other means of vetting that are used by the scientific community and that protect privacy and confidentiality, such as review by EPA's independent Science Advisory Board, peer review, and corroboration through independent studies are insufficient to ensure the integrity of the science EPA relies on. And EPA does not explain why it is appropriate for an agency tasked with basing its decisions on best available science to now discard otherwise valid science simply because a disclosure is not possible.

Indeed, courts that have examined the issue have made clear that it is entirely reasonable for EPA to rely on scientific studies

which data cannot be disclosed. While EPA states in the proposal that many organizations have endorsed data disclosure as a means to increasing transparency, the reality is the proposed rule completely departs from good scientific practice. None of the organizations EPA identifies in the proposed rule have endorsed the practice of disregarding studies where data disclosure is not possible, or that have been subjected to other means of validation, or suggested that regulatory agencies should exclude such studies when using science to inform regulatory actions.

To the contrary, organizations that are deeply committed to transparent science have come forward to stress that policies to promote transparency must be developed within the scientific community and to oppose the notion of disregarding otherwise valid science, simply because the underlying data cannot be disclosed.

Indeed, EPA's own Science Advisory Board, which it failed to consult before issuing this proposal, has raised concerns similar to those we

raise here, noting that EPA provided no analysis of the impact of losing the ability to run on these studies, and that there are other ways to assess the validity of studies without access to data. Not only did EPA skip over review by the Science Advisory Board, but then EPA allowed for only a 48 (indiscernible) review process for the proposal.

This hastened process seriously calls into question the validity of the proposal. The proposal would not even increase transparency. By allowing the administrator to grant exemptions based on vague and discretionary criteria, the proposal would allow EPA to selectively apply this disclosure policy with no public record of the decision or its basis. The risk that the rule will artificially restrict and distort the scientific basis for EPA's decisions is only heightened by its many gaps.

The proposal fails to explain critical details, such as what mechanisms would be used to make data public, what the cost of the Agency and

to researchers would be, and how the peer review provision would fit into EPA's existing peer review requirements. It is not even clear how EPA would determine that a given study is publicly available in a manner sufficient for independent validation. This underscores concerns that this proposal would undermine the integrity and transparency of EPA decisions rather than enhance them.

It is also important to note that this rule was posed under former Administrator Pruitt who actively obscured transparency goals by directing the removal of scientific information from EPA's websites, refusing to publicly release his full and accurate schedule, using secret e-mail addresses, and spending tax payer money in violation of federal laws.

While Pruitt is now gone, this proposal unfortunately suffers from the same disregard for scientific integrity and transparency that infused the former administrator's tenure.

We thus call on Acting Administrator

Wheeler to recognize the redeemably flawed basis for this proposed rule and withdraw it immediately.

MS. ORME-ZAVALETA: Thank you.

MS. BLOOMER: My name is Laura Bloomer, B-L-O-O-M-E-R, and I'm a student at Harvard Law School and the Kennedy School of Government. I am interning at EDF, Environment Defense Fund this summer. I am here testifying on my own behalf.

I am the daughter of two parents who grew up near auto industry towns in Michigan. My mom was born in Flint. Her parents, my grandparents, grew up in Flint and chose to raise their four children there.

Though I'm a proud Texan, as my family moved to Houston when I was in elementary school, most of my family continues to call Michigan home. The Flint water crisis was personal for us.

My aunt, a dental hygienist, volunteered and delivered water to Fling residents after the story broke. She understood the heart wrenching fear a mother would experience when she found out

her child had been drinking contaminated water. She understood the outrage of her home community when they found out that the government they trusted did not care enough to keep their drinking water safe. She understood what it might feel like to have a fundamental safeguard, like clean water, suddenly disappear.

But the water crisis in Flint did not disappear when it left the nightly headlines. Just last week, my mom went to her favorite hotdog shop in Flint and sent me a photo of a poster from the restaurant. It was an advertisement for healthcare, aimed at mothers of children who grew up drinking contaminated water. My mom was devastated.

And though the Flint water crisis is more salient and more visible than this proposed rule, the impacts are far too similar. For decades the EPA has relied on first-rate science to establish protections for our air and water, and most importantly for our public health.

It is because of these safeguards that I

have never experienced the type of pollution my mom describes from her childhood. It is because of incredible researchers and scientific discoveries that many of our communities will never experience a water crisis like Flint is still experiencing. It is because EPA regulates lead in our drinking water, and arsenic in our drinking water, and the many other contaminants that harm our most vulnerable populations that my friends and I grew up in a healthy environment.

It is because EPA has a responsibility to seek out and utilize the best available science at every step of the way, that the next generation of children will be protected from threats to their health as well.

Yet right now, in 2018, when our science has never been more advanced, and when EPA is considering revising the Lead and Copper Rule for drinking water, EPA would choose to voluntarily ignore the best available science. This proposed rule would severely limit the studies on which EPA could rely. It would threaten the enormous amount

that EPA and engaged citizens have accomplished, and it would hamstring any progress we hope to make in the future.

This rule isn't about transparency, and it was not developed with people like my family and me in mind. For the safety of all of us and for future generations, I respectfully ask that this rule be withdrawn. Had this rule been in place decades ago, more communities might be suffering from the same threats to public health that Flint is now facing. Many of EPA's drinking water standards rely on epidemiological studies. Often these studies last decades and follow hundreds, if not thousands of patients, collecting confidential health data, as well as other personal data, like the people's addresses, ages, and genders.

For most of these studies the underlying data cannot be made public, even in redacted form, without sacrificing the participants' privacy. These studies are monumental and state of the art. These are the studies that EPA should hope to rely

on, not the type of studies the EPA should shun. These are the studies that will guarantee that communities don't suffer from the devastating impacts of dirty water and polluted air. Studies like these establish the original limits for lead, and this research continues to essential today.

This proposed rule may seem abstract, but it is anything but that. And it is extremely significant. It will have far-reaching -- far-reaching impacts on the ability of EPA to protect all of us and our families. And it could affect our most important environmental safeguards. It is extremely personal, for my mom, for my family, and for me.

I am here today to ask you to withdraw this proposed rule and recommit to EPA's mission of protecting human health and the environment. Thank you for the opportunity to speak today.

MS. Hall: Thank you. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please come up to the speaker's table. And Speaker Number 24, Michelle

Endo and Speaker Number 25, Jenny Xie, I think, please take a seat at the on-deck chairs.

[Substitution of panel members.]

MR. ROBBINS: Good morning. I'm Chris Robbins. I'm the Acting Deputy Assistant Administrative for Management in the Office of Research and Development.

MS. ORME-ZAVALETA: Good morning.

MR. ROBBINS: Thank you.

MS. DOA: Good morning. My name is Maria Doa , I am in the Office of Research and Development.

MS. WITHERSPOON: Good morning. I'm Nsedu Obot Witherspoon. I'm the Executive Director for the Children's Environmental Health Network. My name is spelled N-S-E-D-U O, B as in boy, O-T W-I-T-H-E-R-S-P-O-O-N.

For over 26 years, the Children's Environmental Health Network, also known as CEHN, has been a national voice committed to protecting all children from the harmful effects of environmental hazards, and to promoting a

healthier environment.

CEHN educates decision makers and advocates for evidence-based child protective policies. We also ensure that those who care for children, personally or professionally, have the information they need to take the steps to reduce children's exposures to harmful toxicants.

As the Executive Director, and on behalf of CEHN, I appreciate the opportunity to provide these comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science."

CEHN is strongly opposed to the rule and is concerned that it will adversely affect EPA's ability to use the best available science in decision-making, and negatively influence existing and future protections for children's health, such as clean air, clean water, and the prevention of toxic exposures.

The exposed rule sets transparency standards that are too rigid and impossible to meet. It requires that all data used in

rulemaking be publicly made available, and allows EPA to exclude data that relies on confidential patient information. Critical studies which have led to significant advancements in protective policies, for example from the NIEHS, EPA's Children's Environmental Health, and Disease Prevention Research Centers may very well be excluded.

The scientific research that EPA uses already undergoes a long-established transparent review process, and makes available the scientific studies it relies on to inform policy. Sometimes studies contain private medical data that legally can't and should not be made public. In those cases, independent review bodies have also examined the studies and weighed in on the research. No legitimate reason exists to exclude those studies and their critical important findings.

Health based research involves people and often the collection of private information. There are no systems in place to protect this

information. The federal government must continue to protect private information about patients, and not allow this information to be made public. Otherwise, patients will not participate in these important studies.

Further, redacting personal information actually sounds easy, however, it is cumbersome and quite costly. EPA will not likely have the resources to redact personal information resulting in exclusion of critical studies.

The proposed rule would restrict EPA's ability to set regulations informed by confidential data that cannot be replicated. This is of serious concern because for many older, long-standing landmark studies, the original data sets were either not maintained, or stored in out of date formats. These could be eliminated under this proposed rule.

The proposed rule could block the use of studies on the harmful impacts of toxic exposures and pollution. Studies which were instrumental in the Clean Air Act, the Safe Drinking Water Act,

and the -- excuse me, Food Quality Protection Act, among many others. We do request that you withdraw this proposal, "Strengthening Transparency and Regulatory Science." If the proposed rule is implemented, an inevitable consequence is that children that could have been protected from chemical exposures will lose those opportunities.

Irreversible damage to children in their growth and development, loss of intelligence, behavior modifications, and overall life achievement is the future ahead, and I would hope, not the legacy that this EPA would like to preserve. Thank you very much.

MR. ROBBINS: Thank you.

MS. ZURCHER: My name is Joanne Zurcher, J-O-A-N-N-E Z-U-R-C-H-E-R, and I'm representing the National Environmental Health Association.

Good morning. Thank you for the opportunity to speak to you on behalf of the environmental health professionals from across the country who've vigorously opposed the Censoring

science rule.

My name is Joanne Zurcher, and I am the Director of Government Affairs for the National Environmental Health Association, NEHA.

Environment health is profoundly local. Simply put, it's the cleanliness of the water from the kitchen faucets. It's the safety of the food we feed our families, our friends, and ourselves. It's the air the children breath during the 1,600 hours they spend inside their schools. It's the cleanliness of our community beaches that our families are spending the summer enjoying.

When things go well, environmental health is not on the front page of the *New York Times*, because environmental health professionals keep us safe every single day.

NEHA has over 7,000 members. Our members anticipate, recognize, evaluate, and control hazards that are likely to cause harm, serious illness, or even death to American families. Examples include lead, radon, legionella viruses, harmful algae blooms, PFOA, PFOS, Zika viruses,

and many other natural and man-made risks. Our members possess strong science and math backgrounds. They must take over 30 units of undergraduate math and science just to sit for our exam. They have the unique ability to work with clinical and nonclinical professionals. They know and work with the regulated community. They are credentialed members of the profession, and the NEHA credential is considered the gold standard.

EPA science is the foundation for informed decision-making for our members. Our members turn to the EPA for best practices. Our members rely on EPA research to promote their community's health.

Our communities see EPA as the shelter of scientific certainty in an era of uncertainty. Our members rely on EPA expertise, whether it's continuing -- excuse me, containing mercury spills in their homes, setting standards to keep toxic chemicals out of drinking water, or cleaning up super fund sites, just to name a few of the few activities we do together. EA professionals work

closely with the EPA every step of the way.

The EPA has administered successfully, the Clean Water Act, and the Clean Air Act, and these acts should be expanded based on scientific research. The EPA should not be working to undermine scientific research. Instead, this EPA should be working to provide running water to the 630,000 American families who do not have running water in their homes.

Let's be clear, this proposed rule undermines the EPA's mission to protect human health. Now is not the time to compromise health of our nation by casting a shadow of uncertainty on the integrity of the EPA -- of EPA's research.

EPA research is globally recognized as the foundation for informed decision-making that affects every person the plant. NEHA and it's 7,000 members are in every community and territory in the nation. Every EH professional relies on EPA research to ensure constituents meet human -- meet their human potential.

The current research system works, which

at once protects the identity of every research participant, while promoting the health of every American. Health research sometimes includes sensitive data from patients, such as medical history and geographic location, which must be continued to be private and protected. Crucial volunteers will cease to come forward for scientific research if their medical history and geographic information will be made public, thus putting critical scientific research at risk. Please do not destroy a national gem, our EPA research, because you, your family, and your community deserve no less than a fully functional research system that protects and identifies research subjects while promoting the health of the nation.

NEHA and the environmental health professionals from across the United States vigorously oppose the censoring scientific rule. Thank you for this opportunity to be heard on this important topic, and please remember, do no harm.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 24, Michelle Endo, and speaker Number 25, Jenny Xie, come up to the speaker's table. And Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, please take a seat at the speaker's -- well, at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. ENDO: My name is Michelle Endo, E-N-D-O, and I'm speaking in a personal capacity, but I'm an intern at the Environmental Defense Fund.

So my name is Michelle Endo, and I'm a second-year student at Georgetown Law. I'm also a legal intern at the Environmental Defense Fund here in Washington, D.C. I'm here today to offer comments on my own behalf and to present my grave concerns with EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

I'm a fourth generation Southern Californian who lived the first 18 years of my life in Northern Los Angeles County. And while I'm proud to be from the Golden State, it also

means that I grew up breathing some of the worst air pollution in the nation. Despite tremendous improvement, 70 percent of Californians live in an area with unhealthy air. As a result, I also grew to be familiar with the dangers of air pollution and the importance of health-protective regulation.

My family lives in a town that, like much of LA County, is in the United States 98th percentile for tropospheric ozone, according to EPA's own Environment Justice Screen.

Tropospheric ozone, commonly referred to as smog, is the visible layer of air pollution that gives LA sunsets their famous striped hues. Several studies have consistently reported there is a significant association between ozone pollution and premature death. According to the American Lung Association, long-term exposure to ozone pollution is also linked to developmental harm, reproductive harm, cardiovascular harm, and increased susceptibility to infections.

While I never had a snow day before

moving to D.C., like most SoCal kids, I'm very familiar with bad air days. Instead of playing outside and building snowmen, children in Southern California lose all outdoor playtime on bad air days in order to avoid the harmful effects of smog. Coughing, impaired athletic performance, eye irritation, chest pain, nausea, headaches, and respiratory congestion.

Smoggy days can also worse asthma, heart disease, bronchitis, and emphysema.

My sister and I enjoyed the early years of childhood with fewer complications relative to my neighbor peers. But before even starting high school we both had missed days of school for nose bleeds that were likely triggered by the irritating smog that settled in the valley, and because ozone forms by the interaction of sunlight with hydrocarbons and nitrogen oxides emitted from cars and trucks, bad air days tended to worse each year, our Southern California summers, broke standard heat records of years before.

Shortly after my sister joined the high

school soccer team, my family started to notice that her once limitless stamina on the field was wearing down. One particularly hot and hazy day, she had no choice but to walk off the field in the middle of the match. Clutching her chest, she struggled to breath. We later learned that she had developed asthma from LA's unhealthful smog, like many of our friends and family in the area.

It was experiences like this that motivated my decision to study environmental policy in college, and that continued to drive my legal career. Having witnessed first-hand the way in which the geography of where one lives, plays, learns, works, and grows determines one's health outcomes, I could not have chosen another path in good conscience.

When I first chose this path, over eight years ago, my hope was to strengthen the laws and regulations that did not go far enough to protect my family and our environment.

Under the Clean Air Act, EPA was required to establish and regularly update federal

standards for hazardous air pollutants, including asthma-causing particulate matter and ozone. These standards and the National Ambient Air Quality Standards or NAAQS, form the backbone of our nation's air quality protections. Although the NAAQS did not prevent my sister's asthma, they have and continue to bring about substantial improvement in our nation's air quality since their first formulation.

The EPA's proposed rule would have excluded peer review studies that form the scientific basis of NAAQS. For example, peer reviewed studies would be excluded because the underlying data and models cannot be disclosed, even in partial form. In fact, the standards would not have been issued had the proposed rule been in place when they were first enacted in the 1970s, because EPA would have tossed out the underlying studies, tying its hands from taking action in imminent public health concerns.

Without a doubt, many more Southern Californians would have had their lives altered,

or even cut short by dangerous levels of air pollution.

If adopted, the proposed rule would deprive EPA policy makers from real world evidence and studies that are vital to the EPA's review of the NAAQS into the future. Further, the proposal directly contravenes the comprehensive federal and state regulatory program congress envisioned when drafting the Clean Air Act of 1970. It reduces our public health legislation to mere declarations, as EPA would severely delayed if not rendered entirely unable to establish future standards using the best available science.

Generations before me, through legislation like the Clean Air Act, recognize that public health and environmental pollution required strong federal leadership and expert agencies like EPA. Departing from the Agency's practice of scientific review for over the last 40 years, practices aligned with national and intergovernmental bodies, like the Royal Society of Medicine, and the World Health Organization,

jeopardizes EPA's ability to utilize its expertise with high cost to people's health.

It is therefore troubling that the Agency has proposed to take this action under the guise of scientific integrity without consulting its own panel of scientific experts, the Science Advisory Board, and against the advice of leading scientific journals and organizations. It is even more troubling when considering the Agency's recent practices toward the public and the press, which have been far from transparent.

To me, it is clear the proposal's purported goal of transparency is a pretext for the Agency's attempt to shirk its statutory command. For the health of my sister, my friends, and all Americans, I urge EPA to abandon this proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. XIE: Good morning. My name is Jenny Xie, J-E-N-N-Y, last name X-I-E, and I'm a policy intern at the Environment Defense Fund, but I'm here today speaking from a personal capacity to

express my personal opposition to EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

Many of the activities that I am involved in on campus involve holding the university accountable for its environmental goals that it has set. I'm currently a student at Cornell University, studying English and Environmental Sustainability Sciences.

In fact, one of the main initiatives that I am involved in calls for the University to disclose as a financial investments and fossil fuels in order to increase transparency, have accountability, and maintain integrity as it works towards its carbon neutrality. It is therefore incredibly disheartening to hear that this EPA administration is championing a proposed rule that claims to be for increased transparency, when in fact the purpose and the fact of the proposed would be to bar EPA from considering rigorous public health science and reduce the transparency of EPA's scientific analysis.

The proposed rule would require the EPA base some of its most important regulatory decisions only upon does response studies where the underlying data can be disclosed. The reality is that key scientific studies backing our nation's critical clean air safeguards which protect our health and environment are based on confidential patient data that in many cases cannot be disclosed in any form.

These rigorous peer-reviewed state of the art studies could be improperly discarded should this rule be finalized. As many scientists have noted, this would undermine and not promote the use of sound science in EPA decisions. Just because the data underlying a study isn't published does not mean that the study cannot be verified using other means.

For example, the American Cancer Society's Cancer Prevention Study II, tracked air pollution, exposure, and personal medical histories of nearly 670,000 people for more than two decades to understand the exact risk of air

pollution on death.

The study was based on private patient information that cannot be publicly disclosed, and yet the study has been subject to reanalysis and its conclusions have been upheld. And allowed under the scientific journal does response, the authors listed 16 key studies alone which supported the original conclusion of the Cancer Prevention Study 2.

Even more concerning is the fact that the proposed rule provides the administrator with broad discretion to make exception to the policy on a case-by-case basis. Former Administrator Pruitt may be out of office now, but Acting Administrator Wheeler's record as a fossil fuel lobbyist for corporations like Murray Energy leaves me and others incredibly skeptical that this rule would be applied fairly with no concrete criteria guiding decision to grant an exception.

This part of the proposal raises a serious risk that this or future administrations could selectively waive the policy to build a

distorted scientific record that is designed to reach a desired result. In fact, just a few weeks ago I was in Pennsylvania where I'm from, talking to an Uber driver. He's a father with a daughter who has asthma, and we talked about the EPA. He had worked in public service before and expressed to me how frustrated he was with the current administration, with the EPA, and how it seemed that despite the endless promises the administration has made to protect its citizens and better our lives, many of those promises were not being fulfilled.

I can't help but think how disappointed he would be if he knew that the EPA has proposed a rule which will make it more difficult for EPA to use the best science to protect the health of him and his family. Citizens are watching and aware, from parents, to scientists, to students like me who advocate for good policy on their own college campuses.

The EPA hastily shuttled this rule past even the OMB, but it must pause to hear the

concerns of the public. EPA's proposal will lead to censored science, not transparent science. Thank you for the opportunity to testify on the proposed rule today.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, come up to the speaker's table. And Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, please take your seat at the on-deck chairs.

MS. MESNIKOFF: Hi. I'm Ann Mesnikoff. It's M-E-S-N-I-K-O-F-F, and A-N-N, no E.

Good morning. I'm Ann Mesnikoff. I'm the Federal Legislative Director for the Environmental Law and Policy Center.

ELPC works throughout the Great Lakes and the Midwest, protecting public health and special places under the belief that environmental protection and economic development can be achieved together.

ELPC appreciates the opportunity to

testify in opposition to EPA's proposal to censor, or otherwise constrain the science it will consider in issuing essential standards that are meant to protect public health and our environment. The Midwest and the Great Lakes region, with its industrial and agricultural heritage is impacted by environmental and public health challenges to air, land, and water, and we depend upon EPA to effectively implement environmental laws to protect the public and our environment.

There is no basis in existing bedrock environmental laws that authorizes EPA to limit science considered in rulemaking processes. EPA cites several key laws in its justification for this proposal. Nowhere in the cited statutes is there a basis for demanding access to raw data, nor does this relate sensibly to any definition of best available science. Rather, this undermines the use of best available science called for in environmental statutes, including the Clean Air Act.

Further, there is no basis for politically appointed administrators to choose which science will be considered, and which may not be. EPA should continue to apply the rigorous standards the Agency has used for decades, and that stakeholders engage in the process that is full and open with regards to science.

EPA's Science Advisory Board voted to review this action during its June 1st meeting. This proposal has also prompted, as we've heard today, vehement reaction from the scientific community. EPA's proposal is not about transparency. It is about undermining public health. The negative effects of this proposed rule on EPA's programs could be far reaching across the Midwest. Midwesterners are exposed to unhealthy levels of air pollutants, including particulates, ozone, and toxic emissions from our industries and agricultural operations.

Achieving and maintaining health air to breath remains a challenge. EPA just finalized not attainment designations for Midwest's biggest

cities. There are millions of people -- where millions of people live, work, and play. Foundational studies about the impact of air pollution to public health are essential. These studies have been reviewed numerous times. Yet, under EPA's proposal, they would be ruled out of bounds, compromising the Agency's ability to truly assess the impacts of air pollution and to set standards are a level that will protect public health as the Clean Air Act requires.

Weaker standards will mean dirtier air in our communities. The elimination of these studies would also skew the evaluation of cost and benefits, leading to less protective rules that will not be based on a true accounting of the public health costs of pollution. We're also concerned about how EPA's proposal to censor science will impact a range of other significant concerns across the Midwest and Great Lakes, from using the best available science and its review of toxic -- the toxic insecticide, chlorpyriphos, the impacts of growing problems of harmful algael

blooms in Lake Erie and other places across the Great Lakes on public health, and in setting standards for lead in water, soil, and in homes.

EPA has shown time and again that achieving cleaner air, and water, and a healthier environment go hand-in-hand with economic growth. Our children's health across the Midwest depends on EPA continuing to do its job and not let industry-driven agenda undermine its essential role. We respectfully ask EPA to withdraw this proposal. We will be submitting more detailed comments to the record. Thank you.

MR. ROBBINS: Thank you.

MR. GAMSE: I am Roy Gam -- I am Roy Gamse, G-A-M-S-E, no S on the end. Formerly EPA Deputy Assistant Administrator. Reading the comments of John Bachmann of the Environmental Protection Network. He served EPA for 33 years, was Associate Director of Science Policy and New Programs for the Office of Air Quality Planning and Standards.

John's comments. "I appreciate the

opportunity to provide the comments on the proposed rulemaking on strengthening transparency on behalf of EPN. EPN will submit the detailed written comments on the proposal later."

"This proposal would not strengthen transparency of regulations. Instead, it would preclude the assessment and use of best scientific information available as required by all major statutes administered by EPA. The process by which it was developed, the misuse of references that ultimately do not support its arguments and the lack of specifics, what EPA actually intends to do are an embarrassment to the agency."

"The new acting administration should withdraw it from consideration as soon as possible. EPA's proposal is a solution in search of a problem. A proposal asserts it's dealing with a replication crisis, but does not cite a single instance where a study used by EPA for any type of major rule was shown to be flawed due to a lack of access to the underlying data. In fact, EPA and the industry funded an independent

reanalysis of the two air pollution studies that were criticized for not releasing confidential health information, and both were successfully reproduced with the results published in 2000. Moreover, their key findings have been replicated dozens of times since then by other investigators using different health and air quality data."

"The proposal to exclude important peer reviewed studies is wholly inconsistent with scientific practice and EPA's past use of science and regulatory decisions, where studies with novel results appear, EPA's assessments have noted limitations and some cases supported reanalysis."

"EPA's science policy related assessments are, themselves, peer-reviewed by the SAB or CASAC to further ensure study evaluations consider all of the relevant scientific literature."

"As noted by the SAB workgroup, the EPA's proposal downplays valid concerns about the risks of providing access to the confidential information of subjects in epidemiology studies. The SAB group noted some of the largest most

useful health effects data sets cannot be made fully public because certain personal information of age, sex, health, and location could be used to identify participants, or because of agreements made with study participants in advance."

"EPA failed to mention various ways to assess the validity of fire epidemiology studies without access to data, nor that the rule may preclude continued use of studies published many years ago."

"The proposal includes a provision for the administrator to waive this requirement. No clear decision criteria provided to allow EPA scientists and stakeholders to understand when and how the waivers would be granted. It appears that requirement could be applied in an arbitrary and capricious manner that does not reflect sound science judgment. Critical decisions like these must be made on the basis of science, not politics. Otherwise, highly relevant studies for which data can't be publicly shared, even if published in the best peer reviewed journals and

replicated may be judged to be inherently untrustworthy."

"The rushed, mostly secret process EPA followed in developing the proposal displays a complete disinterest in transparency, much less in science. In developing this proposal EPA leadership did not provide a role for zone career science experts in crafting the proposal, never included the rule on its regulatory agenda, did not notify of consult with the SAB, much less request the review as required by law. Did not solicit the advice of the NAS on provisions that would change does response models used in risk assessment from those previously recommended by NAS, did not ask for review to solicit the views of other federal agencies that conduct research or use health effect science in developing regulations. Finally, the Agency originally only allowed a 30-day comment period on this remarkable unvetted departure from the past practice."

"In suggesting potential cost of the rule would be minimal, EPA ignored the cost to

researchers who would have to pay to set up and maintain data sharing for their previously published studies to be considered, to EPA for conducting the multiple reanalysis required in Section 30.6 of the rule, and to public health for the disbenefits of undermining existing regulations. Having done no assessment, EPA has no basis for its claim that the benefits of the rule exceed its cost. Scientists and scientific publications that EPA cites as evidence for support for this rule have rejected the proposal's preemption of existing studies based on availability of raw data. Professor John Ioannidis reacted strongly to the proposal in an editorial noting that, quote, 'If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim.' End quote."

"Editors of four major scientific journals whose policies EPA cited as support jointly stated, quote, 'It does not strengthen

policies based on scientific evidence to limit the scientific evidence that can inform them. Excluding relevant studies simply because they don't meet rigid transparency standards will adversely affect decision-making processes.'"

"Finally, EPA should immediately withdraw this flawed proposal from consideration, given the fatal flaw of establishing unnecessary regulation for science assessment that would elevate transparency over any other criterion. We're unable to offer any suggests for improving it."

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, come up to the speaker's table. And Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic), take a seat at the on-deck chairs.

Please remember to speak into the mic and state your organization.

MS. SASS: Hello. My name is Jennifer Sass, S-A-S-S. I'm with NRDC, the Natural

Resources Defense Council.

And I'm here to talk about the concern that scientists and environment health and medical professionals have with this rule. In one of his last acts of aggression against the public before resigning, the corrupt and disgraced EPA Administrator Scott Pruitt, proposed the rule to restrict the scientific studies that EPA could rely on to set safety standards for toxic chemicals.

Ironically, the rule is called science transparency when in truth public health will be seriously harmed. That's why over 40 doctors and scientists released a letter today which was submitted to the docket, raising alarm about the rule and the harms that it would bring about.

In the letter, they say as scientists and health professionals we recognize the importance of data sharing and replicability in scientific practice and discourse. The experts are part of Project Tender, and their letter is also publicly available.

They say the proposed rule is about stiffing science used by EPA, not improving it. They all have careers devoted to protecting children and their families from exposures to neurotoxic chemicals. They say the proposal could also undercut existing safeguards. Regulations that have led to protections against toxic air pollution, lead and drinking water, and dangerous pesticides, such as chlorpyrifos.

Dr. Phil Landrigan, a globally renowned expert on childhood harm from chemical pollutants warned that if you implement this proposed rule the inevitable consequence is that chemicals with potential to damage children's brains and nervous systems will remain longer on the market, and many thousands of children born, and not yet born, who could have been protected against these chemicals, will be unnecessarily exposed. Brain damage with loss of intelligence, disruption of behavior, and diminished lifetime achievement will be the result. Is this the legacy that EPA wishes to leave for America's children?

The Economist also wrote about the rule, very bluntly in an article titled, "Swamp science: Scott Pruitt embarks on a campaign to stifle science at the EPA." In that *Economist* article they emphasized that the proposal rule is really about blocking information used by EPA to protect our health. The rule prohibits the Agency from setting regulations that are supported in part or whole by data that is not publicly available for reanalysis or that cannot be replicated. It will hamstring EPA's use of scientific information, which could only harm EPA's work quality and public credibility.

There are many reasons why a study cannot be made fully public or replicated. For example, the original raw data may no longer be -- exist. Or the original exposure conditions may no longer exist, such as lead exposures from leaded gasoline, and patient protection and privacy rules may prevent full disclosure of the raw data, or information. EPA already has long-established and transparent methods for evaluating data in these

situations.

This rule would block the studies used to set air pollution regulations that will have prevented more than 30,000 premature deaths by 2020, with benefits valued at 30 times the cost of the Clean Air Act, according to EPA scientists and technical experts.

The rule would also block the studies that protect children from lead poisoning in air, water, and soil, and would block the studies of harmed children that support an EPA proposed ban on the neurotoxic pesticide chlorpyrifos, which President Trump and former Administrator Pruitt have already rolled back those proposals.

This may be the most unpopular proposal from an already unpopular EPA administration to date. It is a rule that fundamentally purports to solve a problem that doesn't exist, and it should be abandoned. It cannot be fixed. Thank you.

MR. ROBBINS: Thank you.

MR. MILLER: Hello. My name is Paul Miller. It's M-I-L-L-E-R. I am Deputy Director

of the Northeast States for Coordinated Air Use Management, or NSCAUM. NSCAUM is the regional association of state air agency air quality control agencies in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

My comments today reflect the majority view of NSCAUM's members, while individual members may hold some views different from the majority consensus.

In sum, we are concerned that should this proposal lead EPA to not fully consider the best available science in rulemakings, it will endanger public health and the environment.

The EPA invokes strengthening transparency as a primary driver for this proposal, but fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of work, quote, "EPA has not previously implemented these policies and guidance in a robust and consistent manner," end quote, nor what are the specific

quote, "Agency culture and practices regarding data access," end quote. That requires changing.

The Agency also provides no cost analysis of this proposal. Without additional clarity from EPA we are having difficultly identifying the problem EPA seeks to address. Therefore, for the following reasons we request that EPA withdraw the proposed rule.

First, the proposal is too vague as written to provide the public with meaningful opportunity to comment. EPA solicits comments across a long list of topic areas, but fails to provide the Agency's own sufficient detail and rationale on the solicited comment areas as required by the Administrative Procedure Act.

We are left to speculate on EPA's views, and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment.

Second, EPA must describe how the proposed text in Sections 30.5, 30.7, and 30.9

affect current practice. Section 30.5 states that the Agency shall ensure that those response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.

Section 30.7 states, EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. EPA, however, does not describe what constitutes in its view, independent validation and independent peer review.

Furthermore, Section 30.5 includes qualifying language that EPA will take all reasonable efforts to make data available unless it is not possible due to other constraints, such as legal protections of privacy and confidentiality.

EPA provides no examples of where and how, in the Agency's view, past rulemaking specifically failed to make these same efforts, nor how EPA would change past practice in this context. Adding to the vagueness of Sections 30.5

and 30.7, Section 30.9 would provide the administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions on a case-by-case basis if he or she determines that compliance is impracticable. The proposed rule fails to provide specific criteria for determining when compliance is impracticable.

Lacking clear guidelines for transparent decision-making, the administrator's discretion would appear to be unbounded in application and potentially based on haphazard and non-transparent rationales.

Third, EPA has provided no meaningful cost estimate for the proposed rule. The costs are likely quite significant, however, based on a congressional budget office cost estimate of the similar congressional proposal.

In addition to lack of cost information, EPA offers no accounting of foregone benefits should a broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse

health outcomes.

In conclusion, EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific proposed rule requirements, and its cost and benefits.

These are well understood and basic elements that federal agencies must include to ensure informed public comment. Given that these elements are missing from this proposed, EPA should withdraw it. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic) come to the speaker's table. Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Reaves, take a seat at the on-deck chair.

MR. McKINZIE: Good morning. I'm Matthew

McKinzie, M-C-K-I-N-Z-I-E. I'm a nuclear physicist with the Natural Resources Defense Council, NRDC, and I'm very pleased to talk today about this proposed rule. My remarks will focus in on the radiation protection aspect of the proposed rule.

NRDC, just as background, is a national non-profit organization of scientists, lawyers, and environmental specialists. We are dedicated to protecting the public health and the environment.

NRDC has been engaged with the environmental issues surrounding nuclear energy and nuclear weapons since our founding. There's something strange about the proposed rule in that it does not use the word radiation, and it does not cite the EPA's authority under the Atomic Energy Act.

Nevertheless, the language of the proposed rule seems to clearly implicate radiation protection standards. In particular, appears to undermine the basis, a fundamental basis of

radiation protection standards, the linear no-threshold dose response model. And so that's what I'll focus on with my five minutes.

The science in radiation epidemiological studies has repeatedly demonstrated over decades that linear no-threshold dose response, LNT, provides the most reasonable description of the relation between the low dose, low radiation dose exposure, and the incidence of solid cancers that are induced by that ionizing radiation.

EPA bases its regulatory limits and nonregulatory guidelines for population exposure to low-level ionizing radiation on this linear no threshold model. EPA's radiation protection standards are based on the premise that any radiation does carries some risk, and that risk increases directly with dose.

This method of estimating risk is called LNT. For over 40 years, the LNT dose response model has been commonly utilized when developing practical and prudent guidance on ways to protect workers and members of the public from the

potential for harmful effects from radiation in that balance, with commercially justified and optimized uses of radiation. EPA derives the LNT model from reports by authoritative scientific bodies, including the National Academy of Sciences, NAS, the National Council on Radiation Protection and Measurements, NCRP, and other bodies.

The NCRP published its last commentary on the LNT issue only weeks ago, in April of 2018, reinforcing this -- the LNT as the basis for radiation protection standards.

Epidemiological studies of humans provide evidence that is critically important in establishing potentially causal associations of environmental factors with disease. NAS and other studies that EPA has long relied upon in the radiation standard setting process are epidemiological human cohort studies. EPA's proposed rule, if implemented, would limit EPA staff from basing regulatory actions on precisely these types of studies by requiring that the

underlying data of these studies should be publicly shared, fully publicly shared. This would be a nearly impossible task for the agency.

Data for some of the radiation epidemiological studies are accessible to users, with a detailed description of how a user can access the information. However, public sharing of personally identifiable information is restricted. These are profoundly important studies on radiation health effects that have been peer reviewed for decades, and the science that has emerged from them has been validated multiple times. But these are not studies where the entirety of the public data can be shared or independently replicated.

Replication of these studies is impossible as this data comes from individuals exposed to significant, acute, and protracted doses of radiation. Pruitt's proposed rule would throw out the data from the atomic bomb survivors of World War II. That's a profound, very profound thing.

Adverse consequences for EPA would affect federal guidance reports, nuclear field cycle standards and regulations, minimum amount -- minimum allowed concentrations of radiation in drinking water, soil clean up for super fund sites, radioactive waste disposals, as well as the fundamental concept of ALARA, As Low As Reasonably Achievable, in radiation protection standards.

In conclusion, I urge the EPA to abandon the proposed rule as it fundamentally calls into question basic radiation protection standards that are scientifically founded and have protected the public for many years. Thank you.

MR. ROBBINS: Thank you.

MS. MELLINGER-BIRDSONG: Hi. My name is Anne Mellinger-Birdsong, M-E-L-L-I-N-G-E-R, dash, B-I-R-D-S-O-N-G.

Thank you for allowing me to speak today. My name is Anne Mellinger-Birdsong, and I am a fellow of the American Academy of Pediatrics and a specialist in environmental public health. I have worked at city, county, state, and federal public

health agencies, and Indian health service facilities.

I'm here to speak in opposition to this proposed rule and to state that this proposed rule is unnecessary and it would harm EPA's ability to evaluate health impacts of environmental pollutants. It should not be finalized or implemented.

This proposal has wording that makes it appear noble and well-meaning, but it is a sheep in wolf's clothing. This proposal will severely hamper EPA's ability to use past and future research on health effects of human exposure to environmental chemicals and toxicants. It should be withdrawn.

Both the HIPAA and the federal regulations on human subjects research address privacy as a concern of people who participate in research. It's not as simple as redacting data such as name, birth date, medical record number, et cetera. You also have to not have data that can be used to intuit or figure out who a study

subject is. So you have a study of Town A and people who had heart attacks in July. If there is age or zip code data associated with that, the people that live in Town A could figure out, oh, that's Mr. X down the street. So it would really hamper the ability to use data, and environmental health data often has zip code and year and a lot of stuff that can be used to put together and figure out who people are.

So that's how it would work. And I just would like to say also that children have even more health protections than adults because of being smaller, and we have to be more concerned for them. And especially living human subjects of research who will continue to live, we need to be extra careful to protect their privacy. And this rule would either require data made public, or it would prohibit using a lot of data that would enable -- that would inhibit privacy protection.

So also it would decrease people's trust in participating in research if they are fearful of their personal identifiers being released or

people being able to know that they participated in a study. They may not participate, so we would have worse data for studies in the future because of this rule.

And I would like to say that children do not choose where they live, or where they go to school, or what kind of water quality their water they drink is, or the air that they breathe. It's up to we, who are adults, the adults who are their caretakers who choose where they live, and we who set policies to make these decisions to keep children healthy. And this rule would severely harm children because it will throw out a lot of data, and a lot of data that has been used to form, already, established rules.

So I ask, why was this rule proposed? It would eliminate use of scientific studies and hamper future research. The rule was completely unnecessary. We have mechanisms within scientific institutions to transfer data so it's HIPAA compliant and IRB approved, so we can verify research and reevaluate it and confirm it. We

don't need this rule and it is, again, it's a rule that's unnecessary and would hamper and harm EPA's ability to carry out its functions.

So I'm going to end with a quote by a professor from Carnegie Mellon University, Granger Morgan. He used to chair the EPA Science Advisory Board under George W. Bush. He said, "this proposed rule is an attempt by people who aren't interested in using science to find the truth to raise doubts about what, at this stage, is very clearly established and well-reviewed science."

And I urge the EPA to withdraw this proposed rule and not implement it at all.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Rebeb (sic), come up to the speaker's table. And Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb, take a seat at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. REAVES: Hi. My name is Jennifer Reaves. Reaves spelled R-E-A, V as in Victor, E-S. I represent Moms Clean Air Force, Maryland.

Am I supposed to speak first? Oh, okay.

My name is Jennifer Reaves. I live in Hyattsville, Maryland. Thank you for this opportunity to offer comment. As a member of Moms Clean Air Force, Maryland, I am here today to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name of transparency.

This dangerous censoring sign plan to limit the scientific information EPA can use to identify public health threatens and future and safety of our children. This proposal will essentially require researchers to make private personal medical information public in order for the EPA to use their research in its decision-making.

This proposal also includes loop holes that would exempt industry from having to disclose details of their own studies. It is designed to

favor the fossil fuel and chemical industries, limiting EPA's ability to protect us from toxic pollution and chemicals. High quality science is crucial to understanding the risk of our families face every day, especially when it comes to air pollution and toxic chemical exposure.

This proposal means that many studies on populations, such as elderly, young people, and people of color, groups who are often suffer disproportionately from pollution would be excluded from EPA consideration because making the data public could identify and participating -- identify the participating individuals. Including this important data from consideration means that implementing this proposal could even further exuberate negative environmental impacts on these and other vulnerable communities.

This proposal puts our children's bodies on the line by censoring research, making even low levels of pollution with significant health impacts instead of cleaning up their act. Polluting industries want these kind of studies to

simply disappear.

My family and my fellow Marylanders are counting on the sound and transparent science the EPA has used for decades. And we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MR. ROBBINS: Thank you.

MS. BARDWELL: All right. Excuse me. Thank you. My name is Erica Bardwell. Can you hear me? Okay.

I am a local registered nurse. I work at a local hospital. I'm also a member of Physicians for Social Responsibility. Thanks for taking time today.

Mr. Scott Pruitt is no longer here as EPA administrator, but it does seem that this proposal preserves the hallmark of his tenure. By that I have to say, I mean a complete lack of shame.

This proposal masquerades as an attempt to strengthen science, and by extension, public health. But this is a bald, even shameless lie.

It would actually make public health research impossible, or much, much more difficult, which obviously is the real point.

If someone can't participate in medical research without worrying that their identities or parts of their medical records are going to be rampaging around the public record, then they simply won't do it. Which again, is the point.

Basically, shameless people say that to themselves behind their scenes. But to us they say that they're really concerned about us and public transparency, but it's not true.

I saw a reference to a replication crisis. Last I heard, the replication crisis was mostly social sciences. There's not a huge replication crisis in epidemiology. Certainly not to the point where basic facts are in doubt. There is no doubt that air pollution kills people, that poison in water makes people sick, that toxic soil grows toxic food. This is not in contention. There's no replication crisis here.

So the only purpose of this rule could be

to avoid adding to the already damning weight of this existing evidence. Basically, to make it cheaper for a few people to literally poison people for profit, which is ultimately a tragedy for everybody.

I think the thinking is that sciencing debates are going to bore the public, and most other people have to work on a random Tuesday. I swapped a shift to be here, but most people don't have that option.

MS. DOA: Can you speak into the mic a little bit more?

MS. BARDWELL: Sure. Okay.

MS. DOA: That's better. Thank you.

MS. BARDWELL: So, the true public interest may not be represented here because people have to work. But if this rule is finalized, the public is going to howl once they actually feel its effects and lose the protection that they need from these studies. And I wouldn't want to be the person left holding the bag when that travesty happens.

Finally, as my grandmother used to say, what sauce is for the goose is sauce for the gander. If exposing personal information is really required to have quality medical research, I eagerly await the day this administration proposes similar restrictions on, say, pharmaceutical research. I wait for the day that Pfizer can't get approval for its nth blood sugar pill without revealing incredibly invasive information about all of its research subjects. I don't think that day is ever going to come, because protecting people or advancing science isn't really the goal.

Thanks for your time.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb come to the speaker's table. And Speaker Number 36, Lyndsay Alexander, and Speaker Number -- is there a Speaker Number 37 in the room? What's your name?

MS. BENDER: Laura Bender.

MS. RAUCH: Hi. I'm Molly Rauch. Name is spelled M-O-L-L-Y R-A-U-C-H. I'm Public Health Policy Director with Moms Clean Air Force. We're a national organization of more than a million moms and dads fighting air pollution and climate change for the sake of our children's health.

Thanks for this opportunity to offer comment. On behalf of our more than 1 million members, I am here today to strongly oppose the administration's attempts to censor the science used in public health decision-making. This intentionally misleading proposal is being sold by EPA leadership as an effort to increase transparency. But the facts suggest that the real motivation is simply to sweep under the rug the scientific evidence disfavored by polluting companies.

The proposal would prevent EPA from using studies that are based on personal medical data, thereby eliminating some of the most important long-term epidemiological studies, investigating the impacts of pollution on public health, and

hundreds of scientists have already spoken out against this proposal.

Indeed, this flimsy proposal was designed without adequate input from the scientific community, according to the members of EPA's own Scientific Advisory Board. It was rushed through the regulatory process. It was originally proposed with a gallingly short public comment period that suggested an intention of casting less light on the rulemaking process, not more.

For a proposal that posits a sweeping change in the health-based rulemaking that is the foundation of the EPA, it was quite the slight of hand.

As a public health expert who has been closely following EPA's rulemaking process for more than a decade, it is evident to me that this is a cynical ploy to bolster polluting industries that don't like the results of longitudinal research.

Who does this benefit? Who really benefits from this charade? I must call it a

charade. Not the families everywhere who want to breathe clean air and drink clean water. Not frontline communities dealing with multiple pollution exposures from many industrial sources. Not the millions of children in the U.S. with asthma across the country whose disease can be worsened by small changes in air quality day to day, not the elderly, not those with underlying health problems whose likelihood of being admitted to the hospital, of having a stroke, of having a heart attack, even of dying, could depend on the levels of particulate pollution in the air. It does not benefit these people.

I have a master's degree in public health. One of the most valuable things that I studied in graduate school was how to evaluate the reliability of epidemiological studies. We learn the importance of considering many different criteria in making these evaluations. Whether the raw data was available to me, personally, to review, was never grounds for automatically discounting the credibility or reliability of any

given study.

The idea that an entire library of research would be rejected wholesale, based simply on that one external criteria, represents a crude approach, to put it kindly.

We also, in grad school, learned about the iron-clad importance of treating study subjects ethically and with respect. And this is a touchstone of public health practice. All research on humans must be approved by institutional review boards, and they prioritize the privacy and consent of study subjects. There are laws about this.

When study subjects are disrespected terrible things can happen, which is why we were required to learn about things like the, "Tuskegee Study of Untreated Syphilis in African/American (sic)Men," when we were in public health school. We cannot go back to the time when the study subject was a mere pawn in someone else's game. Treating study subjects ethically requires protecting their privacy.

Finally, we studied the tactics of polluting industries and their shameful legacy of attempting undermine science, whether it was the tobacco industry or the lead industry, we learned about the deliberate, expensive, decades-long campaigns to protect corporate profits, and meanwhile people were literally dying as a result. This is an old story. We've heard it before, and we're hearing that story again. Public health professionals are trained to recognize history and call it out, which is what we are doing today.

This proposal is an excuse to hamstring researchers to weaken public health protections, and to pad the profits of polluting industries. As a public health professional, as a mother, and on behalf of the 1 million members of Moms Clean Air Force, I strongly urge the EPA to stop this proposal for the health and safety of all Americans. Thank you.

MR. TEICHMAN: Thank you.

MS. GOTTLIEB: Good morning. My name is Barbara Gottlieb, G-O-T-T-L-I-E-B. I'm the

Director for Environment and Health at Physicians for Social Responsibility.

On behalf of our 33 members, I'm here to express our opposition to the proposed rule -- "Strengthening Transparency in Regulatory Science."

The U.S. EPA plays a critical role in keeping our nation and our families safe from environmental exposures that can cause illness and death. We thank you for that - and we count on you for it. Because your role is vital to our health and well-being, the nation relies on you to formulate and enforce the most effective protections possible, based on the best available science. The medical and scientific studies that underlie the EPA's decisions must be objective, vetted, and present a full and accurate assessment of the threats to health posed by the pollutants under study.

To provide those full and accurate assessments, studies need to relate exposure levels to actual health outcomes in real human

beings, and to amass large data bases so that researchers can draw valid conclusions.

In order to have reliable data and large sample sizes, researchers frequently study the records of patients treated in hospitals. Hospital records, of course, include personal identifiers, and disclosure of those identifiers would violate privacy and confidentiality laws. Thus, the best available data for many health studies cannot be - in the literal sense -fully and openly shared.

However, to refuse to consider scientific studies simply because they include personal identifiers -- would be a great mistake, nor is it necessary. Reviewers wanting to reproduce a study in order to validate it can arrange to have confidential access to key data. Furthermore, scientists can assess the merits of published research without seeing its data by considering such published features as the study's research design, the methods used for data collection and analysis, and comparison with previous results.

In any case, to exclude credible peer-

reviewed scientific studies because the personal identifiers cannot be released under the law, is to exclude from the EPA's consideration many important and valid studies. This would greatly hamper our ability, your ability, to understand the impacts of serious, even deadly, pollutants.

I'd like to cite, as example, three studies that could be lost to consideration under the proposed rule, on a topic I haven't heard referred to today. These studies reveal statistical correlations between exposure to emissions from fracturing, or fracking, for oil and gas, and serious health outcomes.

So the first is a study by University of Pennsylvania and Columbia University researchers and published in 2015 in the journal, *PLoS ONE*, found that drilling and fracking activity in Pennsylvania was associated with increased rates of hospitalization for cardiology, neurology, cancer, skin conditions, and urological problems.

In communities with the most wells, the rate of cardiology hospitalizations was 27 percent

higher than in control communities with no fracking. These findings are obviously of great concern; we would not want them to be lost to the EPA as you consider regulation of fracking related emissions.

Yet because the data includes such things as patients' names, diagnoses, addresses, and zip codes, this valuable study could be, under the proposed rule, excluded from EPA consideration.

Another study conducted in Pennsylvania between 2005 and 2012, found that living near fracking operations significantly increases asthma attacks. This study was conducted by researchers at Johns Hopkins University and it was based on a study of 35,000 medical records of people with asthma. This is just the sort of study that we want EPA to base its health-protective regulations on: a robust database conducted by researchers at a respected institution and published, as this one was, in the *Journal of the American Medical Association Internal Medicine.*

Yet should the proposed rule be adopted,

this study could be disallowed because its 35,000 medical records cannot easily be scrubbed of personal identifiers.

Third example, a study by the Johns Hopkins Bloomberg School of Public Health and other researchers, used data from the Geisinger Health System on over 9,000 pregnant women and their over 10,000 newborns between January 2009 and January 2013. The researchers found that the pregnant women who live near active fracking operations in Pennsylvania were at a 40 percent increased risk of giving birth prematurely. Premature birth is the leading cause of infant death in this country.

So we're talking about data that indicate that fracking operations could put newborn babies at risk of death. This was a study published in the peer review journal, *Epidemiology*.

Our families should have the benefit of these studies and many more that might be disregarded under the proposed rule. To exclude them would be to weaken the scientific record and

undercut an accuracy and strength of EPA's regulatory process, and to endanger human health.

For that reason, Physicians for Social Responsibility opposes the proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 36, Lyndsay Alexander, and Speaker Number 37, Laura Bender, come up to the speaker's table.

And would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, take your seat at the on-deck chairs.

MS. ALEXANDER: Good morning. My name is Lyndsay Alexander, A-L-E-X-A-N-D-E-R. I direct the National Health Year Campaign at the American Lung Association. I am also the mother of a thriving toddler, who like all children, deserves healthy air to breath, and safe water to drink that won't make him sick or die prematurely.

I am here to ask EPA to withdraw this proposed rule because I'm very concerned that rather than foster transparency in regulatory

science, this rule promotes a callous effort to suppress and censor the science used to inform EPA policy to the detriment of millions of Americans' health and well-being.

EPA's ability to effectively fulfill its mission and protect public health from dangers, such as air pollution, hinges on the ability of its scientists to first evaluate the best available scientific evidence of the health threats of air pollution. Recognizing that scientists' understanding of the relationship between air pollution and public health would continue to evolve, congress wisely required EPA to review the latest evidence and revise air pollution limits for six key pollutants every five years. And then to work with states to reduce pollution to meet the limit.

While more work remains, this basic approach has worked exceedingly well at reducing ambient air pollution, saving lives, and improving health by preventing asthma attacks, heart attacks, and many other negative health outcomes

from air pollution.

This proposed rule would require EPA to exclude many of the best available peer-reviewed and rigorously scrutinized studies from consideration during decision-making, such as its upcoming air quality standard reviews for ozone and particulate matter.

Excluding studies for which raw data are not available due to concerns over patient confidentiality, or which do not meet vague standard of reproducibility because studies were conducted over long periods of time, or connected to real world events beyond the control of researchers, would greatly narrow the body of evidence and the quality of the information that EPA can consider. This would undoubtedly lead to weaker protections and EPA's ability to estimate the true threats of air pollution on human health, and the benefits of reducing pollution, and thus result in weaker air pollution limits.

In 1993, researchers at Harvard University published a landmark air pollution

study, showing that particulate matter air pollution was linked to premature death. The Harvard Six Cities Study, as it is known, tracked the health of 8,111 adults, and 14,000 children in six small cities in the United States, beginning in the 1970s.

This study found that people in cities with cleaner air were living two to three years longer than those living in cities with dirtier air. Residents of Steubenville, Ohio, the city with the dirtiest air, were 26 percent more likely to die prematurely than were citizens of Portage, Wisconsin, the city with the cleanest air.

What surprised researchers was that the culprit was particulate matter, not sulfur-dioxide, as they had thought. This was a very important scientific discovery. This study, and countless others since, have helped EPA to understand that particle pollution in the air we breathe, resulting from activities such as burning coal for electricity, or diesel exhaust from vehicles, harms human health in profound ways in

communities across the nation and has paved the way for stronger air pollution limits designed to protect public health.

But the data for the Harvard Six Cities Study are not publicly available, and the study was conducted over a long period of time that make it very difficult to reproduce. Industry, and their allies in congress previously challenged the findings of this study and other similarly important studies. Instead of blocking the studies, as this proposal would do, EPA took a logical step and referred them to an independent third-party, the Health Effects Institute, for a deep dive review.

There, autonomous reviewers examined the data and developed a report that confirmed their original findings. Other research has since confirmed similar findings, including some studies that use publicly available data sets. Critically important studies, such as the Harvard Six Cities Study would likely be excluded under this proposal to the detriment of health protections. This

proposal would also affect other protections currently in place, such as limits on certain toxic air emissions from tail pipes and smoke stacks, and information on the health effects of many of these; more than 150 chemicals come from older studies built on confidential patient or private business data that cannot be made public.

This could -- this proposal could also cull the use of research that includes confidential business information or older studies that has data stored on older technology that can't be recovered, just to name two other limitations.

Thank you for the opportunity to speak today. The American Lung Association will submit more detailed written comments.

MR. ROBBINS: Thank you.

MS. BENDER: Good morning. My name is Laura Bender, L-A-U-R-A B-E-N-D-E-R, and I'm the National Director of Advocacy of the American Lung Association's Healthy Air Campaign.

The lung association's mission is to save

lives by improving lung health and preventing lung disease. And as you know, we strongly oppose EPA's so-called, "Strengthening Transparency in Regulatory Science," proposal.

Today you've heard from many representatives at the public health and medical community about the ways this proposal would undermine human health. I'd like to take a few minutes to highlight the Lung Association's concerns about the lack of transparency in EPA's work on this rule.

The administration has attempted to rush this rule forward at every turn, consistently sacrificing expert analysis and public health along the way. This is a sweeping proposal that will impact a wide range of public health safeguards, essentially affecting every future decision at EPA based on science. And yet, EPA's process in issuing it has been haphazard, rushed, and anything but transparent.

First, back in April, then Administrator Scott Pruitt, prematurely announced the proposal

while it was still undergoing interagency review at the White House Office of Management and Budget. Then, when media inquired about this discrepancy, OMB actually backdated the clearance by several days. This means that OMB only reviewed the proposal for 48 hours. That's a staggering tight timeline for such a sweeping rule.

In a similar vein, EPA initially only allowed a 30-day comment period with no public hearing. The Lung Association was among the organizations who requested 60 additional days and a hearing. We greatly appreciate the additional time and today's public hearing.

That additional time is crucial, particularly because EPA has failed to complete a regulatory impact analysis that explains the impacts of the proposal, putting the burden on commenters to do so instead.

EPA ignored another important opportunity for review when it failed to consult the Agency's own Science Advisory Board. The SAB, which

includes appointed members from this administration, voted at its May meeting to request to review the proposal.

In a letter to EPA last month, they said that they were only made aware of the rule through the press, and when it was published in the Federal Register. The SAB said unequivocally, quote, "The proposed rule merits review by the Board."

We strongly encourage the Agency to move forward with the SAB review of the proposal. To refuse their request to do so would be unprecedented and in direct contradiction of the Agency's stated claim of wanting the best science to inform its decision-making.

EPA rushed out this proposal after an inadequate review process, and it shows. The proposal falls short in several key ways. First, EPA fails to provide any evidence that the changes outlined in the rule are needed. EPA's existing approach towards science, with its detailed review and deliberation of the research, is already

transparent and has worked well for decades.

First, independent science has revealed that studies prior to publication by recognize journals, then independent and EPA staff scientists reviewed them again and question every aspect of the research in depth. And they do these reviews in wide open processes, including publication, public hearings, and comment periods.

EPA does not acknowledge the rigor of this process in its proposal. Instead, it attempts to justify this rule by claiming that the Agency is following in the footsteps of scientific journals. But last month as other commenters have noted, several scientific journals issued a joint statement highlighting their concerns with EPA's proposal and pointed out that even though many peer-reviewed publications have recently adopted transparency policies, they are still able to assess and use studies for which the underlying data cannot be made public.

Second, EPA fails to define its requirement that studies must be replicable. Does

EPA mean that the Agency couldn't consider a study that looked at health impacts of a one-time event, like a major oil spill?

The SAB also raised questions about EPA's failure to define this and other terms.

Finally, EPA did not explain how the Agency would implement the rule. The proposal offers no process for public hearing, or even consultation with the SAB over implementation. What process would EPA use to review and assess the existing research and revisions? What guidance would the administrator receive to avoid arbitrary decision-making over the fate of this research?

And where would the massive staff time and resources the EPA would need for such a massive additional workload come from? What would have to be sacrificed?

EPA's rushed process, its inadequate review, its false attempt to claim that its policy is supported by scientific journals, and its many unanswered questions about how the proposal would

work, all underscore a core problem with this rule. It would not improve the use of science of EPA. It would not make the Agency's science-based rules more transparent. It would permanently damage EPA's ability to do its job to protect the public.

On behalf of the millions of people with lung disease that we serve who will be hurt by the weaker pollution protections that would result from this proposal, we urge EPA to withdraw this rule to censor science. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 38, Liz Borkowski, and Speaker Number 39, Janice Nolen, come up to the speaker's table. And Speaker Number 40, Albert Donnay, you're already at your seat. Excellent. Also, if Speaker Number 15, Harvey Fernbach, is in the room, you can take a seat at the on-deck chairs. Last call.

MS. BORKOWSKI: Thank you for the opportunity to present comments. My name is Liz Borkowski, and I'm the Managing Director of the

Jacobs Institute of Women's Health, which is at the Milken Institute School of Public Health at the George Washington University.

The Jacobs Institute is concerned about EPA's proposed rule, "Strengthening Transparency in Regulatory Science," due to the harmful impact it would have on women's health and reproductive justice.

We urge EPA to withdraw it based both on its detrimental impacts, and on the lack of a demonstrated need for such a rule. EPA has failed to demonstrate that its current processes for considering science and regulation are inadequate. It has not provided examples of any instances in which insufficient transparency has resulted in outcomes contrary to its statutory mandates or executive orders.

Given extensive existing procedures used by EPA and the scientific community at large to ensure the quality of research, EPA has failed to make a case that additional public access to data is necessary.

The theoretical, but as yet undemonstrated benefits of EPA's proposed rule, must be weighed against the extensive and unequally distributed costs of such an approach. Failing to consider the best available evidence because the underlying data are not publicly available, would result in regulations that fail to sufficiently protect public health. The consequences would fall most severely on sensitive groups not adequately protected by current rules, which include racial and ethnic minorities, those with low socio-economic status, the elderly, and pregnant individuals and their eventual children.

My comments provide a few examples related to reproductive health. First, neurotoxicants are of particular concern to pregnant people and the parents of young children. In regulatory activities, to reduce exposure to neurotoxicants, such as lead and methyl mercury, EPA has relied on an extensive body of research. This research includes longitudinal studies of individuals who are exposed in utero or as young

children to higher levels of lead or methyl mercury than would typically occur in the U.S. today. It would not be ethical to publicly release data from these studies, and it would not be feasible, particularly for older studies that used incompatible storage media to locate all participants and obtain their permission.

EPA's use of research on lead and methyl mercury also has implications for other agencies that address these substances. For instance, the Department of Housing and Urban Development relies on EPA's renovation, repair, and painting rule in its regulation of renovators working in housing units, receiving HUD housing assistance where lead paint is present.

EPA calculated the reference dose for methyl mercury that EPA and the Food and Drug Administration used to create guidelines on fish consumption, including recommendations for pregnant and breast-feeding women.

It does not appear that EPA has undertaken the required interagency review process

to assess the implications of its rule for other agencies.

Another neurotoxicant of concern for reproductive health is the pesticide, chlorpyrifos. Researchers followed a cohort of children exposed to this pesticide before the current ban on indoor use and found lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.

In a rulemaking process regulating agricultural use of chlorpyrifos, EPA requested the underlying data from the Columbia Center for Children's Environmental Health. The response from Columbia University explained that because of the detailed sociodemographic and health-related elements their data set contains, they did not believe they could submit extensive individual-level data to EPA in a way that would ensure participants' confidentiality.

Such concerns are not uncommon with the kids of longitudinal data sets that allow identification of long-term consequences of

environmental exposures. Often, the combination of variables used in an analysis provides enough information to identify individual participants and may include sensitive information, such as diagnosis of neurodevelopmental delays.

In addition, endocrine disrupting chemicals are of great concern and reproductive health and EPA has regulated some of these, such as PCBs and PBDEs, under the Toxic Substances Control Act.

Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence, but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

If EPA moves forward with the rule it has proposed, it will undermine science and regulatory decision-making by making it difficult and potentially impossible to consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health. The Jacobs Institute of

Women's Health urges EPA to withdraw this rule.

MR. ROBBINS: Thank you.

MS. NOLEN: Hi. Thank you. My name is Janice Nolen. It's J-A-N-I-C-E N-O-L-E-N, and I am the National Assistant Vice President for Policy for the American Lung Association.

The American Lung Association turns 114 years old this year. For more than a century we have fought to save lives for protecting lung health and preventing lung disease. We oppose the proposed rule.

Many years ago, in the early 1980s, my mother-in-law asked me to help her recruit participants in a major new study that they were doing. She worked for the American Cancer Society then. They were looking to create a huge database of ordinary Americans would be willing to provide them with confidential information about their health and medical experiences, and would allow them to track those for years to come.

I was so pleased that two men from my church choir in Nashville agreed to participate.

They completed the forms and other paperwork, and became two of the more than half million participants in the cancer prevention study too.

Fast-forward a decade or so and I learned that their data were now part of a landmark study, the American Cancer Society study that revealed the risks to human health from breathing air pollution that I and my colleagues at the lung association were working hard to clean up.

Their data and private health and medical information, from hundreds of thousands of others were -- from hundreds of thousands of other people, who were pointing the way, the need to clean up emissions from power plants, from diesel engines and fuels, and many other sources. I never dreamed when my mother-in-law made her first request to me that EPA scientists and other researchers would mark that study as one of two seminal studies that helped reshape our understanding of the health risks from particulate matter air pollution.

None of us then would have ever dreamed

that the information these two men provided would have helped to identify and underline the threat to human life posed by microscopic particles in the air we breathe.

Furthermore, that study and the Harvard Six Cities Study became examples, not only of ground-breaking research, but of how questions about that research can be reviewed and resolved without having to lose the entire study.

Unfortunately, that is an example that this proposal clearly fails to understand. These two studies with decades-old patient data and others in the long list of studies that found evidence of harm from industrial emissions are unique events that no one hopes to replicate, like gulf oil spills, clearly appear to be targets of this proposed rule.

Studies that have been -- long been targets of industry polluters and their allies, remains so in this proposal.

Once published, these studies raised alarms in the public health community about the

increased likelihood of premature death from particulate matter, widespread in the nation. The studies raised alarms within industry too, about the increased likelihood that their polluting sources would have to clean up their emissions. Industry kicked in messaging developed by the tobacco industry, to challenge the science using the same arguments we have in this proposal.

I have in my office, a page from a 1999 *U.S. News* and *World Report* article on the challenges to these studies that could have been written this year.

Scientists are working to become more transparent in their research. More researchers use publicly available information, but some studies cover populations that are so limited in size or specialized in their characteristics that these data could not be posted on the web for all the world to see. Anyone who has an account on Facebook should have a visceral knowledge of how important keeping confidential data confidential can be.

Meanwhile, EPA could readily review historical data and studies in ways that respect patient confidentiality and the gifts of data from people like my two choir member friends.

So far, EPA has failed to show any reason that these changes are needed in the current system. Failed in its own transparency on this issue, in fact since EPA has not sought SAB review of this, and has not provided sufficient rationale for why EPA needs this change, much less how they would this rule going forward.

We request EPA to withdraw this proposal. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 40, Albert Donnay, come to the speaker's table. And Speaker Number 41, Mona Sarfaty.

MR. DONNAY: Thank you. My name is Albert Donnay. My comments are based on experience gained from 40 years working on regulatory science as an environmental health engineer and toxicologist, as a research

scientist, public health activist, clinician, consultant, peer-reviewer for academic journals, environmental groups and government agencies at all levels, including EPA.

I'm glad I get to follow the last two speakers because I want to highlight that although EPA's proposal to "Strengthen Transparency in Regulatory Science" is needed, did not give any examples of regulations that had been undermined by a lack of such transparency.

I want to remind everyone here what's at stake and what happened the first time EPA, congress, and environmental groups had to decide whether it was okay to base regulatory standards on published scientific studies whose achieves were no longer available for review.

They got the answer right then, and I hope they'll get it right again now. It was May, 1983, 35 years ago, and the EPA was about to publish a new national ambient air quality standard for carbon monoxide based on nine studies by a distinguished cardiologist at the VA, Dr.

Aronow. When the *Washington Post* reported that he'd been barred by FDA a year earlier for submitting a wave of false medical experiments after he admitted, quote, "fudging his lab reports in human drug studies."

Although EPA's head of the Office of Air Quality Planning and Standards said the Agency had, quote, "No reason to believe anything was wrong with Aronow's CO studies," whose data Aronow claimed at the time, "are excellent and can't be questioned." EPA nevertheless appointed a special team of agency and outside scientists to review his work, quote, "When we read that Aronow had done some kooky things."

A month later, *The Post* reported the shocking results under the headline, "EPA Probe Criticizes a Study Used in Air-Quality Standard." The team had said, quote, "Could not resolve the issue of possible falsification of data because," quote, "no data were available." Aronow told them he'd discarded the archives of all of his CO studies after first storing them in his garage for

years, and offering it to EPA because they didn't want it.

The investigators noted considerable concerns about the validity of the results reported, quote, "Raw data were lost or discarded. Adequate records were not maintained, available data were of poor quality, and quality control was nonexistent."

And Aronow's published results were consistently too good to be true. They found it, quote, "Rather remarkable that in 10 years of research his papers showed," quote, "not even one missing data point." They concluded that EPA, quote, "Cannot rely on Aronow's data due to the concerns we've noted." And they recommended the Agency commission new research to attempt to replicate Aronow's findings.

Congressional hearings and the GAO investigation followed, after which Administrator Ruckelshaus agreed that EPA would not rely on any of Aronow's studies in future rulemakings, but only on studies whose archives were still

available for review.

In coordination with the California Air Resources Board and the Health Effects Institute, EPA commissioned a series of new controlled human exposure studies on CO, and since 1994, has based the CO NAAQS exclusively on just six of them, all of which published their individual results in deidentified form so they would be available for public review in perpetuity.

And it's a good thing they did since all the larger archives of these studies were eventually discarded by their authors without being offered to EPA. This history shows that EPA can and should base regulations solely on studies whose methods and data are available for review. To base regulations on studies that can't be reanalyzed is not science, and there is no need for it. Even federal rules that are based on older epi studies, like the last particulate NAAQS rule in 2013 that cited just six studies could and should be based on more recent research that better reflects current air quality.

Over 500 studies a year are now published on particulate epidemiology, and many are in high quality journals that require authors at least to make all their deidentified data and methods available to reviewers, if not to all readers from the posting of supplemental material.

Given EPA's interest in basing regulations on more transparent research, EPA should start requiring all the researches it funds, intermural and extramural, to publish their results in such journals. Hopefully this will prompt less rigorous journals that don't require the posting of supplemental material to update their policies.

In conclusion, the Aronow scandal shows EPA cannot rely exclusively on traditional peer review to detect misconduct. Aronow reviewers at 11 leading journals, as well as EPA staff and their scientific advisors on the CASAC, who also review the studies before recommending that nine be cited as the basis for the CO NAAQS. Unfortunately, despite all this publicity, none of

Aronow's studies were retracted, and the EPA has started citing them again, most recently in the 2010 integrated science assessment of the CO literature.

EPA's proposal to strengthen transparency and regulatory science could stop this from happening again, which is why I support it and encourage my colleagues to do so as well. Thank you.

MR. ROBBINS: Thank you.

MS. SARFATY: Can you hear me?

MR. ROBBINS: Yes.

MS. SARFATY: Yeah. Okay. Respected EPA panelists and fellow citizens, my name is Mona Sarfaty. I'm a physician trained in family medicine and public health. I practice primary care medicine and taught medical and public health students in three different academic medical centers for 35 years.

Today I direct a program in climate and health at George Mason University in Fairfax, Virginia. I also direct a consortium of physician

societies called the Medical Society Consortium on Climate and Health, whose 550,000 members are more than half the physicians in the United States.

The Consortium seeks to inform the public and policy makers about the health harms of climate change, and the health benefits of climate solutions. I'm submitting the formal comment of the consortium in written form in a separate document.

The EPA is proposing to change the rules that dictate what evidence must be considered as the basis for protecting the public's health. As a physician who spent a summer in Southern California during college and didn't see Mount Wilson looming in front of me for an entire week because of smog, I am incredulous.

I remember well the pain in my chest when trying to play tennis on those smoggy days. This was the early 70s, when a republican president was creating the EPA. Now, 50 years hence, tremendous evidence has accumulated that validates my symptoms and the negative effect that unhealthy

hair -- air, has on people who must breathe it.

After that summer, as a practicing physician, I took care of people with asthma and chronic lung disease who were at greater risk on bad air days. So it is shocking to me that the EPA would propose putting aside huge amounts of thoroughly reviewed evidence on the causal connections between air pollution and poor health, claiming that the basis for this conclusion was secret.

Today, I lead a consortium comprised of the country's largest medical societies whose doctor members are highly concerned about the health harms of climate change. The similarities between the current EPA willingness to disregard established science about the connection between carbon dioxide and global warming, and the willingness to disregard solid evidence about the impact of air pollution on health, are glaring.

Despite overlapping evidence from every country in the world, and the entire U.S. climate science enterprise, not to mention major federal

agencies like NOAA and NASA, the EPA leadership does not accept or recognize reality.

To all of us whose lives are dedicated to helping people get and stay healthy, there is a secret lurking in the science of air pollution and global warming. It is not what we have long-known about how burning fossil fuels creates waste products that damage and inflame our lungs. This has been validated by voluminous overlapping research studies. The secret is not that carbon emissions from burning fossil fuels are warming our climate, exacerbating the health harms of air pollution, and causing other dangers to our health, from heat waves, wild fires, pollen, and storms.

The secret is hiding in plain sight. Fighting air pollution is the greatest public health opportunity of our time. It's the greatest public health opportunity of our time.

Reducing polluting fumes and emissions from fossil fuels will rapidly improve our health and fight climate change.

When an EPA's not so secret agenda is to promote fossil fuels, two things follow. The fact that fossil fuels are the major contributor to both air pollution and global warming must be undermined or denied. And the research that documents this reality and how it harms our health must be attacked. It's not hard to see that the approach is to mislead people by wrapping these attacks in rhetoric that's alternatively scary as in secret science, and high-minded, as in transparency.

We're told that the rationale for the new proposed strengthening transparency standard is that individual and medical records included in research were secret. In fact, like all medical records, they were confidential and they remain so.

The record shows that the same argument of secrecy against scientific studies has been used by polluting industries going back many years.

Health providers know that the facts may

be scary when our health is threatened. But we also know that denying or ignoring facts blinds us to discovering and acting on the best ways to heal medical problems and protect our health. We can't let that happen. The EPA must live up to its charge and work to face facts and protect our environment and our health. With this proposed regulation, its leadership is pointing in the opposite direction. Thank you.

MR. ROBBINS: Thank you.

Okay. We're going to take a short recess now and we'll resume at noon.

[Morning session adjourned.] [On the record 12:00 p.m., Afternoon session.]

MS. RADZIKOWSKI: Good afternoon. If everyone will please take their seats? Hello, and thank you for coming. My name is Mary Ellen Radzikowski and I am in the EPA's Office of Research and Development and I'm one of the hearing officials. Joining me is Lynn Flowers, also from the Office of Research and Development and we have a number of folks: Nanishka Albaladejo, Lauren Hall and

Lesley Stobert from SC&A Inc., helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science". EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of the administrative record on which EPA will base its decision.

Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under the authority of 5 U.S.C. 301, in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA receives your comments in an orderly fashion. Although EPA panel members here may ask clarifying questions, the intent of the hearing is to listen to your comments, not to discuss or debate the proposal.

Now I will go through a few housekeeping items and

ground rules: Please refrain from interrupting speakers or asking questions. Shouting, noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies. For everyone's awareness, this hearing is open to the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing.

There is no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again so please be aware of the time.

If you would like to make an oral comment at today's hearing and did not pre-register to speak, please see the hearing staff at the registration

table located right outside the doors here. If you would like to provide a written comment for the official record, you may hand-submit it to EPA staff today, or mail, fax or email your comments. See the staff at the registration table for instructions on how to do that. There is a comment box at the registration table where you can leave hardcopies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments, it is not necessary for you to give the same comments orally; written comments and oral testimonies will receive equal consideration by EPA in preparing its final rulemaking decision.

EPA has extended the comment period. Written comments must now be received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science", so please refrain from making comments that are not related to this action.

EPA will not be providing responses during the hearing. Rather, EPA will prepare a written summary of the comments received that includes responses.

The summary of the Response to Comments, the document, will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered.

The hearing is being recorded by a court reporter, who will be preparing a verbatim record of this hearing.

Please speak clearly and slowly into the microphone so that the court reporter can accurately record your comments. A copy of the transcript will be placed in the docket. This hearing is also being audio streamed through Adobe Connect via the telephones.

The hearing is scheduled -- started at 8 AM this morning and is scheduled to go to 8 PM. We're in the second session: 12pm-4pm.

Public restrooms are located down both sides of

the hall. At the doors we have staff that can escort you out and back. Please note the location of the emergency exits. Please take a moment to silence your cell phones.

Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For this session, the speaker sticker color is white, so if you have a white sticker you're registered for this session.

Speakers will be called to the speakers' table (located right over there) in pairs by their speaker number.

When it is your turn to speak, please come to the table, state and slowly spell your name for the record, and if you are appearing on behalf of someone or another organization. If you are not in the room when it is your turn to speak, I will recall you after all other speakers have made their oral comments. Each speaker will be allotted 5 minutes for remarks. Elected and

appointed government officials may be provided additional time, since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system consists of green, yellow, and red lights. When you begin to speak, the green light will come on to indicate you have your 5 minutes. The yellow light indicates that you have 1-minute left and when the red appears, your 5 minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap-up your testimony to give others an opportunity to speak.

At this time, we are going to begin.

MS. STOBERT: If Speakers Numbers 1, Pamela Miller, and 2, Elizabeth Geltman, will come to the speakers table and Speakers 3 and 4, Patricia Koman and Alexis Adiman would go to the on-deck seating located near the stage.

MS. MILLER: Good afternoon, my name is Pamela Miller, P-A-M-E-L-A, M-I-L-L-E-R. I serve as Executive Director and provide these comments on behalf of Alaska Community Action on Toxics.

We're a nonprofit, public interest environmental health, research and advocacy organization, dedicated to protecting public health. I also serve as principle investigator of multiyear research studies involving several universities that investigate exposures and health outcomes concerning endocrine-disrupting chemicals in collaboration with Arctic indigenous communities in Alaska. I traveled the distance to Washington, D.C., from St. Lawrence Island, Alaska, in the Northern Bering Sea, two full days of travel, where we are conducting summer field research and interrupted this because EPA did not make it possible to provide remote testimony.

Through a process known as global distillation, the Arctic has become a hemispheric sink for contaminants that are carried on atmospheric and oceanic currents into the north where they concentrate in the bodies of fish, wildlife and people. Indigenous peoples of the Arctic are among the most highly exposed populations on Earth to persistent bio-cumulative and toxic chemicals

because of their reliance on traditional foods including fish and marine mammals that they use for their spiritual, cultural and physical sustenance. The communities that I work with on St. Lawrence Island also have higher exposures to chemical contaminants from military operations associated with formerly used defense sites. Our research elucidates exposure pathways, body burdens and health outcomes associated with chemicals including PCBs, PBDEs (or polybrominated diphenyl ethers) and other flame retardants and also perfluorinated substances in homes, in air, water, traditional foods and in the blood serum of the Yupik people of St. Lawrence Island. Our studies have shown elevated body burdens as well as disruption of thyroid function associated with these exposures to certain PBDEs and perfluorinated substances. We are now beginning a research study to investigate exposures to PCBs, PBDEs and currently used organophosphate flame retardants in young Yupik children, age 2 to 12, because elders and other community leaders are

concerned about possible adverse effects on children's neurodevelopment. They're concerned that chemical exposures might harm the children's abilities to learn the languages, songs and stories that are so vital for the continuance of the culture of Yupik people. Participation is dependent on the trust of confidentiality that they give to us as researchers. Our research team submits each proposal to rigorous review to the National Institute of Environmental Health Sciences. In the process of the research, we submit also to several institutional review boards for approval to collect sensitive and detailed information on health and behavior as well as spatial and demographic data in an ethical manner that protects human subjects. We have published results of our research in 11 peer-reviewed journal articles after receiving approval from the tribal leadership. These findings help inform interventions and policies to reduce burdens of toxic exposures and prevent further harm to public health. These studies are possible only because

we guarantee to protect the medical privacy of participants, again dependent on trust of the researchers. We gather detailed information about peoples' health and occupational histories, practices in their homes and communities that might relate to chemical exposures. If the proposed rule were to go into effect, studies such as these would not be considered by EPA when it makes decisions about chemicals and pollutants that are poisoning the people of the Arctic such as decisions to limit the production and use of persistent biocumulative toxics and other chemicals including those regulated under TSCA and FIFRA and in regulations that hold military and industrial polluters responsible for contamination of air, waters and lands under CERCLA, the Clean Air Act and the Clean Water Act. EPA indicates that the proposed rule is intended to strengthen transparency of EPA regulatory science; however, we find this a duplicitous claim. It would favor industry data protected as confidential business information over public peer-reviewed research.

We support the best scientific evidence to inform regulatory decisions. However, this rule would have a dangerous counter effect by limiting the science that should be used to inform decisions about public health. Furthermore, we disagree with the agency's conclusions as stated in the proposed rule document that this action does not have tribal implication as specified in the executive order and requiring government to consult with tribes. This rule would disproportionately affect vulnerable populations including American Indian and Alaska Native People and, therefore, is relevant and requires consultation.

MS. RADZIKOWSKI: Excuse me, your time is up. We need to be fair to others.

MS. MILLER: I'll wrap up to say that we urge EPA to end this rulemaking promptly and we strongly oppose the proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. GELTMAN: Good afternoon. Thank you for the opportunity to comment on EPA's proposal entitled,

"Strengthening Transparency in Regulatory Science." My name is Elizabeth Glass Geltman, G-E-L-T-M-A-N. I am a Professor of Environmental Health Policy at the City University of New York -- the CUNY School of Public Health, located in Harlem. I am the author of 17 books on environmental and natural resources policy, a peer-reviewer of numerous journals and have worked on EPA-regulated matters for over 30 years. I am also the Chair Elect of the Law Section of the American Public Health Association. As a professor, I aim to advance public health by preventing people from getting sick. My efforts address reducing health impacts, and hence controlling health costs, by evaluating chemical and environmental determinants of health. Although EPA's rule aims to establish a clear policy concerning the use of dose-response data and models that underlie pivotal regulatory policy, the rule is, in fact, a continuation of the Trump administration's two for one regulatory reform policy announced in Executive Orders 13771,

13777, and 13783. The rule promises, "to change agency culture and practices regarding data access so that scientific justification for regulatory actions is truly available for validation and analysis." However, the new rule, in fact, creates new regulatory hurdles by discounting and precluding consideration of long-standing, established scientific practice. Rather than promoting the transparency of scientific information used to create environmental regulations, the rule will obscure the democratic process, slow the pace of science and progress, and potentially prevent important health data from being considered by U.S. EPA in outlying important environmental policy. Administrative procedure requires the EPA consider data submitted by the public in evaluating regulations. Let's be clear, scientific studies have always been of uneven quality. EPA has a process in place, including use of Scientific Advisory Board testimony and written and oral public notice and comment, using internal and external peer review to evaluate

data. Depending on context some studies are given greater weight than others. Some studies are disregarded entirely. It is inappropriate, however, and unlikely unlawful -- and likely to be unlawful -- under the Administrative Procedure Act. For EPA to categorically eliminate certain types of studies, and hence certain types of data, without considering context. But, even more important, eliminating studies, unless all underlying data is made public, is hazardous to human health and the environment. Longitudinal medical and epidemiological studies are often conducted over years, if not decades. Many studies require people who are study subjects to share very, very personal information, often on the legal or ethical condition that private medical information provided will be protected from public view. EPA is not, and has never been, in the regular business of replicating studies. Timing and the cuts in EPA funding make replicating studies as a condition of promulgating regulations an impossibility. EPA has presented

no scientific reason to prevent use of human health studies simply because the underlining medical records are not available for public inspection and review. One size fits all rarely works in fashion and it is even more unworkable in science and regulation. It is imperative the EPA allow consideration of all available scientific data pertinent to a proposed environmental rule or regulation including random, controlled human health trials and other epidemiological studies. Eliminating certain classes of human health studies would be like picking NFL players in the draft without allowing any scouting reports or eliminating the minor league in baseball. It doesn't make sense in sports; it makes even less sense when we're safeguarding our nation's air, water and land. For the reasons stated, I respectfully request the EPA withdraw the misleadingly-named rule entitled, "Strengthening Transparency in Regulatory Science." Thank you very much for allowing me to speak. My comments are my own. I'm happy to answer questions and I

will submit more detailed comments for the record.
MS. RADZIKOWSKI: Thank you.
MS. STOBERT: Speaker Number 5 is Alexis Andiman. Also, if Speaker Number 6 could take a seat on the on-deck seating: Sarah Kogel-Smucker. Speaker Number 3, Patricia Koman, and Speaker Number 4, Alexis Andiman.
MS. PATRICIA KOMAN: Thank you. My name is Patricia Koman, K-O-M-A-N. I'm an environmental epidemiologist at The University of Michigan School of Public Health. I'm a member of the American Public Health Association, and in my comments I'm representing myself and my colleagues at the University of California at San Francisco Program for Reproductive Health and the Environment. As a scientist who has formerly served at the U.S. EPA and has been significantly involved in analyzing science to create regulation and programs that protect the public's health from diesel and air pollution, I value the importance of open science which includes appropriate data sharing and full reporting of methods. However,

U.S. EPA's proposed rule is not consistent with the principles of open science, inappropriately codifies how science should be conducted, and codifies science policy decision in direct conflict with consensus reports from the National Academies of Sciences 2009 and often the enabling environmental statutes such as the Clean Air Act and the amended Toxic Substances Control Act. Therefore, EPA should withdraw this proposed rule immediately. Instead, EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies. The proposed rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human subject data. The rule's requirements for specific types of test methods, defaults, dose response models and/or other analyses are not supported by current science and these provisions should be removed. The rule is counter to mandates in the amended Toxic Substances Control Act, to use the best available

science and systematic reviews for chemical evaluations. Specifically, the proposed rule inappropriately codifies particular data analysis approach such as dose response modeling that should be made based on empirical considerations. This proposed rule will lead EPA to utilize inadequate science resulting in inaccurate analysis and, consequently, inadequate public health protections. The proposed rule does not expressly address the issue of how the new procedures will be protective of public health. Alternatively, existing open science guidelines can and should be used to protect public health such as the 2013 memo from the Office of Science and Technology Policy. In addition, protocols and guidelines such as CONSORT, ARRIVE and STROBE do not require public access to all study data and will still improve the scientific basis of evaluating studies and thus promote public health goals.

I want to call your attention to especially troublesome provisions of the proposed rule which

is not consistent with current scientific practice and why this proposal should be withdrawn. For example, it is not appropriate to require the use of standardized test methods, guideline studies or so-called good laboratory practice studies. These types of studies are not designed to address health effects from low-dose exposures, complex and systematic endocrine effects, behavioral or learning effects, or metabolic changes. In addition, the so-called good laboratory practice and guideline studies are not consistently associated with higher quality research, proper study design or correct statistical analysis. Further, by dictating the model choices without empirical basis the proposed rule sets a dangerous precedent of prescribing how science should be conducted without regard to the data, or hypothesis or peer review. This is especially troublesome for dose response models. Simply using a greater number of models as the proposal preference is unlikely to improve results without considering the models' assumptions and whether

they fit the data set, the goals of the analysis, and many other issues. Therefore, giving priority to studies based on the number or range of models used is scientifically inappropriate.

Contrary to the proposed rule's statement about growing evidence of nonlinearity in concentration response functions, the body of empirical evidence points to the opposite, that for most chemicals and pollutants there is likely no safe threshold on a population level because of ongoing exposures and preexisting vulnerabilities. The rule mandates reconsidering using a linear no-threshold dose response but the National Academy of Sciences recommends exactly the opposite in considering low-dose effects. "The committee recommends that cancer and non-cancer responses be assumed to be linear as a default." Regarding other defaults, I oppose provisions that mandate reconsideration of established science-based defaults on a case by case basis. This is in direct contradiction to the National Academy of Sciences recommendations. The rule is counter to the mandates in the amended

Toxic Substances Control Act to use the best available science and systematic reviews for chemical evaluations. In contrast, this proposed rule will have EPA ignore well-conducted, relevant studies simply because all the data are not publically available and/or may not conform to the rule's invalid assumptions about good laboratory practices and guidelines, studies, and dose response modeling. This is inconsistent with modern science and the TSCA statutory mandates. Further, EPA's risk evaluation framework rules under TSCA mandate the use of systematic review methods. Well conducted systematic reviews consider the entire body of scientific evidence and the quality and strength of all relevant individual studies are considered to reach the overall conclusion.

Therefore, for these reasons, and those outlined in my full written comments, I strongly oppose this proposed regulation and recommend that EPA withdraw it immediately. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. ANDIMAN: Good afternoon, my name is Alexis Andiman, A-N-D-I-M-A-N. I am an Associate Attorney at Earthjustice, the nation's original and largest nonprofit environmental law organization. Earthjustice strongly opposes the proposed rule entitled, "Strengthening Transparency in Regulatory Science." If finalized, this rule would drastically undermine the U.S. Environmental Protection Agency's ability to protect public health and the environment through science-based regulations restricting the presence of chemicals and pollutants in our air, drinking water, food and consumer products. Under the guise of increasing transparency, the proposed rule would authorize EPA to ignore scientific studies that incorporate personal data and other information that researchers cannot practically, legally or ethically disclose. Indeed, EPA admits that the rule would preclude it from considering landmark studies assessing the health consequences including risks to children associated with exposure to particulate matter and lead. This is

unnecessary and unacceptable.

The proposed rule raises more issues than I can address during five minutes of testimony. In partnership with other environmental and public health organizations, Earthjustice plans to submit extensive written comments detailing our serious concerns about the rule's procedural and substantive defects. Today, I will focus on three key points.

First, EPA lacks authority to adopt the proposed rule. Second, the rule would directly conflict with laws that EPA is charged with implementing and enforcing. And finally, the proposed rule would harm the communities of color and low-income communities that are most in need of strong, science-based protections.

First, EPA lacks authority to issue the proposed rule: It is axiomatic that administrative agencies may act only pursuant to authority delegated to them by Congress. The Administrative Procedure Act requires that each notice of proposed rulemaking reference the legal authority

under which the rule is proposed. EPA failed to identify any meaningful authority for the proposed rule at issue today. In announcing the rule, EPA cited provisions of numerous environmental laws but virtually every provision cited authorizes or directs EPA to undertake research, not to impose unfounded limitations on the research it will take into account. EPA also cited provisions that authorize it to promulgate rules necessary to achieve the goals of these environmental statutes, but ignoring credible scientific evidence is neither necessary nor consistent with the statutes enacted to protect public health and the environment.

Second, the proposed rule directly conflicts with numerous laws. Multiple statutes require EPA to ground its decisions in credible science. For instance, the Safe Drinking Water Act directs EPA to rely on the best available, peer-reviewed science and the best available public health information. The Toxic Substances Control Act similarly mandates that EPA consider all

reasonably available information and act in a manner consistent with the best available science. At no point do these statutes suggest that the quality of a scientific study depends on the public's ability to access the underlying data. Indeed, as the EPA previously determined, and as the U.S. Court of Appeals for the D.C. Circuit agreed requiring agencies to obtain and publicize the data underlying all studies on which they rely would be impractical and unnecessary.

Finally, the proposed rule would harm the communities that are most in need of strong, science-based protections. Decades of scientific research have established that communities of color and low-income communities are disproportionately likely to experience exposure to chemicals and pollutants. This research is also critical to establishing regulatory safeguards that will protect these communities and their environment. Nonetheless, the proposed rule would preclude EPA from considering this research simply because it incorporates personal health

information and other non-public data. As a result, the rule would eliminate an important means of understanding and beginning to resolve the harms suffered by over-burdened communities and that's what perpetuates the environmental injustices these communities already face. Earthjustice urges EPA to withdraw the proposed rule without delay. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Number 5, Alexis Andiman, is already seated at the table. She's speaking on behalf of Devon Hall. If speaker Number 6, Sarah Kogel-Smucker would come to the speaking table. If we could have Speaker Number 7, John Doherty and Speaker Number 8, Tricia Sheehan, come to the on-deck seating. Speaker 5.

MS. ANDIMAN: Good afternoon. I am reading testimony on behalf of Devon Hall. D-E-V-O-N, H-A-L-L, who was unable to make it today. My name is Devon Hall. I am the Cofounder and Program Manager at the Rural Empowerment Association for Community Health, also known as REACH. On behalf

of REACH and the community we serve, I urge the U.S. Environmental Protection Agency to withdraw its proposed rule entitled, "Strengthening Transparency in Regulatory Science." I cofounded REACH in 2002 to address social, economic and environmental inequities in and around Duplin County, North Carolina. Our primary focus is protecting our community from pollution caused by industrial animal operations. North Carolina is a leading producer of swine and poultry. There are nearly 2-1/2 million hogs and pigs and more than 16 million chickens and turkeys in Duplin County alone. Together, these animals generate well over 2 billion gallons of wet waste and more than 190,000 pounds of dirty litter each year. This waste produces an overpowering odor and pollutes our well water, rivers and streams. REACH uses scientific research as a tool to educate and empower our community. Common sense tells you that it's not healthy to breathe air that smells bad enough to make you gag and that makes your nose run and your eyes water. I began to work as

a citizen scientist in 2004 because I wanted to understand exactly what I was breathing and how it was likely to affect my body so that I could better protect myself and help my neighbors protect themselves. So far, I have coauthored nine published studies documenting the threats that under-regulated industrial animal operations pose to community health. For example, I contributed to a study showing that kids who attend school downwind of industrial hog operations are exposed to relatively high levels of hydrogen sulfide, putting them at greater risk of symptoms like difficulty breathing and impaired lung function. I also worked on a study finding that children of people who work in industrial hog operations are more likely to carry dangerous, antibiotic-resistant bacteria on their bodies, even though those children likely never set foot in industrial hog operations themselves. REACH has no interest in putting anybody out of business, but we believe it is possible for industrial animal operations to be more

environmentally friendly and more community friendly. It is not enough for us to talk about our symptoms and our diminished quality of life. No matter what we say there will always be some people who think we are just complaining or making things up. My neighbors and I want to be part of the science so that we can gather proof about what we're living with on a daily basis. We hope that policy makers will listen to that science which reflects the experiences of real people and begin to make some changes. If adopted the proposed rule would prevent EPA from considering the scientific studies that REACH helps to conduct. We cannot make all of our data publically available because we cannot risk compromising the confidentiality of the people who contribute to our work. Because we live in a rural community it would be relatively easy to identify study participants based on de-identified information like age, sex, occupation and number in households, even if the participants' names were redacted. Simply put, people would not

participate in our studies if they knew that the identifying information they shared could become publically available. Even if EPA were to expand on its vague promise to protect confidentiality, I would not trust the government to deliver. Once, I called the North Carolina Department of Environmental Quality to report a permit violation at an industrial animal operation and, even though I asked to remain anonymous, I received a call back directly from the operator I had complained about. The government apologized to me later, but the damage was done. My anonymity had been violated and I felt violated as a result.

On another occasion, the North Carolina Pork Council tried to obtain the identities of study participants from Dr. Steve Wing, a researcher who worked closely with our community. Dr. Wing worked hard to protect our trust, but I know that the legal problems he experienced deterred other researchers from studying the health effects of industrial animal operations. EPA's proposed rule might also deter researchers from partnering with

communities like ours to study public health impacts because it would dramatically reduce the influence of those studies in agency rulemaking. Contributing to research about a polluting industry is a lot like acting as a police informant. You're providing information that could help to make everyone more safe, but you are putting yourself at risk, too. People who work at industrial animal operations would lose their jobs if their employers knew they were participating in a scientific study. And losing your job is not the only risk. I have been spoken to hard by powerful people who do not like the work I do. And I know people who have been physically and verbally threatened by industry representatives. EPA has investigated this issue and in January 2017, it expressed grave concerns about the intimidation we have experienced.

I'll wrap up quickly. My first priority is to the people I serve. I will never do anything to violate their trust or put them in danger. If EPA cares about keeping people safe, it should

withdraw the proposed rule immediately and instead take steps to support community-based research. Thank you.

MS. KOGEL-SMUCKER: Good afternoon, my name is Sarah Kogel-Smucker, Special Assistant Attorney General at the Office of the Attorney General for the District of Columbia. I am commenting on behalf of Karl A. Racine, the Attorney General for the District of Columbia. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," is a solution in search of a problem. Instead of strengthening ways in which EPA can benefit from advances in scientific studies, the proposed rule limits EPA's access to important studies and hampers the development of regulations needed to protect the public health and welfare of the residents of the District of Columbia and the nation. The proposed rule should be withdrawn. In these comments, I will briefly address why the proposed rule limits the use of valid, peer-reviewed scientific studies, violates several environmental statutes and lacks sufficient

details to be appropriately evaluated and implemented.

First, the proposed rule impedes EPA's decision-making by creating burdensome, and potentially impossible, barriers to the use of certain scientific studies needed to determine the impacts of pollutants and toxic materials on air quality, water quality and human health. The proposed rule requires that EPA's significant regulatory decisions be justified only by studies based on dose response data and models that area available to the public. This requirement limits EPA's ability to rely on otherwise peer-reviewed scientifically valid studies that do not or cannot make their data publically available because of confidentiality concerns. For example, EPA used the landmark Harvard Six Cities study demonstrating a dramatic link between premature mortality and air pollution as part of its justification for key clean air regulation. The study has been rigorously independently peer reviewed but the subjects were promised

confidentiality and the data is not public. Studies with confidential data can still be appropriately peer reviewed through the use of confidentiality agreements and subject to rigorous scientific scrutiny over their methods and conclusions. Where cost-effective and appropriate use of open or publically available data should be encouraged. EPA, however, should not provide blanket limits on the use of studies that cannot be made public because they contain confidential health or business information. Scrubbing studies of such information may be impossible while still keeping the study reproducible. The proposed rule may also have important implications for rules subject to periodic update like the Clean Air Act, NAAQS, if EPA can no longer use the same or similar methods that were used to support the existing rules.

Second, the proposed rule violates several environmental statutes because it hinders EPA's ability to rely on best available science or most up to date information as they require. The Clean

Air Act, Clean Water Act, Safe Drinking Water Act, Toxic Substances Control Act, and Emergency Planning and Community Right-to-Know Act all require certain decisions or regulatory criteria be based on the most up-to-date science. These criteria are described as best available science, latest scientific knowledge and best available public health information. The proposed rule would illegally limit EPA's ability to rely on best available science in violation of these statutes.

The nearly 700,000 residents of the District of Columbia rely on EPA to protect their health and environment. While air quality in the District has improved over the last several decades, many residents who face disproportionate exposure risks because of where they live or work still face risks to their health from air pollution. For example, the American Lung Association's "2018 State of the Air (sic)" report gave the District a failing grade for the period from 2014 to 2016 because of the number of days that the air was

unhealthy for vulnerable populations due to high levels of ozone. The District's vulnerable populations, including the estimated 10,415 children in the District with asthma, are entitled to protection from unhealthy air. Because people of color and children living in poverty disproportionately suffer from childhood asthma, environmental justice demands that EPA continue to use advances in scientific research to improve air quality through appropriate regulation. EPA should not be artificially hampered in this duty just because the data or models from a high-quality, peer-reviewed study are not publically available.

Lastly, the proposed regulations are too vague to be meaningfully evaluated and successfully implemented. For example, it is unclear whether Section 30.7 requires EPA to conduct its own peer review of all pivotal regulatory science and, if so, whether EPA has the capacity or capability to perform those reviews. Likewise, the exemption process does not provide sufficient standards to

ensure that the administrator made consistent determinations. For these reasons, the proposed rule should be withdrawn. Subsequent EPA transparency initiatives, if any, should be based on consultation with the National Academy of Sciences and should not restrict EPA's ability to rely on the universe of best available science when promulgating regulations. Thank you for the opportunity to comment today.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker Number 7, John Doherty, and Speaker Number 8, Trisha Sheehan, would come to the speaker's table. Speaker Number 9, James Duffy, and Speaker Number 10, Erika Rosen, if you'd go to the on-deck seating.

MR. DOHERTY: As a retired EPA toxicologist I know the firsthand frustrations of having to deal with epidemiological reports. However, I believe that epidemiological reports are valuable but more, critical, initial review is needed. Today, I hope to present a path forward. The animal studies that I've reviewed are required to support the

registration of pesticides follow very strict quality assurance, good laboratory practices and ethics and reporting standards. Multiple layers of primary and secondary reviewers are identified and assigned to review documents to assure quality assurance and transparency. Every force, however, has a mixed bag of standards to my experience for QLT, quality assurance ethics in reporting. They are often accepted at their face value without documentation of independent review. There is no way to verify the procedures or results presented and the EPA reviewers are not identified. This is very unfair to the public. Historically, I would like to mention two situations where more critical initial evaluation would have prevented social and medical problems. The first is the report on the Kallikak family published in 1912 by Henry Goddard. The book was the foundation of eugenics and was well received at first, but very serious social consequences resulted. However, closer examination revealed that much of the interviewing reflected the biases of the interviewers. Goddard

later regretted publication of this book. The other is associated with vaccinations and autism that could not be verified. The publisher retracted the original publication; however, within the past two years there is an increase in measles in Minnesota because people feared autism from vaccinations. When the concept of disparity in the views of animal versus epidemiological studies, and the need to provide a more critical initial review the EPA posed, I am proposing an epidemiology peer review consult with the goal of creating a transparent document reflecting a thorough review be established at EPA. The Council will consist of six independent subcommittee and relevant experts as follows: First would be an ethics subcommittee. All aspects of assuring the personal safety and identities of the individuals on the study would be protected. Second is an end-point evaluation. The relevant experts knowledgeable in cancer and rural behavioral, or whatever the condition is, they would discuss the factors like how many

people are really needed in a cohort to make a decision. Identify what is known about that particular condition environmental factors or chemicals are known to cause it. The other -- is self-explanatory. Exposure evaluation, statistic evaluation, analytical chemistry and animal toxicity and structure activity correlations. Each subcommittee will articulate why additional data are or are not needed. The Council will consist of qualified individuals from the EPA, FDA or other agencies' consultants as needed. The Council will have considered the reports of the six independent subcommittees and make their recommendations especially with regard to additional data needed to support a transparent regulatory decision.

The report of the Council -- the final report of the Council, will append each of the six subcommittee reports as well as any dissenting opinions. The Council owns the decisions and since all responsible individuals will be identified, the report is thus transparent. Thus

AP may further review the Council report. In conclusion, controversies associated with epidemiologic reports may not be eliminated by the Council, but the Council should contribute to minimizing these controversies. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. SHEEHAN: Good afternoon, my name is Trisha Sheehan, S-H-E-E-H-A-N, and I'm representing Moms Clean Air Force. I traveled here today from my home in New Jersey. I'm the National Field Manager for Moms Clean Air Force. We are an organization of over 1 million members from across the country who are fighting every day to protect the health and safety of their children from toxic chemicals, air pollution and dangerous climate change. I am also a mom to three young boys and last week my family and I joined Democratic House Leader, Nancy Pelosi, to share our own story of how my family was impacted from a toxic chemical accident and today I'm here to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name

of transparency. Limiting the scientific information the EPA can use to identify public health threats and protect us from pollution is reckless and dangerous. Not only does this proposal compel EPA to subject high-quality research to extreme unnecessary and untenable levels of disclosure, but it also includes loopholes that would allow the administration to exempt industry from having to disclose details of their own studies. American families depend on the EPA and high-quality science to protect families like mine from the impacts of air pollution and toxic chemicals. This proposal puts that protection in jeopardy, placing the health of our children at risk. This proposal is misleading. It would require the EPA to only consider those studies that use public data. This would prevent the EPA from using studies that are based on personal medical data, eliminating some of the most important long-term epidemiological studies that investigate the impacts of pollution on public health. This proposal would

significantly limit the research and data the EPA can use to make informed policy decisions under major public health and environmental laws including the Clean Air Act, the Safe Drinking Water Act and the Toxic Substances Control Act. This proposal means that many studies on populations such as the elderly, children and people of color, groups who often suffer disproportionately from pollution, would be excluded from EPA consideration because making the data public could identify the participating individuals. Excluding this important data from consideration means that implementing the proposal could even further exacerbate negative environmental impacts on these and other vulnerable communities. As a mom who has witnessed her children's health deteriorate due to polluted air they were breathing, I know personally what it's like to rely on scientific studies whose data informed us during that horrifying time. On behalf of my family and Moms Clean Air Force's one million members, I strongly

urge the EPA to withdraw this dangerous proposal for the health and safety of our children. Thank you.

MS. STOBERT: Speaker 9, James Duffy, and Speaker 10, Erika Rosen, if you would come to the speaker's table. Speaker 11, Gretchman Goldman, and Speaker 12, Maggie Flaherty, if you would come to the on-deck seating.

MR. DUFFY: Good afternoon, my name is J. Duffy. I am an Associate Attorney with Clean Air Task Force. CATF seeks to help safeguard against the worst impacts of climate change by working to categorize the rapid global development and deployment of low carbon energy and other climate-protecting technologies through research and analysis and public advocacy leadership. EPA's proposal at best is a solution in search of a problem. The Agency has failed to identify a need for further review of the already extensively peer-reviewed public health and environmental science it uses in its decision-making, nor has it made the case the underlying health data must be

made more public than current statutes and practices allow. The only thing transparent about the proposal is that is an attempt to undermine EPA's ability to use the best available science by placing arbitrary limits on the ability to consider these studies.

As a professor who has cited multiple times the proposal recently stated, if this proposal is finalized, science will be practically eliminated from all decision-making processes so that public health and environmental regulation would then depend on opinion and whim. Banning the use of fully peer-reviewed studies because their underlying data must be kept confidential would eliminate the consideration of vital information in critical public health-making decisions. This is not only unnecessary, it also represents a significant shift in decades-long policy without any justification. As the D.C. Circuit has held when considering this exact question, requiring agencies to obtain and publicize the data underlying the studies on which they rely would be

impractical and it would be unnecessary. Congress has clearly spoken, moreover, mandating that the agencies must consider all relevant science. It is well understood, and it has been for decades, that many of the most important public health studies are those based on actual patient information. Because that information must be kept highly confidential and because making even some of the patients' details public would allow them to be identified, the information must be kept private. But that does not mean that these studies can't be, or haven't been, verified. For example, the Harvard Six Cities Study linking fine particulate matter and mortality has been exhaustively reanalyzed by independent institutions, including by the researchers under the auspices of the Health Effects Institute. This reanalysis confirmed the study's essential findings while keeping confidential the underlying data. There are already several ways in which the public can access the studies that EPA uses and in some cases their underlying data without the

release of confidential information, including through the Freedom of Information Act which provides an avenue to request raw data, including a process to ensure that sensitive data is protected. The proposal puts the EPA in the untenable position of either violating its mandate to consider all relevant science or violating confidentiality laws. Additionally, the proposal is impermissibly scatter-shot, it's vague, it's confusing, it's insufficiently formed to allow for meaningful comment. It seems more like a request for ideas about how to discredit the best available science than for how to make it more accessible. For example, the proposal claims that it is consistent with the Data Quality Act and HIPAA as well as various executive orders, but each of these contain checks on the release of confidential information. In fact, the longstanding OMB guidelines stemming from the Data Quality Act recognizes peer review as the per se marker of objectivity and the Harvard Six Cities Study reanalysis set the gold standard for

reproducibility.

Finally, in violation of Executive Order 12866, the proposal fails to perform any analysis regarding the impact this rulemaking could have on the environment, public health or science generally -- or even on what it would cost to implement. Because the Agency does not have authority to undertake this effort, and because it would undermine the consideration of relevant science in its public health and environmental rulemaking, it should be abandoned. Thank you.

MS. RADZIKOWSKI: Thank you. I'd like to remind speakers to please speak into the microphone.

MS. ROSEN: Good afternoon, this testimony is on behalf of Lynn Goldman. She is a pediatrician and an epidemiologist and has been Dean of the Milken Institute School of Public Health at the George Washington University since 2010 and former Assistant Administrator for Toxic Substances at the US Environmental Protection Agency. My name is Erika Rosen and I am delivering this oral testimony on her behalf. Her full written

comments will be submitted for the record. This proposal suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as similar agencies internationally, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision- making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as

Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking. The proposal ignores the "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences and the National Toxicology Program. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments.

Risk assessment activities at EPA are extensive and its programs are performing more than 1,000 risk assessments per year. The proposal does not consider the costs, the significant time and paperwork burdens, and major regulatory delays that will occur when EPA is waiting for data to be made publically available, which may not ever happen.

For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base underpinning EPA's decisions.

The proposal misrepresents the recommendations of prior expert reviews such as the so-called NAS "Silver Book" and the Bi-Partisan Commission review. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. Single studies are used to inform risk assessors of the possible shape of dose response curves. Instead, EPA evaluates all of the scientific information to gain a biological understanding of the "mode of action". When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens, and certain noncancer effects that have no practically identifiable thresholds.

This proposed rule for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

I strongly urge the EPA administrator: (1) not to use the Agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community. What is at stake is no less than the credibility of the Agency with the American public and public confidence in the integrity of EPA's science and decisions.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 11, Gretchen Goldman, and

Speaker 12, Maggie Flaherty, if you would come to the stage. Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, if you'll come to the on-deck seating.

MS. GOLDMAN: my name is Gretchen Goldman, G-R-E-T-C-H-E-N, G-O-L-D-M-A-N. I'm the Research Director at the Center for Science and Democracy at the Union of Concerned Scientists, and I'm also a mom. As a scientist, I'm deeply troubled by this proposal. As a mom, I'm alarmed by it, and the risks that it poses to my children and others. The EPA's mission is to protect public health but this proposal does the opposite. This proposal needlessly restricts the science that EPA can use to make decisions about all of our families' health. Many crucial scientific studies that rely on public health data, intellectual property, confidential business information and other scientific information that may not be publically acceptable would be unavailable to EPA experts under this proposal. As a result, the EPA will be prevented from making rules that protect people

using the best available science. There is no reason for such a rule. The EPA already follows a rigorous, science-based process for determining when and how studies are used in its decisions. I've seen this first-hand when the EPA contacted me about my own scientific research. The Agency needed to obtain results data from my peer-reviewed studies looking at ambient air pollution exposure in time series' epidemiologic studies. I can attest to the fact that the EPA already ensures it is using reliable and robust scientific information to make decisions. When my son was born he spent five days in the neonatal intensive care unit because of a respiratory problem and when I took him home I knew it would be important for me to make sure that he could breathe clean air. I can't protect him from the air outside always but the EPA can. When my children breathe outside I need to know that the air is healthy. When my children play in the grass I need to know that there aren't harmful pesticides in it. When my children drink from their sippy cups, they need

to know -- I need to know that the water is safe. How can EPA scientists protect my family and others if they can't use the best available science?

I urge you to withdraw this proposal and instead focus on EPA's mission of ensuring safe water, air and land for people across the country. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. FLAHERTY: Good afternoon and thank you for the opportunity to speak today. My name is Maggie Flaherty, F-L-A-H-E-R-T-Y, and I would like to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule. I would first like to emphasize that this rule proposed during Scott Pruitt's time as administrator of the EPA is a purely political decision. It is modeled after past efforts from the tobacco and fossil fuel industries for similar policies that prevent the use of science that reveals the harmful human health impacts of such industries. This proposed rule is not about

legitimate transparency; it is about making it harder for the EPA to make decisions based on the best available science. Under this rule studies that rely on personal health data, confidential business information, intellectual property, or studies whose data is no longer available would be excluded from the EPA's consideration when making decisions regarding regulations. When it comes to regulating things such as air pollution, water pollution and toxic substances, some of the most vital scientific information comes from studies of respiratory illnesses, cardiovascular diseases, and premature deaths, all of which rely on personal health data. If such vital studies are excluded because of this arbitrary rule, the EPA would be lacking critical public health information when making decisions that directly impact our health and environment.

If EPA is truly worried about transparency in science they would listen to the voices of the numerous scientists who have come out in opposition to this proposed rule and who have,

additionally, suggested other ways of introducing transparency. Instead of focusing on disclosure of data that can contain confidential and private information, a rule that truly increased transparency in science would focus on funding disclosure. Despite how strict the peer review process is, people should be able to know who is funding a study. This rule proposed by the EPA does not address the issue of funding transparency at all. According to an article in the *Journal of the American Medical Association* if all of the EPA's proposed changes to environmental policies since the election of President Trump go into effect, the result would be at least 80,000 unnecessary deaths per decade. This assessment is based on numerous scientific studies that would most likely be excluded by this rule. The EPA should not exclude studies that demonstrate the true health costs of their actions and remember their true mission of protecting our public health and the environment. I therefore urge the EPA to withdraw this proposed rule. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, will come to the speakers' table. Speaker 15, David Coursen, and Speaker 16, Abigail Omojola would come to the on-deck seating.

MR. FINKEL: Thank you. I appreciate the opportunity to comment as a former chief regulatory official at OSHA and a former member of the EPA Science Advisory Board and Board of Scientific Counselors. I support a wide spectrum of efforts to improve the transparency of the inputs to and the outputs of risk assessment and cost-benefit analysis, especially if they involve a more honest disclosure of uncertainty and variability. I will submit a recent paper I wrote with George Gray in this regard. But this proposal decreases transparency and reliability in three ways: It fails to identify a legitimate problem; it ignores closely related and glaring actual problems with regulatory analysis; and it promotes remedies that add noise while decreasing

signal.

First, the central dogma of regulatory policy since 1993, and most enthusiastically touted by this administration, holds that no regulation can be proposed absent a real problem to be solved, like market failure. Here, there is no failure of the scientific market and hence no need for a disruptive set of hurdles. By its own policies it developed to constrain its own regulatory excess, EPA should demonstrate, and not just with an anecdote or two, the crisis justifying the need for this proposal, or else should scrap it. I note that of the five URLs the EPA provides in Footnote 12 to document its claim that there is a "replication crisis," two of the links are broken and the other three discuss psychology and clinical trials. The end points in epidemiology, toxicology and exposure studies are simply not as subjective as psychology experiments are. There have been some problems found with clinical trials but the unmeasured variability is likely much more important with respect to whether a drug will cure

and weather a pollutant will harm. Most importantly, the EPA has cited no studies giving even guesstimate of what percentage of environmental science studies might be in need of replication or reanalysis and, of course, some of the shrill prior claims of error others have noted in the Six Cities Study have turned out to be fallacious. Surely EPA does not intend that most epi studies or bio-assays need to actually be replicated. Some epi studies can be redone but surely not natural experiments we never want to repeat such as the atomic bomb survivors study or the changes in air pollution during groundings right after 911. Lifetime animal bio-assays already use multiple doses, species and sexes and they are expensive and take years to complete. Why would we waste time and money duplicating them? And so, what if someone did try another species and got a lower potency estimate or didn't get positive results? Would we allow a rat or mouse carcinogen in unlimited quantities because it might not also be an aardvark carcinogen? I

don't think so. So, EPA probably means reanalyze, not replicate, and it should say so. But then EPA presents no evidence that anyone is hindering anyone else from reanalyzing anything. Any bio-acid that the EPA would use would already have individual tumor data and exposures and could be reanalyzed with any model that anyone wanted. Ditto for epi studies. But what would a reanalysis program actually do other than be costly and invite delay? What if someone reanalyzed a health study and got a different answer? One that suggests the first study had exaggerated the harm. In such a case the second study would be right and the first wrong only if both of these conditions were true. First, the difference in the results was not already acknowledged or contained within the uncertainties in each answer. If somebody claimed that banning a chemical would save between 500 and 1000 lives across the country, EPA chose to estimate it at an expected value of 750; another study that said 550 would not be different from the first study at

all. And secondly, the first study would have to be not just different, but wrong. Anybody can take the same data and botch the risk analysis of it making seem like they have a better answer. Just like there are potential problems with an analysis that doesn't control for some variable, it can be a mistake to control for a variable that shouldn't be included.

In short, EPA should never refuse to look at a study just because someone could reanalyze it but hasn't, has done so and gotten a different but not a better answer, or has done so, didn't like what it saw, and suppressed the results while claiming the original study still needs to be reanalyzed. Secondly, there is a crisis in regulatory analysis and EPA is completely ignoring it for reasons that are obvious to me. It's the economists' analysis of the costs of regulation and the values of benefits that are flawed, opaque and in need of reanalysis. Every criticism leveled at this proposal ought to first be applied to regulatory economics. They are obviously as pivotal as

estimates of risk. Regulatory cost estimates are notoriously biased high and they are surrounded by more uncertainty than surrounding risk estimates, but unlike risk estimates, cost estimates are rarely, if ever, presented with uncertainties and are sometimes even of the wrong side. In my written comments I'll give two examples. I have a paper newly published with Brandon Johnson. We looked at more than 1000 estimates, the value of a statistical life, certainly the most pivotal quantity in all of risk regulation derived from hundreds of studies. Only 40% of those studies gave any information about the ranges or standard deviations of the individual VSL values. So, no one can reanalyze that work to see what higher or lower values of the VSL are also compatible with the data. And perhaps the most well-known so-called study of the costs of regulation is the series of reports from Mark and Nichole Crane suggesting that regulations "cost the U.S. nearly two trillion dollars a year."

MS. RADZIKOWSKI: Excuse me, sir, we are out of

time.

MR. FINKEL: I'm sorry?

MS. FLOWERS: We are out of time, in fairness to others.

MR. FINKEL: I'm sorry, I didn't realize. The third one is about defaults and I will submit those, but EPA is a protection Agency, not a prediction Agency. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WILSON: Good afternoon, my name is Augusta Wilson, and I am here representing the Climate Science Legal Defense Fund. The first name is spelled A-U-G-U-S-T-A. I appreciate the opportunity to speak to you today and the Climate Science Legal Defense Fund will file more detailed written comments in the online docket for this proposed rulemaking. CSLDF is a nonprofit organization whose mission is to protect the scientific endeavor. In this capacity, we work closely with scientists at government agencies and at research institutions, so we have particular insight into how attempts to silence science

negatively impact both researchers on an individual level and the conduct of scientific research as a whole. There are numerous reasons why EPA should not proceed with this rule. In the time I have today I will focus on a few of the most important from the perspective of protecting the integrity of the scientific endeavor. First, studies that involve human subjects, particularly those investigating the human health impacts of exposure to environmental pollutants, are among the most relevant to EPA's core mission. In order to conduct such studies, scientists need participants willing to allow researchers access to their confidential health information. If enacted as currently proposed, this rule would make it much more difficult for scientists to credibly promise study subjects that their patient information will remain confidential. This could have deeply concerning, chilling effects on the conduct of important human health studies. Privacy concerns could influence what science gets done and what science does not get done. Lines of

scientific inquiry that would have been pursued may not be. The quality of data may be poorer than it otherwise would have been. Furthermore, the justification for this rule to the extent it exists seems to be based on the false premise that scientific studies cannot be adequately evaluated or reproduced unless all of their underlying data are made public. This is simply not the case. On the contrary, the reviewers can evaluate the merits of studies even when they rely on data that cannot be made publically available. This is because part of a scientist's core, fundamental training is the ability to assess research based on the strength of the experimental design and the precision with which experimental methods and analyses are described. In addition, when necessary and appropriate, reviewers, as well as other researchers seeking to reproduce or extend scientific analysis, can have confidential access to key data in conformity with privacy requirements.

That said, the scientific community has certainly

recognized that recent technological developments allow for significant improvements in data sharing and reproducibility and that such improvements can benefit science. There are numerous scientific societies, journals, and other organizations, as well as individual researchers, who are actively engaged in a dialogue about how to improve transparency while protecting scientists and taking into account issues like patient confidentiality and proprietary business information. If EPA is genuinely concerned about these issues, it should engage deeply in this discussion and with the scientists who are having it and should move forward only in concert with them. As written, this rule which EPA professes is intended to strengthen science will ultimately do significant damage to it and to the United States' ability to lead the world in research. EPA should not promulgate such a rule. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 15, David Coursen, and Speaker 16, Abigail Omojola, would come to the

speakers' table. Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford, if you would come to the on-deck seating.

MR. COURSEN: Good afternoon. My name is David Coursen, C-O-U-R-S-E-N, and I'm here on behalf of the Environmental Protection Network, a nonprofit organization of EPA alums working to protect the Agency's progress toward clean air, water, land and climate protection. There are so many things wrong with this proposal that it's easy to downplay the most important one: The harm it will do to peoples' health and the environment. The proposal hides this in a fog of ambiguous language, meaningless generalities and vague platitudes about the value of transparency. It requires EPA to wear a blindfold when it is developing major rules by ignoring what relevant and reliable science tells us about health risks any time the raw supporting data is not publically available. Transparency is important, but it is not part of the Environmental Protection Agency's mission and certainly cannot be the basis for a

one-size-fits-all litmus test for when the Agency must ignore what science tells us about the risks of pollution.

The laws governing EPA programs require it to consider all of the available scientific information in deciding how to protect peoples' health and the environment. Ignoring such information would be both arbitrary and unlawful. EPA rulemaking has always relied on the best available science, a principal the proposal gives lip service even as it outlines a scheme to prevent the EPA from using even the best available science if it is not "transparent." The proposal would put even the most persuasive and useful science off limits subject only to a vague and standardless exemption process. The proposal does not show that the EPA's existing practices have produced bad environmental outcomes or that increasing so-called transparency will lead to better outcomes. Those are not things the proposal seems to care about. There is no legal or environmental basis for the proposed

restriction and, not surprisingly, the proposal fails to mention that EPA's statutes do not allow the Agency to ignore available information about the risks of pollution. Inevitably, restricting the science EPA considers in rulemaking will produce less informed and less protective decisions. In effect, the proposal sacrifices relevant and reliable scientific information, a cornerstone of effective environmental protection on the altar of so-called transparency. A proposal to ignore science when all of the supporting data is not public would preclude using even recent studies that are subject to confidentiality agreements or legal restrictions on disclosure. It also will certainly and deliberately exclude older studies where the data is no longer available, even if their findings are widely accepted as authoritative and form the basis for EPA regulations that have proven effective in protecting peoples' health for many years.

The proposal is evasive about its targets using

footnote language only a lawyer could understand to identify two seminal air pollution studies that it excludes and says nothing at all about what other important studies it would ban. Written comments via the Environmental Protection network will spell out the policies that proposes many legal and policy defects in detail. The proposal is brief and cursory and provides far too little information to meet the legal requirement to alert the public to its substance and basis. It would prohibit EPA from considering important science in rulemaking even though the laws governing EPA's use of science require it casting a wide net. It sheds little light on how the proposal would work and no light at all on its environmental consequences. Instead of explaining how EPA will implement and interpret the rule, it largely throws these questions to the public. It doesn't show a need for any rule much less an absolute rule that sweeps across eight statutes. It claims its approach is consistent with a host of policies and studies but what Environmental Protection

Agency looked at them it found almost no support for the proposal and in some cases the authors have objected to the use of their studies and it posed the proposal. In sum, there is neither a legal basis nor a need for this rule. It would require the EPA violate explicit statutory provisions and unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of reliability and environmental protection to so-called transparency, a term not found in the relevant EPA statutory provisions. It is too full of undefined or ambiguous terms to create a workable legal frame work. In other words, the proposal is unintelligible, unlawful and unworkable. EPA, I respectfully request that EPA withdraw it.

MS. RADZIKOWSKI: Thank you.

MS. OMOJOLA: Good afternoon, my name is Abigail Omojola, O-M-O-J-O-L-A, and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would not serve to provide the public with greater "confidence in and understanding of" EPA's regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard not to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of

breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule's requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would

provide.

An example of the kind of study this proposed rule could eliminate from the EPA's regulatory process is the National Institute of Environmental Health Sciences' Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.

This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publically available. This is particularly true

for vulnerable marginalized communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research already. There is the competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to prevent this devastating disease. This proposal takes a hard step away from that goal.

Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford will take seats at the speaking table. If Number 19, Paul Allwood, and Speaker 20, John Stine, would take seats at the on-deck seating.

Mr. LOCKWOOD: Good afternoon, my name is Alan Lockwood, A-L-A-N, L-O-C-K-W-O-O-D. Thank you for this opportunity to speak on behalf of Physicians for Social Responsibility. I am a board-certified neurologist and an elected fellow of the American Neurological Association and the American Academy of Neurology, and Professor Emeritus of Neurology

at the University at Buffalo. PSR is a 501(c)(3) scientific and educational organization headquartered in Washington DC with over 30,000 physicians, medical students, and others across the country. Our mission is to protect human life from the gravest threats to health and survival. We submit this testimony in strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposed rule would change the standards for the inclusion of studies used by the Agency and lead to the abolition or weakening of virtually all protections under the purview of the Agency. Under the misleading veil of "transparency," the proposed rule could force investigators to invade the confidentiality of research participants and make confidential and private data open to all. A similar concern was voiced by the current Scientific Advisory Board, writing, "there are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests ..." The rule could replace evidence-

based decision-making with arbitrary determinations based on political considerations. Peer-reviewed research has led to important gains in health. The Clean Air Act protects us from air pollution and is arguably the most health-protective law in effect. I have written extensively about this in The Silent Epidemic. Peer-reviewed studies link air pollutants with leading causes of death in the United States including heart disease, stroke, and respiratory diseases. Additional studies link particulates to Alzheimer's disease and Type II Diabetes. Seminal studies include the Harvard Six Cities Study that involved 8,111 adults followed for between 14 and 16 years showing a clear link between pollution and mortality. The Women's Health Initiative study involving 65,893 post-menopausal women that demonstrated a link between particulates, and cardiovascular disease and stroke mortality. I attended closely to the study of 1,705 neurologist-confirmed strokes showing that a transient increase in small particles was

associated with a statistically significant increase in strokes even though levels were within limits "generally considered safe" by the EPA. A congressionally mandated report prepared by the EPA projected that by 2020 Clean Air Act provisions would save two trillion dollars per year in adverse health impacts. Many savings will positively impact the budgets of state and federal agencies at a time of ballooning deficits.

EPA rules provide significant protection for the developing brains of children by establishing limits on lead. Lead impairs brain development and has adverse effects on behavior and cognition. Other data link arsenic levels in drinking water to Type II diabetes and cancer.

Natural gas production, particularly "fracking" harms health due to human proximity to wells, pumping stations, and contamination of water supplies and contributes to climate change.

Protecting the privacy of research participants is a keystone of biomedical research and one with which I have had years of personal experience as a

member then chairman of the Buffalo VA Institutional Review Board. Peer-reviewed journals require authors to affirm their adherence to federal privacy protections as a pre-condition for publication. This standard should not be abolished. PSR's mission is to "to protect human life from the gravest threats to health and survival." To protect the scientific integrity of the EPA and protect health, we oppose the deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WOOLFORD: My name is Elizabeth Woolford and I am an undergraduate student at Wesley University and an intern with the National Parks Conservation Association. My comments are my own. Today, I would like to express my strong opposition for the proposed rule titled, "Strengthening Transparency in Regulatory Science." This rule would have sweeping impacts on the ability for the EPA to consult public health studies, as almost all utilized data from medical records that are

protected from public scrutiny. Their proposal would force the Agency to disregard such studies unless scientists reveal their participants' private medical information. Scientists conducting public health research would then be left with two unacceptable options: To break confidentiality agreements in order to disclose the personal health records of their subjects; or not to have their studies consulted by policy makers at all. As a result, some of the most significant research from the past decade, for example studies linking air pollution to premature deaths and measuring human exposure to pesticides would be left completely unavailable to the Agency. I would like to emphasize that data of a sensitive nature does not imply inherent unreliability, rather this kind of information is essential to achieve an accurate understanding about how human health is impacted by chemicals, chemical compounds and other substances. Such an understanding is necessary for the EPA to fulfill its mission to protect public health and protect

the environment with the creation of effective regulations under the Clean Air Act, Clean Water Act, CERCLA, and other cornerstone environmental laws.

This proposal is based on a false premise about data quality and acceptability. There is no reason why one cannot protect the confidentiality of subjects and at the same time use information about them. This rule questions the integrity of the scientists and doctors conducting public health studies by implying that these professionals may have biased their subjects to achieve a particular outcome. However, it is evident that peer review already protects against for such bias.

For these reasons, one must consider how this proposal fails to achieve the requirements of OMB's Information Quality Act. It is clear that this proposal is overkill and would unnecessarily exclude scientific studies simply because they do not meet an unrealistic transparency standard. This would all be to the detriment of public and

environmental health.

In addition, this rule would create a blatantly political and dangerous double standard by eliminating the use of studies that follow confidential health guidelines while allowing polluting industries to keep their data under wraps. That alarming imbalance would skew regulation inherently favoring polluters over those impacted by their pollution.

Furthermore, this proposed rule would cross Agency lines and interfering with informed policy making and undermining the safeguards that protect millions of people, our public lands, and the space and places we call home. EPA's scientific research and related policies influences the decisions of other agencies charged with protecting our health and environment. For example, the National Parks Service needs access to the best available science to inform decisions that protect parks' air, land, water, wildlife and people. If EPA goes forward in placing unreasonable limits on the scientific record, the

National Parks Service and similar agencies will be unable to protect public health and the environment to the extent they otherwise could. As a young person, this proposal leaves me frightened. Within a decade I will be part of the generation that inherits the responsibility for this nation. If adopted, the negative implications of this rule will not be short-lived and could forever change the safeguards that EPA is supposed to develop to protect public health and our environment. In the many more decades of life I have in front of me, I intend to finish my education in this country, I intend to raise a family in this country, I intend to enjoy public lands and outdoor spaces in this country, and I intend to breathe this country's air and drink this country's water and eat this country's food. I hope to do so knowing that the regulatory body charged with keeping my body and environment safe has made decisions based on nothing less than the best scientific information there is. For these reasons, I urge the EPA to abandon this dangerous

and misguided proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Numbers 19 and 20, Paul Allwood and John Stine, if you would take seats up here. And Speaker Number 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would take seats the on-deck seating.

MR. ALLWOOD: Good afternoon, my name is Paul Allwood. I am Assistant Commissioner of Health Protection at the Minnesota Department of Public Health. Commissioner Stine is with me and we're going to do this joint testimony. Commissioner Stine will go first.

MR. STINE: Thank you. As Commissioner of the Minnesota Department of Health, Mr. Allwood is the Assistant Commissioner there, and as Commissioner of the Minnesota Pollution Control Agency, my name is John Link Stine, S-T-I-N-E. We are appointees of Minnesota's Governor, Mark Dayton. We are deeply disappointed in and troubled by this proposed rule, "Strengthening Transparency in Regulatory Science." We have traveled 1100 miles

from our home in Minnesota to be here today to speak against this rule. On May 15, 2018, our two state agencies commented against this rule in a letter from Commissioner Malcolm of the Health Department and myself. Our testimony today expands upon those comments and provides specific examples from Minnesota that show why this arbitrary and non-ethical rule must not be adopted.

MR. ALLWOOD: The first example is that the State of Minnesota is dealing with a massive area of contamination with PFAS chemicals, otherwise known as PFCs. The contamination came from 3M Manufacturing and disposal sites that contaminated groundwater on a very massive scale impacting over 150,000 residents. Minnesota's Department of Health conducted bio-monitoring studies of over 200 people living in those impacted communities to be able to understand their exposure and their potential health implications. Those studies help Minnesota derive health protected values under state law and furthermore also help the state of

Minnesota reach a settlement with 3M Company of over 890 million dollars. Now, without these studies and without these data we would not have been able to be successful in our litigation with 3M Company and residents of the communities that were impacted by this pollution would have had to foot this bill.

Now, these studies are only possible because we provided absolute guarantees to the participants that their data would be protected and that we would assure its confidentiality. The proposed rule will make it unlikely that public health data such as this -- and you heard it from other testifiers -- would be available for states to use, but even more so for the EPA to use in its decision-making. This is to be avoided.

MR. STINE: Our second example is the 2015 study and report that our agencies jointly released "Life and Breath". We released that report regarding the health impacts of air pollution in the Twin Cities Metropolitan Area of Minneapolis and St. Paul. The study used public health data

and mathematical modeling software developed by the U.S. EPA. EPA's modeling software is based on published, peer-reviewed scientific studies of the relationship between human health and air pollution. The study confirmed air pollution leads to increased disease and death in our population. Every year about 2000 premature deaths, 400 hospitalizations and 600 emergency room visits occur in the Twin Cities Metropolitan Area that are caused by fine particle or ground-level ozone exposure. In fact, the study found that fine particle air pollution and ground-level ozone was a causal factor for some deaths and hospital visits for lung and heart conditions. The implications of the proposed rule are that under this rule's requirement for the use of public data, future public health data on which studies like our "Life and Breath" were based would not be available. Public health data and research relies on citizen confidence in confidentiality of their personal information. We believe the rule would lead to an over-reliance

on animal studies and toxicological data which cannot estimate disease burden as well as population health data and studies. The proposed rule would lead to weaker environmental regulations, more air pollution, greater levels of heart and lung disease and death. As a result, health care costs will increase. Asthma already costs the United States 56 billion dollars annually and the incidence of asthma is increasing. The rule language under Part 30.8 requires that EPA implement the rule in a manner that minimizes cost. Ironically, the rule will lower the cost to EPA and environmental polluters. A fundamental principal of our environmental protection law is that polluters pay. The plain truth is that your rule does not address the increased costs that come with relaxed regulations. In fact, the polluters will pay less and costs will shift onto the public in health insurance. With that I'll kick it to Mr. Allwood.

MR. ALLWOOD: So, to conclude, to say that state as public officials we are responsible for

protecting the health of our state population, it's really important for us to be assured that EPA is going to use the best science in its regulatory decision-making. This rule severely brings that into question and we would like you to know that we are looking at this as an urgent matter that requires the EPA's attention and would urge that time be taken to suspend and slow the process of adopting this rule so that a full and complete review can be done. Thank you.

MR. STINE: Thank you.

MS. RADZIKOWSKI: Thank you both.

MS. STOBERT: Speaker 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would come to the speakers' table. Speaker 23, Steve Milloy, and Speaker 24, Steve Milloy for John Dunn, if you would have seats at the on-deck seating?

MS. RUIZ: Good afternoon, my name is Virginia Ruiz. I am the Director of Occupational and Environmental Health at Farmworker Justice, an organization devoted to working with migrant and seasonal farmworkers to improve their living and

working conditions. On behalf of my colleagues at Farmworker Justice and the farmworkers that we represent, I strongly urge the U.S. EPA to withdraw its proposed rule, "Strengthening Transparency in Regulatory Science." If finalized, this rule would endanger farmworkers and other vulnerable people across the country. We oppose EPA's proposed rule for three reasons: First the rule would prohibit EPA from considering credible scientific evidence about the dangers farmworkers face including exposure to pesticides and other chemicals. Second, the rule would deter farmworkers themselves from participating in future scientific studies. Third, the rule would make it more difficult for Farmworker Justice to obtain the research we need to advance our mission. With respect to the first point, the proposed rule would prohibit EPA from considering credible scientific evidence about the dangers that farmworkers face. As EPA's own Science Advisory Board acknowledged, there are many reasons why researchers and study participants

might choose to keep data confidential, and many of these reasons have no bearing on the credibility of a scientific study. For instance, because farmworkers are often migratory, moving for work across domestic and international borders, researchers may be unable to locate farmworkers they last encountered as study participants years ago, and thus unable to renegotiate privacy agreements struck at the time the research was conducted. Farmworkers themselves may also have legitimate reasons for wanting to preserve their privacy. For example, some research shows that farmworkers face an increased risk of exposure to chemicals that impair fetal development resulting in lower IQ scores, an outcome associated with significant social stigma. We already suffer from the dearth of scientific evidence and information about occupational and environmental health risks that farmworkers face. EPA should base its regulatory decisions on the credibility of scientific evidence and not on arbitrary factors like the

public availability of research data.

With respect to the second point, the proposed rule would deter farmworkers from participating in future scientific studies. Farmworkers are extremely vulnerable members of our society and it's unlikely they would agree to participate in scientific research without an iron clad guarantee that their identities would be kept confidential. Farmworkers value their privacy for a number of reasons including an undocumented or other tenuous immigration status and insecure employment. Farmworkers whose identities are exposed would risk retaliation from their employers ranging from termination to deportation. As a result the proposed rule would present farmworkers with a false dilemma. They could choose to participate in research studies that might eventually yield better regulatory protections at great personal risk, or they could choose to protect their privacy by refusing to participate in research studies, thus forgoing badly needed protections, also at great personal cost. EPA should not

present farmworkers with such a choice.
Finally, the rule would frustrate Farmworker Justice's ability to achieve our mission. We rely on credible scientific evidence to educate farmworkers, policy makers and the public at large about the risks farmworkers face. Much of this evidence comes in the form of epidemiological studies that the proposed rule would categorically exclude from consideration unless the underlying data were made publically available. If EPA's proposed rule were to result in fewer scientific studies focusing on farmworkers, as seems inevitable, we would lack information we need to carry out this important aspect of our mission. It would severely undercut our ability to effectively advocate for farmworker health and safety.
Accordingly, we urge EPA to protect farmworkers and other vulnerable communities by withdrawing the proposed rule without delay.
MS. RADZIKOWSKI: Thank you.
MS. MONGOVEN: Good afternoon, I'm Karen Mongoven;

K-A-R-E-N, M-O-N-G-O-V-E-N, Senior Staff Assistant at NACAA, National Association of Clean Air Agencies, and I appreciate the opportunity to testify today on behalf of NACAA. NACAA recommends that EPA withdraw this proposed rule. In our view the proposal would likely undermine the very objectives that it's supposed to promote. In particular, we believe it would hinder EPA's use of best available science and environmental regulations and it would likely diminish, rather than improve, public confidence in the integrity of EPA's scientific decision-making. Reliance on best available science is a fundamental requirement of the Clean Air Act and other environmental statutes the EPA administers. Indeed, science-based decision-making is at the very core of our shared mission as air regulators to protect public health and the environment from the harmful effects of air pollution.

There is a long-term trend toward increased transparency in science including toward providing greater public access to underlying data and

analytical techniques after scientific studies are published. We think this trend is a laudable one, but complete public access to underlying data is not always possible, especially in the case of the epidemiological studies based on private health data that must remain confidential. Transparency concerns must not override EPA's obligation to consider the full range of peer-reviewed, sound, scientific research that is available and relevant to its regulatory decisions.

Full public access to underlying data and models is not necessary to assure the validity of scientific studies. Rather, the most effective assurance is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all of these components to establish validity. The process of peer review

has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it should explain exactly why it believes the process is inadequate and how this proposal specifically addresses those inadequacies. If adopted, the proposed rule could serve to bar EPA's consideration of relevant scientific literature and the establishment of air regulations to protect public health and the environment resulting in serious adverse effects on the nation's air program.

In a footnote in the proposal, EPA cites two D.C. Circuit cases that upheld the Agency's reliance on confidential data in setting health-based air quality standards for lead and fine particulate matter. In that footnote, EPA states that it is "proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions." The clear implication is that EPA will discard rigorously vetted scientific literature in the service of greater transparency. This would be an

abdication of EPA's legal obligations and stated intention to rely on the best available science. NACAA is also concerned with a provision that would require EPA to conduct its own "independent peer review of scientific studies underlying significant regulatory decisions." The EPA included no details about how this provision would be implemented and moreover the proposal failed to acknowledge the EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts including a Science Advisory Board and its Clean Air Scientific Advisory Committee. EPA does not explain why scientific literature that has already undergone peer review and been vetted by EPA's science advisory panel should be subjected to an additional layer of peer review. We do recognize that the proposal would allow the EPA administrator to grant exemptions to the rule's requirements on a case by case basis if he or she determines that "it is not feasible to make underlying data publically available or to conduct

an independent peer review of scientific studies." However, the rule does not include any criteria for how the administrator would make such a determination. We believe this provision would have the effect of interjecting the appearance of politics into what should be a fair and unbiased assessment. It's an opportunity for arbitrary decision-making and it is insufficient to protect against the exclusion of relevant valid scientific studies.

EPA requested comments on whether the proposal should be applied retroactively or retrospectively should they decide to adopt it. We believe the rule should not be applied retrospectively. To do otherwise would create significant regulatory uncertainty by calling into question existing standards as well as prevent state implementation plans and other decisions that are based on those standards.

In conclusion, NACAA respectfully requests that EPA withdraw the proposed rule. If the Agency does intend to update its approach to transparency

and reproducibility it should do so in consultation with the National Academy of Sciences and in the spirit of cooperative federalism EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation's environmental laws. NACAA appreciates the opportunity to provide the testimony I offered today and we also intent to submit written comments to further elaborate on the concerns I discussed here. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Steve Malloy, Speakers 23 and 24 would come to the speaker's table. Speaker 25, Meredith McCormick, and Speaker 26, Olivia Bartlett if you would go to the on-deck seating.

MR. MILLOY: Good afternoon, my name is Steve Milloy. I publish *JunkScience.com*.. I am making my comments here on behalf of myself and also Dr. John Dale Dunn, who is an emergency room physician in Texas. We are here to support the proposed transparency initiative. Science transparency in EPA is long past overdue. When I first started

working on EPA issues in 1990, the main controversy with EPA science was the use of science policy and default assumptions, like linear no-threshold model of carcinogenesis. The problem wasn't necessarily the use of science policy default assumptions, the problem was, rather, the EPA's failure to disclose the nature of those default assumptions in regulatory actions. In other words, what part of the regulatory actions was science, what part was guesswork and what was politics? When I first reported on this problem from the Department of Energy in 1994, the Clinton administration tried to censor my report but they failed. But I didn't and many others didn't. So here we are, many years later, making progress on this important issue.

More recently, the major problem with EPA science has been what has become known as secret science. Since the 1990's EPA grantees like Harvard's Doug Dockery and Brigham Young University's Arden Pope, have refused to make available to the public the

raw data used in their epidemiologic studies, and this is true despite the fact that these studies were cited by EPA as the principle scientific basis for major air quality rules like those that constituted the Obama administration's war on coal.

Worse, prior EPA administrations actually aided and abetted Dockery and Pope hiding their data from public review. In 1996 and 1997 the Clinton administration refused a request of Congress. In the 2000's things got so bad Congress actually had to subpoena the Obama EPA for the data and they refused to provide it.

I can only conclude that this is because independent review of the Harvard Six Cities and the American Cancer Society line of studies would prove them to be highly problematic, embarrassing and even fraudulent. Desperate to defend the indefensible, supporters of Dockery and Pope have wrongly maintained that making the data in question public would violate medical and personal privacy rights. Nothing could be further from the

truth. For the most part, data is electronic. Scrubbed files with key data needed for independent review can easily be made available. No one -- no one -- is interested in any personal or medical data. It has no value to anyone. The State of California has made such data files available for use for many years. I know. I have obtained this data -- over 2 million death certificates to be precise -- and with it enabled research to be published that completely debunks the secret science of Dockery and Pope. Fear of exposure of their research as faulty, if not fake, is why Dockery and Pope are so scared of producing their data for independent review. To make these comments current, up to date, efforts have been made this month to obtain the Dockery and Pope data but they continue to keep their data secret. Given that the Dockery and Pope research and related PM2.5 research has been funded by taxpayers to the tune of more than 600 million dollars and then this research is used to regulate the public costing untold billions more dollars

without providing any public health or environmental benefits, the conspiratorial hiding of this secret data is more akin to crime than science.

If EPA wants to regulate, that is fine, but the basis of the regulations and the reason for the regulations must be clearly laid out so there could be full and fair debate. Harvard's Doug Dockery and Brigham Young's Arden Pope don't want independent scientists to check their work for some reason. Dockery and Pope supporters may offer whatever excuses they like but we all know what the reality is: Fear of exposure. Thanks to the Trump administration the days of secret science are coming to an end. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 25 and Speaker 26, Meredith McCormack and Olivia Bartlett are now onstage. If Speaker 27, Dan Byers, and Speaker 28, Antonia Herzog, would come to the on-deck seating.

MS. McCORMACK: Meredith McCormack, M-E-R-E-D-I-T-H, M-c-C-O-R-M-A-C-K. My name is Meredith

McCormack and I'm a pulmonary critical care physician at Johns Hopkins University where I care for patients and I also investigate the effects of air pollution on lung health in cohort studies of children and adults. I serve on the American Thoracic Society Environmental Health Policy Committee and I'm speaking today on behalf of the ATS, the American Thoracic Society.

The ATS is extremely concerned about the proposed EPA policy. In short, we believe this policy is not in the best interests of our profession, the patients that we serve, or the public health. The focus on transparency is highly reminiscent of the rhetoric used by tobacco lawyers decades ago. As revealed in tobacco industry documents, in 1996 a tobacco industry lawyer drafted a plan for tobacco giant, R.J. Reynolds, to combat research that documented the health effects of second-hand smoke. A tobacco industry lawyer described a plan to construct explicit procedural hurdles the Agency must follow. The memo used the same terms of transparency, sound science and calls for

reproducible science, the language that the EPA is now using in its proposed policy. While the guidance provided in that memo was intended to undermine research studies that documented the adverse effects of second-hand smoke, the recommendations provide a road map for any industry seeking to undermine science that could lead to greater regulation. While concerning, it is no accident that EPA is proposing policy once touted by tobacco industry lawyers. By proposing this policy, EPA is literally taking a page out of tobacco industry's playbook to undermine the legitimate role that science plays in public policy formation.

The ATS supports transparency in upholding scientific rigor but the approach proposed in this rule is flawed. The proposed policy would require all science and biomedical research used by the Agency in major regulatory actions to have its raw data and health records made publically available under the guise of allowing third party analysis to confirm the results of the research. This

artificial standard cannot be met without forcing the release of confidential patient information and is in direct conflict with the mandates of our institutional review boards and updated privacy laws.

As a physician, no doctor or medical society would advocate ignoring large portions of the medical literature because the underlying data were not in the public domain. Medical guidelines are based on the best available evidence: Evidence that emerges from multiple peer reviewed publications, not a single study. The medical field is rapidly moving towards increasing transparency but this cannot be applied retroactively. Is the best available science only the subset of studies whose data are available for analysis by the public? That is not the case for medical research studies and is certainly not the case for studies of environmental health effects.

EPA's new transparency standard introduces a more severe standard than the FDA uses to make decisions about the approval of drugs or that

Medicare uses to decide which treatments to cover. As a doctor I would do my patients a disservice if I ignore the best available evidence to guide my clinical decision-making. The proposed rule will allow the EPA to ignore the best scientific evidence in future decision-making about health effects of the air that we breathe and the water that we drink. The Transparency Rule fails to recognize the power of replication, a key criteria for defining the strength of scientific evidence. Replication refers to the fact that consistent findings from studies in different populations in different places strengthens the likelihood of an effect. The proposed rule would create a context for the EPA administrator to have the discretion to disregard studies that have provided the strongest scientific evidence underlying the dramatic health effects and dramatic improvements in air quality in the U.S. -- improvements that have led to measurable health benefits to our children, our patients and the general public. For the EPA to use these studies will patients

forego their confidential information? Or will the EPA now ignore the evidence from dozens of studies that have replicated findings that pollution is associated with increased risks of premature death. The Transparency Rule is unnecessary as there are processes in place to rigorously review the scientific integrity of the studies that are used in regulatory science.

In short, we fully concur with the statement from the editors of several leading scientific journals that the merits of studies relying on data that cannot be made publically available can still be judged. It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them.

In summary, this policy is issued in bad faith, is bad for science and bad for patients and bad for public health. The ATS strongly urges the Agency to withdraw this ill-conceived policy proposal.

Thank you.

MS. RADZIKOWSKI:

MS. BARTLETT: I'm Olivia Bartlett. B-A-R-T-L-E-

T-T. I'm from Bethesda, Maryland and I represent the 1200 members of Do the Most Good, Montgomery County. I am a retired PhD health scientist. For 15 years I conducted research involving human subjects and also served as a peer reviewer for both grant applications and research papers submitted for publication. For the next 30 years I oversaw the scientific peer review of thousands of applications for funding of a wide variety of health science studies including the women's health study that was mentioned by a previous speaker, so I'm very familiar with the scientific research and publication process and the rules regarding protection of human subjects. I also have asthma, as do my son and my grandson, so I am also very familiar with the impact of soot and smog in the air on the ability to breathe. EPA's mission is to protect health and the environment. I strongly oppose EPA's so-called Transparency Rule since it will restrict the scientific studies that EPA can use to carry out that mission and to set safety standards for toxic

chemicals and pollutants in the air we all breathe and the water we all drink. The proposed rule was given an appealing title but it's just a politically motivated attempt to undermine decades of progress in protecting human health from hazards, particularly small particulate pollutants in the environment, while allowing soot-producing industries off the hook. The proposed rule is seriously flawed in several important ways. First, it reflects former EPA Administrator Pruitt's woefully inadequate understanding of scientific research methods, the nature of the long-term large-scale epidemiologic studies necessary to gather the kinds of data needed to determine toxicity of a pollutant and the rigor of peer review of both research grant applications and publications. Peer reviewers carefully scrutinize the methods that will be used to collect and analyze the data before a research study is ever funded. Additional peer reviewers and different ones scrutinize the data collection and analysis methods and whether the data supports

the conclusions, again prior to publication. Studies with flaws in design, data collection or data analysis don't make it into reputable journals. The proposed rule also seriously underestimates the burden and the consequences of making all raw data publically available. Most research funding agencies and journals now have policies that require researchers to make their data available to other scientists for reanalysis, validation and meta-analyses after publication and this has already been mentioned by previous speakers. However, many studies involve sensitive and personal data that could identify individual subjects even if the subject's name and address are redacted, so releasing these data sets to the public would violate patient confidentiality rules. The proposed rule may also violate the requirements of the Clean Air Act and Clean Water Act and other standard acts already mentioned to use criteria that accurately reflect the latest scientific knowledge, the best available science and inclusive analysis of all

available studies in assessing potential effects on public health. Furthermore, the proposed rule would create an unacceptable double standard for industry-sponsored and academic research by allowing companies to shield their confidential business data, thus corporate secret science would be okay but data sets that expose individual subjects' identities would have to be made public or would be excluded from consideration in rulemaking. This ill-conceived proposed rule has been condemned by hundreds of scientists, all but one of the previous speakers today, and numerous scientific societies across health and environmental fields. Editors of prestigious journals have denounced the proposed rule and stated excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes. The bipartisan policy center, the bipartisan environmental protection network represented earlier by a speaker, the Attorney Generals of seven states and D.C. who was here earlier and

EPA's own Science Advisory Board have also denounced the proposed rule. Rather than increasing transparency, the proposed rule will hamstring EPA, eliminate some of the best science available to inform standards under the National Ambient Air Quality Standards program and jeopardize both the environment and public health by making it more difficult to adopt rules that protect public health and the environment in the future. EPA's long-standing process using data from peer-reviewed science, EPA in-house scientists and the EPA Science Advisory Board works well and mirrors the processes of other science-based agencies. The system isn't broken and doesn't need to be fixed. If EPA wants to accomplish its mission, the proposed rule should be withdrawn immediately and should not affect any rulemaking going forward or any of the studies used in periodic reanalysis of existing rules. Thank you for allowing me to comment.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 27, Dan Byers, and Speaker

28, Antonia Herzog, if you would take seats on the stage. Speaker 29, Tess Dermbach, and Speaker 30, Mary Angly, if you would take seats in the on-deck seating.

MR. BYERS: Good afternoon. My name is Dan Byers. The U.S. Chamber of Commerce strongly supports the intent of the proposed rule and applauds EPA for addressing a long-standing problem inherent in much of its regulatory decision-making processes. While the Agency's proposed reforms are clearly controversial they are grounded in a universally-accepted democratic principle: Citizens have a right to the data and information that are used in the development of public policy. This spirit of openness with respect to the regulatory process is found throughout government. It is enshrined in statute and countless federal directives and EPA memos reinforce the principle and detailed guidance for implementing it. It is also supported by experts of all political stripes. In 2012, congressional testimony, President Obama's Science Advisor, Dr. John Holdren, unequivocally

endorsed this idea, stating that: "Absolutely the data on which regulatory decisions and other decisions are based should be made available to the committee and should be made public. The Chair of EPA's Science Advisory Board during the Obama administration subsequently echoed this sentiment. Unfortunately, while this principle is generally accepted, EPA has not followed it consistently in practice. In fact, for many years EPA has relied upon non-public data to justify its aggressive regulatory agenda. The most egregious, but certainly not the only, example of this involves two controversial studies undertaken in the 1980s that suggest a linkage between certain types of particulate matter and health outcomes. The data associated with these decades-old studies has never been made public but EPA nonetheless has used them to monetize regulatory benefit claims that dominate the communications and regulatory marketing associated with nearly all of its major rules. It's also worth pointing out here that, separate from the studies themselves, EPA's

benefit monetization is highly subjective and controversial in and of itself. For example, in 2009 the Agency modified its assumptions in a manner that resulted in a quadrupling of purported benefits without any change to the underlying data and information used to monetize it. We hope that these sorts of subjective and questionable practices will be addressed since the Agency concurrently examines the development of regulatory cost-benefit analyses. The scale of EPA's practice in this respect is mind boggling. Data compiled by the U.S. Chamber found that between 2000 and 2016, EPA issued 62 rules claiming a total of 923 billion dollars in regulatory benefits. Incredibly 898 billion of these benefits, or 97%, were monetized based on the non-public data associated with PM2.5. In fact, these benefits comprise nearly 80% of all regulatory benefits across the entire federal government. Even though the vast majority of these rules were not intended to address PM2.5, and even though the vast majority of their

corresponding claim benefits came from areas of the country already deemed safe and in compliance with the standard, the Agency repeatedly touted these figures to build public support for its regulations. It's one thing to be cavalier about transparency principles when their application has little or no import to public policy. The federal rules that impact millions of people and billions of dollars should be held to a higher standard. For these reasons, we applaud EPA's effort to establish and meet a higher standard and we commend the Agency for doing so through the formal public comment and rulemaking process rather than simply instituting a new policy. As EPA makes clear throughout the rule, these changes will require considerable effort and cooperation, and despite suggestions otherwise, the proposal clearly states that its aim is not to exclude science but rather to ensure: "That over time more of the data and models underlying the science that informs regulatory decisions is available to the public for validation." And, to more broadly

quote: "Change Agency culture and practices regarding data access." The outcome will not just lead to better public policy, it will improve the integrity of the rulemaking process and in doing so increase public trust in, and support for, EPA itself. Whether you agree with the administration's regulatory approach or not, that is a good thing. With that fundamental background in mind I will close by calling attention to six high-level areas that warrant emphasis and attention as the Agency works to finalize the rule. These are elaborated on in my written comments.

1) Protect sensitive information;

2) Formally coordinate with other agencies working to address similar regulatory transparency challenges;

3) Develop further guidance and processes for employing the administrator's exemption authority under the rule;

4) Consider alternative approaches to balancing trade-offs between goals related to

transparency and maximizing the quantity and quality of information relied upon. For example this could include assigning greater decision-making weight to publically available data while still allowing for the consideration of nontransparent data;

5) Where possible, work to protect and de-identify sensitive information to allow for its continued use in regulatory decision-making, and;

6) Ensure that relevant transparency information is incorporated into public communications and marketing materials associated with regulatory initiatives. Thank you for your time and consideration today.

[Substitution of panel members.]

MS. HUBBARD: Thank you.

MS. HERZOG: Hello, my name is Antonia Herzog, H-E-R-Z-O-G, and I am a scientist with a doctorate in Physics. I am particularly concerned about preserving the scientific integrity of the EPA. I work in the Environment and Health Program at Physicians for Social Responsibility, a nonprofit

organization here in D.C. with chapters in multiple states across the country and over thirty thousand members and activists around the country. Our mission is to protect human life from the gravest threats to health and survival; we number environmental pollution among those key threats. PSR would like to express its strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." This proposed rule could arbitrarily exclude many important scientific studies-including thousands of public health and epidemiological studies that the Agency uses to make informed policy decisions regarding major public health and environmental laws. While it pretends to be about "transparency", the policy actually will limit the Agency's ability to use the best available science thereby weakening protections for public health and the environment. In essence it could censor and block much of the peer reviewed scientific research that has allowed us to address many serious environmental health threats over the decades.

EPA's proposed rule would place crippling restrictions on the use of data the Agency would accept in the rulemaking process by ultimately requiring investigators to divulge personal information about the participants in research studies. Scientific studies that failed to meet this criterion would not be acceptable to the Agency. At present, this kind of information must be kept confidential according to the generally accepted rules that govern the conduct of research that must be adhered to by agencies of the federal government and institutions that receive federal funds. A particular example that is concerning to me and is particularly relevant today where it's so hot outside and the air quality is questionable, is the Clean Air Act, a bedrock environmental law that protects us from dangerous air pollutants. It is such a critical health protection that would be endangered under this proposed rule because it relies on a longitudinal epidemiologic study of thousands of individuals. This includes the National Ambient Air Quality

Standards (NAAQS) in the Clean Air Act. These standards address six major classes of common air pollutants, including standards for fine particles {PM2.5), and these are the backbone of the U.S. air quality management system.

The Clean Air Act specifies that new or revised NAAQS be based on scientific criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." EPA has relied largely on community epidemiology and controlled human studies in establishing the specific pollutant levels and averaging times for NAAQS. If these studies were excluded by the EPA restrictions it would greatly reduce the availability of information that has proved to be significant in assessing the consistency and coherence of the evidence upon which the standards are based and would certainly weaken the scientific basis for maintaining or strengthening

those current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.

PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 29, Tess Dernbach, and Speaker 30, Mary Angly. If you come to the speakers' table. Is Mary Angly in the room? Okay, we'll come back to her at the end.

MS. DERNBACH: My name is Tess Dernbach, T-E-S-S,

D-E-R-N-B-A-C-H. I am a third-year law student at Columbia Law School and a legal intern at Earthjustice, speaking on behalf of Earthjustice. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," requires a choice between breaching medical privacy or ignoring data for rulemaking decisions altogether. Breaching a patient's medical confidentiality can have severe and wide-ranging consequences for patients' lives and livelihoods. Various groups have often tried to access patient data for retaliatory purposes. For example, when pork industry associates tried to access the identities of individuals who had participated in a study by the University of North Carolina Professor Steve Wing, about the harmful health impacts of hog farming, or when the Department of Justice tried to access names of women who had late term abortions for use in litigation challenging the Partial Birth Abortion Ban Act. Employees' health information can be and is used against them by employers as an excuse for termination or other poor treatment. Moreover,

when the medical confidentiality of research participants is breached, people are deterred from participating in research altogether. Medical confidentiality is a necessary element of modern medicine. Patients must feel safe telling their doctors the most intimate details of their lives. The expectation of confidentiality fosters openness and trust between doctors and patients and is crucial to the delivery of medicine and conducting clinical research. Courts recognize, too, the importance of medical confidentiality and privacy. In 1928, Justice Brandeis described the right of privacy as: "The most comprehensive of rights and the right most valued by civilized men." At least five circuit courts have recognized an individual's constitutional interest in or right to the privacy of their medical information. In Farnsworth v Procter and Gamble in the 11th Circuit, the court recognized that: "Even without an express guarantee of confidentiality, there is still an expectation, not unjustified, that when highly personal and

potential embarrassing information is given for the sake of medical information it will remain private." This right to medical privacy can extend to beyond publication of medical data to situations where medical information is available to those without a legitimate interest in it. See, for example, Tucson Women's Clinic v Eden in the 9th Circuit, where the court observed that even if safeguards against public disclosure were adequate, the lack of safeguards against release of information to government employees who have no need for the information could create a violation of the right to privacy.

The EPA claims, vaguely, that confidential data will be protected by redaction or de-identification. However, these mechanisms are entirely inadequate to maintain patient confidentiality. Latanya Sweeney, a Harvard Professor of Government and Technology, found in her study simple demographics often identify people uniquely that she was able to identify 87% of people in the United States with only their

gender, zip code and birth date. She has also found particular problems in patient confidentiality de-identification observing that in many healthcare data sets there will be unique data about people that can be used to identify them even when they are not explicitly identified in the data set. Sweeney found that even without identifying data in health data sets: "The remaining data can be used to re-identify individuals by linking or matching the data to other databases or by looking at unique characteristics found in the fields and records of the database itself."

Paul Ohm from the Georgetown Law School found in his pivotal work: *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, that using traditional, personally identifiable information focused anonymization techniques, any data that is even minutely useful can never be perfectly anonymous. These studies seriously undermine government claims that de-identifying data will provide adequate privacy for

patient data contained within research studies. Because of these reasons and those given before me, I strongly urge EPA to revoke the proposed rule immediately. Thank you.

MS. HUBBARD: Thank you.

MS. ANGLY: Hello, my name is Mary Angly and I'm interning for the organization Physicians for Social Responsibility and I've come to speak against the proposed rule, "Strengthening Transparency in Regulatory Science." Medical studies, clinical reports, and real-world field studies all include data and information that cannot be made public without violating confidentiality in patient protection laws. The proposed rule implies that these studies are not transparent because researchers necessarily suppress names and other identifying information about patients whose health information is relevant to study findings. Releasing individual participants' data to the public would violate confidentiality requirements legally mandated by the IRB and/or by HIPAA. By restricting these

studies, the proposed rule would essentially force the EPA to base many of its regulatory decisions on industry-sponsored studies and this rule could have huge environmental and public health implications. Despite a supposed scientific process, the funding source for a study can have significant implications on study findings. For example, in a review of research into the health effects of EPA an evaluation of 115 relevant studies was conducted in 2009. The review found that 94% of the publically funded studies found that chemicals have harmful effects whereas none of the industry-backed studies found these same findings. This is a huge disparity that cannot have occurred due to chance alone. Successful regulatory policies can have huge and quantifiable effects on exposure levels in human health. Biannually, the CDC collects data recording the blood and urine levels of 265 chemicals in people across the country. Longitudinal data can be used to visualize falling exposure levels and thus not measure the impact of a policy. For instance,

following the 1970's era lead regulations, 2009 blood lead levels were 8% of 1980 levels, which is a compelling example of a successful public benefit that occurred as a result of regulatory efforts. This is especially important when one considers that the detrimental effects of lead exposure are well known and well documented. Lead exposures leading to a blood concentration of 1 mcg/dL are correlated with an IQ loss of about 0.2 points. Each IQ point is estimated to raise worker productivity about 2%. Moral arguments aside, when considered from a population perspective, lead regulation has had huge economic benefits. A review of the EPA's archives shows that much of the original clinical research that formed the EPA's decision to regulate lead would have contained private health information. Under the proposed rule many of these studies would not have been able to be taken into consideration which is why it's so important that these studies are allowed to regulate future chemicals. Although lead specifically, and its health effects

are well known and well documented, my fear is that the future regulation of dangerous chemicals will be prevented due to the restrictive nature of this rule. Barring the use of major health studies under the veil of transparency will have huge and detrimental effects on the breadth and validity of the sources the EPA is able to consider when making regulatory decisions. Dangerous chemicals will not be able to be adequately regulated if the scientific processes are stymied.

I urge you to consider the health of this country when deciding whether or not to implement this rule. If the health implications are not enough to prevent the enactment, please consider the economic implications. The cornerstone of a healthy and productive population is a healthy environment. This rule would pose a serious barrier to the EPA's ability to effectively regulate. The power of landmark laws defined to protect human health such as the Clean Air Act, Safe Drinking Water Act, and Toxic Substances

Control Act, could be significantly undermined if this rule comes to fruition. Thank you for your time.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 31, Brenda Munive, and Speaker 32, George Thurston, if you would come to the speakers' table. Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the on-deck seating.

MS. MUNIVE: Good afternoon. My name is Brenda Munive and I am currently interning with the nonprofit organization called Physicians for Social Responsibility. I am a recent graduate of the University of California, Santa Barbara, with degrees in Environmental Studies and Communication. I am testifying today to voice my opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." I believe that scientific transparency is critical. Scientists, policy makers, and the public alike must all be able to trust and rely upon the scientific evidence that shapes our

society and the extent of human knowledge. However, I believe the EPA's proposed rule instead represents a serious misunderstanding of the institution of science. Furthermore, I believe that the proposed rule risks unnecessarily excluding valid scientific evidence from informing EPA policy, and therefore harms our fellow Americans through the creation of ineffective policies. The nature of the scientific field is unique. While most professions are motivated by political, economic or societal interests, scientists are motivated by seeking truth. Scientists perform research with the sole objective of uncovering the reality of how our world operates and gain status and recognition by succeeding in that goal. Top scientists are granted tenure or the assurance they cannot be fired from their position for whatever reason. Tenure guarantees scientists that they will not lose their position even if their research points to facts that are controversial or at odds with the current political societal climate. For these

reasons, ideally, they are not suspect to the same biases as most of the public. To prove this point it is helpful to look at the four norms of scientists as explained by renowned sociologist, Robert Merton. These are: Universalism, or the idea that truth applies to all regardless of belief; communalism -- the fact that all scientific knowledge belongs to the public; disinterestedness -- the fact that scientists are not concerned with the outcome of the research, only that it is factual; and organized skepticism or the tendency to be doubtful of any research to ensuring the deep truth. These norms describe the ideal foundation on which scientists and their research operate. Because of communalism, we can be confident that scientific research is as open as possible. Being intentionally secretive violates this ideal, so critical data must be accurately presented. This norm does not mean that all data is presented, however. Minute details, such as the identities of the subjects, are usually withheld in research studies of all

types to protect privacy and ensure participation -- or, encourage participation. It is important to emphasize that these omissions do not diminish the quality or the outcome of the research, but are made in the interest of the well-being of the participants. Because of this intrusiveness, the public can be confident that scientific research is virtually free of any bias favoring one agenda, and because of organized skepticism, scientific research is subjected to heavy review and fact checking before it is published in a scientific journal, so the public can be confident that published research is factually sound. Of course, there are exceptions to these ideals. For example, the norm of disinterestedness could be jeopardized if a scientist is hired by an outside party such as a company or noted member of the industry. The outside party introduces a monetary benefit and a desired outcome for the research, putting unconventional pressure on the scientist to fulfill the desires of whoever hires them. If the EPA's proposed rule is enacted, industry

funded research could comprise a disproportionate amount of what informs EPA policies, giving the industry, and not the scientific community, a large degree of input in shaping environmental protections.

Based on this knowledge, the proposed EPA rule is unnecessary. Mandating that underlying data be made public in order for scientific research to be utilized in informing EPA policies, attempts to increase transparency but fails to recognize that scientists already take thorough and exhaustive steps to assure their published research is unbiased, truthful and as transparent as possible. Research that does not meet these standards is rejected by the scientific community. The rule would restrict valid scientific data, particularly within health research where patient confidentiality mandates that identifying information remain anonymous. The result would be ineffective and harmful policies that could allow for practices and chemicals that genuinely harm our nation to remain rampant and unregulated.

This outcome would benefit no one and runs contrary to the EPA's mission of protecting public health and the environment. Furthermore, a healthy economy depends on healthy communities. For these reasons, I implore the EPA to reconsider enacting this rule. Thank you for this opportunity to present my testimony.

MS. HUBBARD: Thank you.

MR. THURSTON: Good afternoon, I'm George Thurston. I'm a professor at the New York University School of Medicine. Today I'm here representing the International Society for Environmental Epidemiology, the ISEE, which includes researchers who study environmental causes of ill health including ambient air pollution subject to the National Ambient Air Quality Standards, or NAAQS, promulgated by the EPA, as well as its standards for heavy metals, pesticides, drinking water and other environmental contaminants. As such, our members have supplied a substantial part of the research that is the basis of those standards. We strongly oppose the

implementation of EPA's proposed changes to the way that studies are considered in setting such standards. Based on an incorrect interpretation of transparency and replication in science, the proposed rule would deprive policy makers of the real-world epidemiological evidence based on real exposures of real people that have been, and will continue to be, vital for future considerations of EPA's health-based standards. I especially want to highlight for you the manuscript that I wrote 20 years ago entitled, "Band-Aiding the Release of Health Research Data: Issues and Implications," and the article is already posted on EPA's SAB web page. This article considered a similar proposal that was made in July of 1997 as an amendment to the U.S. House Appropriations Bill without any hearings. The problems I raised at that time are directly relevant to today's transparency proposal.

First, the increased potential for compromise of medical record confidentiality. As you've heard before today in a time of big data it's all too

easy to crack any de-identification process, especially when lots of publically available spatial and environmental data are matched to people in the study as they are in the studies that EPA considers. The solving of the Golden State Killer case, for example, is one example where a combination of two separate databases allowed de-identification of an individual. Second a loss of researchers' intellectual property. This can involve lost publications and academic career derailment. Third, the imposition of a government unfunded mandate. The USOMB has estimated that a similar law considered in the Congress, but that was never passed by the Senate, could cost the government up to 250 million dollars per year. There would also be the data prep costs to the scientists and their institutions.

Fourth, damage to future scientific research. When people no longer wish to enroll for fear that their medical data will be released, new scientific studies could be inhibited. Fifth, the

proposed rule will allow the EPA to ignore large portions of the scientific literature in decisions that are supposed to protect public health. In cases where key studies are excluded from the evaluation of environmental issue because of an inability to release study participants' private health records, the EPA may then ignore key scientific studies. This would diminish the evidence supporting protective health studies, potentially allowing the EPA to conclude that there's insufficient evidence to support proper health protective standards.

Sixth, the abuse of research data to undermine science credibility. This problem is likely the most dangerous aspect of this proposal. Past documented examples of abuse by consultants to a vested interest resulted when the state of Georgia set up an open records law and the R.J. Reynolds Company used it to obtain research data to attack study findings that the use of cartoon characters, such as Joe Camel, in tobacco advertising influenced children's product recognition. That

research was later validated in other studies but the damage was done and the physician involved left research for private practice. Thus, this data release approach has already been tried in the past and shown to be too easily abused by vested interests. There is also a tobacco connection to today's proposal. Just before the 1997 open data amendment was presented to the House, there was a December 1996 memo from the consultant of the tobacco industry, from Christopher Horner, laying out a similar strategy to address federal agency science with respect to second-hand smoke including a now familiar call for science transparency.

Finally, there's no need for this rule. Independent validation has already been conducted by groups such as the Health Effects Institute for air pollution studies, such as for the ACS and the Six Cities studies. Indeed, these are the studies mentioned by an earlier speaker, I believe it was Steven (sic) Milloy, and he incorrectly said that they were never released, they would never release

their data, and in fact they did release it. So, his testimony was incorrect. And whoever it was, I think it was Steven (sic) Milloy, but anyway, earlier speaker who said that Pope and Dockery had not released their data. They have done so and, in fact, it's an excellent example of how the system works. So, finally just to say such independent evaluations could easily be applied again to any new cases of concern for data validation without the above-noted risks. Thus, this dangerous rule seeks to needlessly solve a purported problem that just doesn't exist. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 33, Brittany Meyer, and Speaker 34, Adam Spanier, if you would come to the speakers' table. Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you would come to the on-deck seating.

MS. MEYER: Hi. My name is Brittany Meyer and I am the Associate Director of Public Policy at the Michael J. Fox Foundation for Parkinson's

Research. I am here on behalf of the nearly one million people with Parkinson's disease in the United States who rely on the Environmental Protection Agency to safeguard their health and inform them about potential hazards in the environment.

For over the past ten years, we've learned a lot about the mechanisms of Parkinson's disease and now know that the condition is caused by both genetic and environmental factors. It is now very clear that when coupled with a genetic risk factor, exposure to several chemicals, most notably solvents and certain pesticides, can trigger the disease. Just eight weeks ago, a study out of Canada suggested that low-level exposure to pesticides disrupts cells in a way that mimics the effects of mutations known to cause Parkinson's. More research is needed to fully understand the mechanisms at work and how to prevent them.

Many of the studies used to identify risk factors for Parkinson's disease are investigated via large population-based epidemiology studies and will be

impacted by EPA's proposal. I am going to highlight one clear example- though along with my health and science colleagues here today, we can provide hundreds of examples of studies that could be impacted.

A 2009 study used GPS to estimate participants' well-water contamination exposure from agricultural pesticides. The results showed that consuming well water from a private well located in an area with historical pesticide use resulted in an increased risk of Parkinson's disease. Due to the nature of wells - typically serving a relatively limited number of people within a very small radius - the detail needed to perform the study renders proper de-identification impossible. All one needs to know is that a certain person lives near a particular well along with a demographic detail such as their age, gender, race, etc., and privacy is at great risk. Data from studies like this cannot be de-identified to the degree needed to protect patient's identification while still providing the

amount of specificity needed to help a scientist trying to replicate the results. Obtaining consent is not a solution. Some people make the choice to not disclose their Parkinson's diagnosis for a variety of reasons including privacy concerns, fear of prejudice or retaliation at work, and others. It is simply unreasonable to put people in the position of outing their diagnosis or to decline to participate in a study that could someday find a cure for their condition. Additionally, people who are willing to sign away their privacy and those who are not are different in ways we cannot predict or control for in study analysis.

The Michael J. Fox Foundation believes in open, reliable, and replicable science. We fund approximately 90 million dollars in research per year and hold our funded scientists to the highest standards. Our contracts require science studies to be peer reviewed and most require data to be as available as possible while protecting precious health data. We echo the call of our fellow public

health groups here today and the nearly seventy public health, science, academic, and medical groups who signed on to a joint statement calling for the rule to be abandoned for the sake of science and for our health. Thank you.

MS. HUBBARD: Thank you.

MR. SPANIER: Good afternoon, my name is Adam Spanier, S-P-A-N-I-E-R. I am a pediatrician and Associate Professor in the Department of Pediatrics at the University of Maryland School of Medicine. I'm also a member of the American Academy of Pediatrics, Council on Environmental Health Executive Committee. I'm here today on behalf of the American Academy of Pediatrics. The AAP strongly objects to EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposal will require EPA to ignore the best available, peer-reviewed scientific evidence on pediatric and reproductive environmental health, may violate patient confidentiality, and could dampen scientific processes by creating barriers to the use of

quality research in EPA science. Children and pregnant women are disproportionately affected by environmental pollutants and changes. Between 1990 and 2010, the Clean Air Act prevented over 160,000 premature deaths, 54,000 cases of chronic bronchitis, 130,000 acute myocardial infarctions, 1.7 million asthma exacerbations, 3.2 million lost school days and 13 million lost work days. Landmark academic studies guided EPA to implement policies leading to these dramatically positive outcomes. However, EPA's proposed rule will no longer allow EPA scientists to use much of the scientific evidence that's brought on these life-saving regulatory changes.

Scientific studies used by EPA to make regulatory changes are already rigorously examined prior to being published in peer-reviewed scientific journals. Scientists not associated with the research study must review the study design to ensure that it is scientifically sound before the study can be published. Many of the studies that inform EPA policy to protect the health of

children and pregnant women are based on IRB approved studies of the health of human subjects that require data confidentiality. Such studies involve observing the longitudinal effects on reproductive and child health from exposures to lead, particulate matter and other toxic substances. Replicating such investigations for the purpose of providing open access data for EPA to use would be morally unacceptable as it would require exposing children to lead, ozone and other damaging pollution. It would also not be ethical to exempt the study participants from data confidentiality protections. By requiring reproducibility the rule may also exclude many landmark public health studies that were so scientifically rigorous and resource-intensive that they could not be reproduced, such as the Framingham Heart Study, a 70-year-long cardiovascular epidemiologic study. Requiring reproducibility may also exclude studies done after landmark ecologic events such as oil spills and natural disasters. This rule does not improve

the scientific merit of the studies used for EPA policies, and, instead, creates significant barriers to EPA's assessment of past, current and future scientific work. This proposed rule contravenes EPA's mission to ensure that American pregnant women, children and families have clean air, land and water, and the AAP strongly urges you to not move forward with it. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 35, Sean Moulton, and Speaker 36, Andrew Bergman, if you'll come to the speakers table. Before they speak I wanted to note that the time is now 2:39 and Speakers 35 and 36 are the last two speakers here to speak during the afternoon session. So, at this time if there's any speakers currently registered for the evening session but would like to speak now, if you would go to the registration desk we can get you a speaker number. Go ahead.

MR. MOULTON: Good afternoon, my name is Sean Moulton, Senior Policy Analyst at the Project On Government Oversight, a national nonprofit,

nonpartisan, government accountability organization. Thank you for the opportunity to speak this afternoon. I'm here to express my organization's strong objections to the proposed rule, "Strengthening Transparency in Regulatory Science," and urge the Agency to withdraw it. In the proposed rule the Agency notes that the best available science must serve as the foundation for EPA's regulatory actions. It is hard to argue with that fundamental principle, but this policy won't make scientific information better, nor more available. Instead, the new rule will often mean the best available science is off limits to the Agency, create delays in rulemaking and result in greater litigation.

I'd like to focus primarily on the rulemaking process and first raise serious concerns about the insufficient development process that produced this rule, a rule that fundamentally changes what information can and cannot be used in future rulemakings is a major undertaking and requires a great deal of certainty and evidence, yet this

proposal offers no clear explanation of the precise problem, no supporting evidence, no studies establishing that EPA has an information problem, nor citations that the proposed standard has been successfully used before or that EPA understands what its impact will be on the regulatory process when implemented. Even if the Agency truly believes there is some deficiency in its information policies and procedures, this proposed rule is premature. The starting point should be conducting studies of the issue to better understand the scope of the problem, if there is one, and the best way to improve transparency of regulatory science. The Agency should allow the Science Advisory Board to fully investigate and offer specific recommendations before moving forward with any proposed rule. There are any number of steps that the EPA should be completing before rushing into a formal rulemaking. The incomplete foundations for this rule reveal themselves in the vague language and unclear standards. The rule does not specify how

the new standards will be implemented, what mechanisms will be made available to allow publishing of more detailed data. More importantly the rule doesn't address how it will fit into the legal requirements the Agency has under the Administrative Procedure Act or other environmental laws.

The proposed rule is being done at EPA's discretion with no statutory authority backing it up. So, should this policy come into conflict with statutory requirements under existing law, those laws take precedent, and laws governing rulemaking have a number of requirements that this proposed rule would be in conflict with. The Administrative Procedure Act makes clear that an Agency cannot engage in arbitrary, capricious actions or decisions in its rulemaking; while the Agency has authority in its given area, that authority is not absolute. The Agency must have clear and strong justifications for its actions. Given the lack of supporting evidence for this policy or a statutory requirement from Congress,

EPA will be hard pressed to prove that this untested standard is not arbitrary. Even if the rule isn't immediately dismissed under the APA, the EPA's requirements under other laws, such as the Clean Air Act, that it consider all available, or best available, science in rulemaking and this policy would be in direct conflict with those. If the Agency seeks to apply this new standard in areas ungoverned by such statutory requirements, it will result in a confusing patchwork of standards where a study may be available for consideration under a Clean Air Act rule or a TSCA rule, but that same study would not be considerable in another rule.

I wanted to note in a case before the U.S. Court of Appeals for D.C. around the availability of air quality data study information, the court addressed this very issue, stating that, "If the EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant

scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment." Placing large portions of scientific research off limits simply goes against common sense. EPA should be able to use any and all available information to produce the best, most up-to-date rules. If a study is unreliable or flawed in some way, then the Agency can decide that based solely on that study's merits, and sometimes even flawed or partial studies can offer important insights that the EPA should benefit from.

We strongly urge EPA to withdraw this rule. Thank you very much for your time.

MS. HUBBARD: Thank you.

MR. BERGMAN: I'm Andrew Bergman, and I'm speaking today as the Special Environmental Advisor at the Project On Government Oversight, but I'm also currently a Ph.D. student in applied physics at Harvard University.

While the proposed "Strengthening Transparency in Regulatory Science" rule uses the words

"transparency" and "reproducibility" to project lofty goals, it's real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process. I'm here today to urge EPA to withdraw this rule. My colleague, Sean Moulton, has just addressed how the proposed rule conflicts with the EPA's regulatory process, and the statutory requirements underlying that process, but the rule will also have a direct impact on how the EPA approaches science.

The rule fails to properly address its two key considerations that will have a major impact on how it is implemented. First, the rule states that data relied on in making regulations must be made publically available, but it doesn't suggest a mechanism for how personally identifiable information or confidential business information would be handled.

This is an incredibly important issue, as so many studies that EPA uses rely on this type of confidential data. Yet it's reasonable to conclude

from the rule that, if it goes into effect, the EPA will no longer be able to use most longitudinal human health studies to craft public safeguards, even though those studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity. Instead, they will be left with industry studies that more often use animal test subjects, which don't have any personal privacy concerns.

Second, while the rule refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' reproducibility, which has a wholly different meaning in a scientific context. But because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule intends the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings.

The Agency uses many studies, however, such as

those that link leaded gasoline to brain damage in children or a study that found a link between fine particulate air pollution and premature deaths, that examine dangerous real-world exposures and cannot, of course, be safely repeated. Just because they can't, or shouldn't, be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future. Without knowing the details of how these two provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. We can conclude that the result will be that large swaths of studies will be arbitrarily ruled out for use in future rulemakings.

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially. The CBO found that a policy very similar to the proposed rule,

when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding--a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary." The three-judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying

them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all. Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation?

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made

in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed, "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule. Thank you for your time and for the opportunity to comment on this important proposal.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 37a, Emma Glidesgame, and Speaker 38a, Jyotsna Pandey if you would come to the speakers' table. Speaker 39a, Patricia Cohen speaking on behalf of Tracy Woodruff, if you would come to the on-deck seating.

MS. GLIDESGAME: Good afternoon. My name is Emma

Gildesgame, G-I-L-D-E-S-G-A-M-E. I'm a Master of Environmental Management student at the Yale School of Forestry and Environmental Studies, and an intern with the National Parks Conservation Association. My comments today are my own. I'm here to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule, that would censor science and threaten the health of all Americans. Last week, many of us in D.C. awoke to alerts warning of potential contamination in our water system. We were told to boil water before drinking or brushing our teeth or to avoid tap water altogether. For those few days, stores sold out of bottle water, Starbucks stopped selling coffee, and public pool splash pads and water fountains went dry. In the face of an urgent public health risk we did not censor the science that told us that contamination in our water is a threat. To know that clean water is important we didn't need the health records of every person who participated in landmark studies that helped us

understand the effects of contaminated water on our bodies and brains. The science is real. It's not secret, it's been repeated. It's been peer reviewed, analyzed and reaffirmed by generations of experts.

Just as the residents of D.C. took precautionary actions to protect ourselves and our loved ones in the face of a potential public health threat, the EPA must be allowed to use the best available scientific data to accurately assess environmental and public health threats to protect all Americans. The Clean Air Act, Clean Water Act, Safe Drinking Water Act and other historic laws that helped the United States become a leader in environmental protection recognized something that we forget far too often: Human health is environmental health. They are one in the same. Pollutants in the air travel hundreds of miles to become pollutants in our lungs. Contaminated soils grow contaminated food. Toxic river water becomes toxic drinking water. At the same time, clean air builds stronger kids. Healthy rivers,

lakes and watersheds build healthy communities. Good environmental and public health policies rely on a strong backbone of good science. The proposed rule would eliminate many credible, respected, long-standing, peer-reviewed, scientific studies from EPA consideration because they rely on confidential health information which cannot be made public. This proposal allows politically appointed regulators to pick and choose which studies they want to consider and would force scientists to choose between their ethical obligation to protect their subjects' privacy and the obligation to contribute knowledge to apply to regulatory science. Using good science to make strong policy has made America great for decades. The EPA and other agencies have kept countless Americans healthier, safer and more prosperous by using science to inform conservative, proactive protections for human health and the environment. We have protected historic and cultural monuments like the Jefferson Memorial, Statue of Liberty and even the Capitol

Building from the corrosive power of acid rain. We have reduced smog and air pollution in national parks like Great Smoky Mountains, Joshua Tree and Yosemite. We have improved water quality from the Great Lakes to the Everglades. Thanks to the EPA, my peers and I were born into an era of healthier air, cleaner rivers, and safer drinking water than our parents. I hope that someday my children can say the same, and that is why today I am joining thousands of scientists and public health professionals all over the country in speaking out against this rule and asking you to stop it in its tracks. We are all counting on you to listen to the sound and transparent science the EPA has used for decades and we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MS. HUBBARD: Thank you.

MS. PANDEY: Good afternoon, my name is Jyotsna Pandey, and I'm the Quality Manager for the American Institute of Biological Sciences. My

organization appreciates the opportunity to comment on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." We thank EPA for extending the initial 30-day public comment period and scheduling this public hearing on the proposed rule. We support the objective of increased transparency in the rulemaking process. But, the proposed rule is inadequately defined and thus itself lacks transparency and appropriate public protections. We request the EPA rescind the proposed rule and initiate an open process for gathering the information required to more thoroughly articulate the proposed rule. Any proposal to increase transparency in the regulatory process must not arbitrarily exclude important scientific information from the decision-making process, nor can personal information about individuals, such as genetic information or health status be sacrificed. A failure to protect these data will hinder future scientific investigations of people who refuse to participate in recent studies if they are not

confident that their most personal information is protected. Importantly, scientific journals take steps to protect personal information. They are not aware of any secure way to mask or protect personally identifiable information in the public domain and therefore think that any rule requiring this information be made public is needlessly risky. These data are important, however, to informing the decision-making process and should not be excluded for rulemaking processes because they are not publically disclosed.

As far as this request for comment, EPA has solicited input and measures to "provide protected access to identifiable and sensitive data." This is a significant issue and one that EPA should fully understand prior to moving forward with any new rule. Time and expertise are required to identify and properly evaluate the feasibility, cost and effectiveness of potential actions. It is unlikely that EPA can effectively gather and evaluate this information in the time prescribed by the proposed rule. We recommend that EPA

initiate a formal request for public comment on this issue alone and use what it learns to help inform and guide any potential future rule on transparency.

High-quality, curated and vetted mega data are generally required for someone else to appropriately reanalyze or use data such as those that could be made available by the proposed rule. The proposal is silent on meta data standards and practices. This is a significant challenge and another major problem with the proposed rule. We support EPA's goal of conducting independent peer reviews of the science and data used to inform regulatory decisions but thinks the section lacks adequate specificity. Who will conduct and manage the peer review process? Will these reviews be managed by the Office of Research and Development or by the various regulatory offices within EPA? Does EPA have appropriate staffing, expertise and resources to manage these peer reviews? We recommend that EPA partner with scientific organizations and professional communities to

administer and manage these reviews. Such outsourcing and partnerships will help to ensure that EPA gains access to independent and highly qualified experts and to promote greater public confidence in the independence of these peer reviews. This kind of process for managing peer review will also allow EPA to more cost effectively, nimbly and rapidly conduct reviews as it will not require EPA to substantially increase staffing for the remaining reviews. Such a process would also provide EPA with greater capacity to conduct reviews on time skills that do not needlessly delay regulatory and rulemaking schedules. After reviewing this proposed rule the AIBS respectfully urges EPA to rescind the current proposal. We ask that EPA initiate a new transparent and interactive process with the scientific, public health and environmental management communities, as well as other appropriate stakeholders, to identify responsible and viable approaches for promoting greater understanding of the science and data used to

inform EPA decision-making. Thank you for your consideration of our request.

MS. HUBBARD: Thank you.

MS. STOBERT: Patricia Koman, if you'd come to the speakers' table.

MS. KOMAN: Good afternoon. My name is Patricia Koman, spelled K-O-M-A-N. I am speaking on behalf of Dr. Tracy Woodruff, W-O-O-D-R-U-F-F. Dr. Woodruff is a professor in the Department of OB/GYN and the Director of the Program on Reproductive Health and the Environment at the University of California, San Francisco. Dr. Woodruff is a PI, or Principle Investigator, for a Children's Environmental Health Center and she, along with 15 other principle investigators of other Children's Centers, have submitted comments to the EPA about this proposed rule in writing. They are concerned that the proposed rule will adversely affect EPA's ability to use science in decision-making and ultimately negatively influence protections for children's health. Research from Children's Centers contribute

significantly to the foundation of science that informs and supports the Agency's ability to protect the public health. The National Academy of Sciences highlighted that Children's Centers have led to an improved understanding of the environmental impacts on child health and development. Children's Centers research identified the critical contributions of environmental exposures to asthma, obesity, ADHD, cancer, autism and other childhood illnesses. This research has led to new direction, treatment and prevention strategies for these diseases including informing EPA standards for cleaner air which has improved the quality of life for children. Collectively, we have research data from thousands of participants across the country, including some of our most vulnerable populations, children and women in communities of color. To not use or consider studies that do not comply with the proposed rule is inconsistent with scientific principles and evidence-based policy and this would put the public's health at risk

from toxic chemicals. Institutional review boards require that we protect the privacy and confidentiality of our participants, but institutional review boards' requirements conflict with this rule's mandate to publically reveal individual level data. Data masking, coding and de-identification techniques have limitations, because re-identification of participants is still possible. We are especially concerned that the rule inappropriately codifies specific data analysis approaches such as dose response modeling and other scientific decisions that should be made on the basis of scientific judgment and empirical considerations. This will hinder scientific inquiry and lead to inaccurate results. As scientists, we value open science but the mandates laid out in this rule will not improve data sharing, replicability or transparency. Instead, implementation of this rule, especially retroactively, could lead to EPA excluding numerous relevant studies from policy decisions to the ultimate detriment of children's health. We

urge EPA not to move forward with this proposed rule.

Finally, I want to comment about this public hearing and its lack of access to all stakeholders. By not providing the ability to make comments remotely or virtually, EPA limits the public comments to those that have the financial resources to travel to Washington D.C. and limits the participation of populations that are going to be most affected by this rulemaking. This undermines civic engagement and conflicts with the principles of a fair democracy. This is not a technical issue, as U.S. EPA has made virtual public comment in the past.

Finally, we urge EPA not to move forward with this proposed rule. Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: It's now 3:02 p.m. This was our last speaker for this session that we know of. We are going to repeat the request that if there is any speaker that has registered but is registered for the evening session, if you'd like to speak

now go to the registration desk and you will receive a speaker number for this session. We're going to wait a few minutes and see if there's anybody that decides to speak now. Otherwise, we will break until the 4:00 session starts.

MS. HUBBARD: And if I could just make a quick announcement, we do have a member of Congress who is on his way to speak who should be here shortly, so we won't go into recess quite yet, so if everyone could just remain in their seats if you're interested in hearing him speak, otherwise feel free to go on and head on out and then we'll go into recess after that.

MS. STOBERT: Sorry, Peter Ferrara, speaker 40a, if you would come to the speakers' table?

MR. FERRARA: Good afternoon. My name is Peter Ferrara, that's F-as in Frank, E-R-R-A-R-A. I'm the Senior Fellow for Legal Affairs at the Heartland Institute. We submitted our comments during the comment period online in response to the notice for public comment in rulemaking posted on April 30, 2018. EPA proposes the rule I am

commenting on intending the strengthen the transparency and integrity of EPA regulatory science. The proposed rule provides that EPA should ensure that the data and models underlying scientific studies pivotal to EPA regulations are publically available in a manner sufficient for independent validation, especially concerning regulations for which the public is likely to bear the cost of compliance. We applaud this proposed rule and find that governing statutes and executive orders, not to mention the basics of the scientific method, authorize the proposed rule and indeed have long required it. In not following the proposed rule in the past, EPA has been flouting the governing statutes and executive orders, departing from the scientific method and abusing its authority. The proposed rule provides that for science pivotal to significant regulatory action, EPA will ensure that the data and models underlying the science are publically available in a manner sufficient for validation and analysis. This new policy is needed because EPA admits to

having not previously implemented these policies and guidance in a world-best, robust and consistent manner.

Examples where EPA previously has fallen short include the public health research used to implement and defend the PM2.5 particulate matter standards, the corporate average fuel economy standards, the ozone standards and carbon dioxide standards. EPA's admitted reliance on secret science occurs at a time when the publications *Nature*, *PLoS*, *Science*, *The Economist* and other report half or more of published research on public health issues cannot be replicated. This replication crisis is genuine and even more broad and critical than the sources cited by the EPA for this proposed rule are willing to admit. A scientific publishing industry has been created by lavish government funding of politically directed research. Examples of this include supposedly scientific studies finding human impact on the climate or an association between ozone and climate. It may take generations before the

effects of this corruption can be overcome. The root cause of EPA science malfunction has been corruption of EPA's peer review process. Peer review for the EPA has become power review with insiders typically armed with millions of dollars in government funding acting to censor and exclude scientists who disagree with the reigning political agenda. That perverts the whole point of peer review, turning it into a tool used to shut out anyone who disagrees, instead of a process forcing scientists to defend their work against critics. The more widespread replication crisis is proof that this disease has affected most of the world's leading science journals and even its National Academies of Sciences. One scientific finding that has been suppressed by the corruption of peer review was just singled out by EPA in its call for comments, is evidence of non-linearity in the concentration response function for many pollutants. The entire regulatory model is precariously perched on an invalid assumption of linearity and the resulting scientific crisis

continuing to build must now be openly faced, removed and regulations based on such science malfunction, or even outright corruption, must be revised and repealed entirely. EPA's new policy of scientific integrity and transparency should be applied to computer climate models that currently prevail in EPA's funded published and cited climate science. The continued use of default models, not consideration of alternatives or model uncertainty create a false scientific justification for EPA actions, policies and regulatory burdens.

So, we applaud this new proposed rule and encourage the EPA to implement it rapidly.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 41a, Liz Hitchcock, and Speaker 42a, Benjamin Kirby, if you would come to the speakers' table.

MS. HITCHCOCK: Good afternoon, my name is Liz Hitchcock, and I direct Safer Chemicals Healthy Families. We lead a coalition of hundreds of local, state and national groups. This variety of

groups of labor, consumer, parents, educators, scientists, health care providers, health-affected and others shares the concern about the growing recognition of the links between our exposures to toxic chemicals and the increases in cancers and other chronic illnesses and in learning and developmental disabilities, and we share a commitment to reducing and eliminating exposures to toxic chemicals in our homes, our places of work, and the products that we use every day. I thank the Agency for responding to the large number of public comments that objected to the length of the initial comment period by extending it and for scheduling this hearing.

Safer Chemicals Healthy Families joins a long day of voices in opposition to this proposal. Many of our coalition partners and a number of respected scientists have offered strong cases for withdrawing the proposal already today and I thank those speakers for their comments and will try to keep my own comments brief.

The proposed rule is irreparably flawed and

misconceived. In the name of transparency it will prove needlessly burdensome, requiring unnecessary and costly procedures of EPA scientists that are counter to the Agency's longstanding application to base public health decisions on the best available science. Under this proposal without a guarantee of full public access, the study will be considered unreliable and will play no role in assessing a chemical's health effects on human health. This ignores the many ways in which the scientific community, regulators and the public have traditionally determined the quality and relevance of study results. It also disregards the way that hard-working EPA science professionals have taken seriously their charge to use the best available science in their decision-making. Safer Chemicals Healthy Families played a key role in the reform of the Toxic Substances Control Act which requires that EPA use the best available science in the review and management of toxic chemicals. As EPA begins to review the tens of thousands of chemicals already on the market we

are concerned that they be able to take into consideration all information that is reasonably available. For the fence line communities that have been harmed by their exposures to chemicals, for the families who have lost loved ones to asbestos-related diseases, for the firefighters exposed to a soup of toxics as they protect our communities, and to children who are born pre-polluted by a range of industrial chemicals, the stakes are high for these evaluations. EPA scientists working on risk and hazard assessments collect and review thousands of studies. Published reports of these studies typically do not include all the underlying data. This proposal would add the burdensome requirement in such cases that EPA contact the researcher, determine the nature and extent of the underlying data, and put in place a mechanism for the public to access the data. Many before me have called this proposal a solution in search of a problem, but it bears repeating. In proposing this rule EPA leaders have painted a stark picture of EPA

reliance on so-called secret science developed behind closed doors, but is this really so? EPA science assessments generally include an exhaustive and critical review of relevant studies and a full explanation of how they are being interpreted. Extensive information about each study is typically part of the public record, even if all underlying data may not be included. EPA assessments are normally subject to public comment and independent peer review and members of the regulatory community are free at any time to replicate studies they deem flawed or to independently seek access to underlying data and reanalyze them. In short, the so-called problem that the proposed rule seeks to fix is largely fiction.

In conclusion, EPA should withdraw this proposed rule. The public health stakes are just too high. Thank you.

MS. HUBBARD: Thank you.

MR. KIRBY: My name is Ben Kirby. I'm an environmental engineer with a doctorate and

master's degree in environmental engineering from Virginia Tech and George Mason University respectively. I'm representing Hall and Associates, and environmental consulting firm in Washington D.C. We support the application of this rule to EPA's environmental impact analyses, particularly TMDLs, or Total Maximum Daily Loads, and NPDES or National Pollutant and Discharge Elimination permits under the Clean Water Act. These legally binding permits include ethylene limits for wastewater treatment facilities for pollutants such as lead, mercury or phosphorus. Slight alterations in these permit limits can cost a single wastewater facility tens of millions of dollars, the cost of which is passed on to individual local rate bearers. These permit limits are supposed to be derived in a manner similar to dose-response relationships as mentioned in the rule where, for example, a lower level of the pollutant in the discharge will result in a measurable increase in receiving water quality working with health. However, we have

dealt with instances throughout the country where environmental agencies have based regulations on publically unavailable data, outdated science or faulty science, even in the face of data or studies which indicate stringent permit limits imposed by these agencies are not anticipated to result in any quantifiable environmental or human health benefit despite the cost. We hope that this rule would remedy these shortcomings.

We also strongly support the use of independent expert peer reviews as an additional level of review for fiscal regulatory science. Our firm has been involved in independent peer reviews of various Clean Water Act related EPA regulations which have concluded that the technical basis for EPA's regulations and permit limits were scientifically indefensible. Had no peer reviews occurred, these regulations would have imposed hundreds of millions of dollars of wastewater treatment costs to rate bearers with no anticipated benefit. As a science-based Agency applying science-based statutes it is critical to

both receiving water quality and rate payers throughout the country that these permits and regulations are based on sound science and not speculation.

In this regard, we support application of EPA's proposed rule to Clean Water Act regulations.

Thank you for the opportunity to come.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker A, Dan Lipinski, you are now invited to speak at either the table or the podium.

MR. LIPINSKI: Good afternoon, I'm Congressman Dan Lipinski of the Third District of Illinois. I'm here to ask the EPA to rescind the proposed rule. The origins of the rule are in the 2014 House Bill called, the Secret Science Reform Act, which I voted against in that year and again in 2015, and when it was reintroduced as the Honest Act in 2017. The goal of these bills and of the proposed rule, contrary to its name, is to limit availability of science to inform regulatory decision-making. I'm disappointed to see the

Trump administration circumventing the will of Congress, attempting to administratively implement policies that cannot pass through the Legislature. On June 7th of this year, I joined 102 of my colleagues from both political parties in sending a letter to then Administrator Pruitt urging him to withdraw the proposed rule. My comments today build on that earlier commentary and expand on my opposition to this misguided policy.

EPA's admission, as it appears on the Agency website, is to protect public health and the environment and to ensure that national efforts to reduce environmental risks are based on the best available scientific information. The proposed rule works in direct opposition to that mission by requiring that the data underlying the scientific studies used in informed regulatory actions are available to the public. The proposed rule will exclude vast quantities of valuable research including that based on personal health data, confidential business information, and even older studies whose authors or data sets are no longer

available. In some cases, the rule will require the exclusion of the best available scientific information. To make matters worse, this rule would grant the administrator wide latitude to exclude studies from its provisions, enabling him or her to cherry pick studies in order to affect the outcome on the rulemaking process. There is no basis in any of the statutes under which EPA operates for giving an administrator such broad authority to choose which science is used in rulemaking.

Let me give an example of how the proposed rule could affect a future EPA rulemaking. EPA is planning to update its lead and copper rule in the near future the rule that limits the levels of these metals in drinking water. This update cannot come soon enough. We all know about the drinking water crisis in Flint, Michigan. Chicago and Washington D.C., as well as many other cities around the country, are finding troubling levels of lead in drinking water right now. Most of what we know about the health effects of lead exposure

comes from older studies of children with high levels of lead in their blood. Yet these studies may be excluded from consideration, both because their data are not publically available and because it would be unethical to replicate them. As a result, it is possible that an Agency could conclude that there is no evidence that lead is bad for you and, therefore, does not need to be updated. This would be a tremendous mistake. I have spent my career in Congress working to enable science-based decision-making in government. The proposed rule represents a significant step backward and I urge the Agency, in the strongest terms possible, to rescind it. Thank you.

MS. STOBERT: Speaker 43a, Mahealani Daniels. If you'd come to the speakers table.

MS. DANIELS: Good afternoon. My name is Mahealani Daniels and I'll spell that M-A-H-E-A-L-A-N-I, D-A-N-I-E-L-S. I would just like to thank you for allowing me the opportunity to share my comments in opposition to the EPA's new policy on so-called transparency. The EPA must utilize

the best available science to inform its actions in the creation of environmental and public health laws. Judicial precedents establish that the best available science is all existing scientist evidence relevant to the decision. In further supporting these precedents, the EPA's own regulations state that the best available science would be information that the EPA possesses or could reasonably generate, obtain or synthesize, whether or not that be information that is confidential business information that is protected from public discourse. While increasing transparency and ending an era of secrete science are two statements that publically resonate as appealing advances, when digging deeper it is clear that the EPA's implementation of these standards would do just the opposite and would actually violate judicial precedent as well as the Agency's own regulations. A majority of confidential health data can't be used with the EPA's new standards of transparency, thus limiting the scientific evidence they could use to inform

studies and standards. Since personal health data informs the production of environmental laws that protect public health, it's exceptionally important that the EPA continues to use it. For example, a recent study released by MIT demonstrates that 200,000 early deaths occur every year in the United States as a result of air pollution. Utilizing data on patients' health is not only necessary to establish the aforementioned research, but is also necessary when the EPA goes to set standards on environmental and pollution regulations that affect the lives and health of millions of Americans. I am hopeful that just as a majority of Americans are guided by their own personal values to abide by the laws established by our government, the EPA will too decide to function under judicial precedents and be guided by its principle to utilize the best available science. And with that, I thank you so much for your time.

MS. STOBERT: Thank you. I believe that was the last speaker for this session, so we will recess

now and resume the hearing at 4:00 p.m. Thank you.

[Off the record 3:26 p.m.]

[On the record 4:00 p.m., Evening session. Substitution of panel members.]

MR. RODAN: Okay, so welcome back at 4:00. Let us commence session three of this public hearing. Hello and thank you for coming. This public hearing is now in session. My name is Bruce Rodan and I am in EPA's Office of Research and Development. I will be one of the hearing officials of this two-hour period. Lou D'Amico, also from the Office of Research and Development will be joining me. We also have Nanishka, Lauren and Lesley from SC&A Incorporated helping with logistics.

The purpose of today's hearing is to accept public comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science." EPA is accepting comments on all aspects of the proposed regulation. This public hearing is a formal legal proceeding and the testimonies will become part of

the administrative record on which EPA will base its decision. Public notice of this hearing was published in the Federal Register on April 30, 2018 (83 FR 18768). EPA is proposing this rule under authority of 5 U.S. Code 301 in addition to the authorities listed in the proposed rule document dated April 30, 2018.

My role is to ensure that the EPA received your comments in an orderly fashion. Although EPA panel members may ask clarifying questions the intent of this hearing is to listen to your comments, not to discuss or debate the proposal.

Now for a few housekeeping items and ground rules. Please refrain from interrupting speakers or asking questions. Shouting and noisemaking or any disruptive conduct which prevents speakers or hearing officials from being heard are not permitted. Please listen quietly so that we can hear each testimony and to ensure that the court reporter is able to record comments accurately and listeners on the phone hear the oral testimonies.

For everyone's awareness, this hearing is open to

the press and we may have members of the media present with us today. This event is also open to any form of recording, video, audio and photos. We ask that you not cause any disruption to those testifying or observing the hearing. There was no formal lunch break scheduled. You may leave and return to the hearing. Please note that you will need to clear security again, so please be aware of time and the rain outside. If you'd like to make an oral comment in today's hearing and did not pre-register to speak, please see the hearing staff at the registration table positioned at the entrance of the room. If you would like to provide a written comment to the official record, you may hand submit it to the EPA staff today or mail, fax or email your comment. See staff at the registration table for instructions on how to submit written comments. There is a comment box at the registration table where you can leave hard copies of your oral testimony or written comments. All comments received will be included in the official docket. If you submit written comments

it is not necessary for you to give the same comments orally. Written comments and oral testimonies will receive equal consideration by EPA in preparing the final rulemaking decision. EPA has extended the comment period. Written comments must have been received on or before August 16, 2018. EPA will only consider comments related to the proposed rule, "Strengthening Transparency in Regulatory Science," so please refrain from making comments that are not related to this action. EPA will not provide responses during the hearing, rather EPA will prepare a written summary of the comments received that includes responses. The Response to Comments, RTC, document will be available at the time EPA issues its final decision. EPA will not make a final decision until all comments submitted during the public comment period have been considered. The hearing is being recorded by a court reporter who will be preparing a verbatim record of the hearing. Please speak clearly and slowly into the microphone so that the court reporter can record

your comments accurately. A copy of the transcript will be placed in the docket. The hearing is also being audio streamed through Adobe Connect and via phone lines.

The hearing is scheduled from 8:00 a.m. to 8:00 p.m., or one hour after the last registered speaker has spoken, whichever is earlier, and is divided into three sessions: 8:00 a.m. to 12:00 p.m., 12:00 p.m. to 4:00 p.m., and this session 4:00 p.m. to 8:00 p.m. Public restrooms are located down both sides of the hall and we have staff to escort you. Please note the location of the emergency exits.

Please take a moment to silence your cell phone (I've done that). Speakers should have been given a sticker upon check-in that lists your assigned session. If you plan to speak and have not received a sticker, please be sure to check in at the registration table. For the current 4:00 p.m. to 8:00 p.m. session, the speaker sticker collar is blue. Speakers will be called to the speakers' table located directly across from the EPA panel

members' table in pairs by their speaker number. When it is your turn to speak, please come up to the table and watch your step. State and slowly spell your name for the record, and if you are appearing on behalf of someone or an organization. If you are not in the room when it is your turn to speak I will recall you after all other speakers have made their oral comments. Each speaker will be allotted five minutes for remarks. Elected and appointed government officials may be provided additional time since they represent large groups of constituents. Speakers will be notified when their time has ended. Our timekeeping system or speaker timer consists of green, yellow and red lights. When you begin to speak, the green light will come on to indicate you have five minutes to speak. The yellow light indicates that you have one-minute left to speak. When the red light appears your five minutes are over. At that moment, if needed, I will politely interrupt you and ask you to wrap up your testimony. So, let's begin.

Speakers Numbers 1 and 2 in the afternoon session, please come forward and take a seat at the speakers' table. We will start with Speaker Number 1. Again, please speak directly into the microphone and state and spell your name for the record.

MR. SHIPPS: Thank you for this opportunity to provide public comments on EPA's proposed rule, "Strengthening Transparency in Regulatory Science." My name is Karl Shipps. That's spelled K-A-R-L, S-H-I-P-P-S. I live in New Carleton, Maryland, and I'm speaking as an individual. I am not employed by EPA or an EPA contractor, I am simply a very concerned person. I am a Navy submarine veteran, a grandfather, and have a master's degree in applied physics from the Johns Hopkins University. Because my time is limited I will confine my remarks today to three observations about the proposed rule and two recommendations.

My first observation is this: The proposed rule is based on a faulty premise, namely that only

studies whose underlying data are publically available sufficient to support replication should be considered by EPA as it develops regulations governing clean air, clean water and exposure to toxic substances and pesticides. The rule's premise, which was also the premise of the Secret Science Reform Act and the Honest Act, cannot stand. There are valid peer-reviewed studies that should be included in EPA's regulatory work even though their underlying data sets cannot be released to the public. Two of the most widely known are the Harvard School of Health's Six Cities Study, and the American Cancer Society's Cancer Prevention Study II. Those studies were revalidated by the Health Effects Institute in July of 2000 using an independent oversight board and a competitively selected analysis team. They remain valuable today. Since the proposed rule is based on a faulty premise, I recommend that it be withdrawn. A new rule addressing concerns about reproducibility and replicability should be developed in public with participation by the

scientific community, the environmental community and industry. The rule developers should avail themselves of the results of the ongoing reproducibility and replicability study being conducted by the National Academies of Sciences. That study will report in December 2018. Perhaps the EPA will not take my recommendation to withdraw the proposed rule. In that event, my second observation is germane. My second observation is that the EPA administrator is given extraordinary powers under Section 30.9 of the proposed rule for new EPA regulations or for regulations undergoing periodic update, the administrator could waive or not waive the provisions of the rule. This puts potentially thousands of studies underpinning EPA's regulations at risk of being discarded out of hand at the administrator's whim. The result would not be the best science and it would reduce public confidence in EPA rulemaking, not increase it. Based on that prospect, I recommend what the Texas Commission on Environmental Quality recommended,

namely to give governing authority for granting exceptions to the proposed data Transparency Rule, as well as the oversight of raw data collection, storage and access, to an external entity or entities to ensure independence and objectivity. You can see Docket comment EPA-HQ-OA-2018-0259-2426.

My final observation is that the scientific community was not consulted as the proposed rule was prepared. Even EPA's own Science Advisory Board was not consulted, learning about the rule only through press accounts and publication in the Federal Register. The joint statement on the EPA proposed rule and public availability of data in the 30 April edition of *Science* disagrees with the proposed rule. EPA should heed the concerns being voiced by the scientific community. Thank you for your attention.

MS. WHITE: Good afternoon. My name is Dr. White, W-H-I-T-E, on behalf of the American Chemistry Council's Formaldehyde Panel. I appreciate the opportunity to provide feedback on EPA's proposed

rulemaking. Utilization of transparent, objective and modern scientific approaches to draw conclusions regarding human health risks is critical to developing sound regulatory decisions. Throughout the EPA the application of scientific information to underpin regulatory activities has often been inconsistent and unclear, leading to concerns regarding how the Agency incorporates the best available science, evaluates the quality of that science, and applies 21st century knowledge concerning cause and effect. The panel has regularly met with EPA scientists related to the IRIS program regarding its subjective use of available science and resistance to moving away from default linear low-dose extrapolations, even when published scientific data support other modeling alternatives, including threshold-based approaches. This stance has often led to the generation of EPA values that are below natural background levels and not indicative of human health risks associated with real world exposures. Perhaps the most telling example can be found in

the case of formaldehyde, where a draft IRIS assessment sets values suggesting that human breath could pose a cancer risk. Formaldehyde has been the subject of scientific study for years and large bodies of evidence show that the levels of formaldehyde most people encounter on a daily basis do not cause adverse health effects, a conclusion reached by several international agencies using alternative models other than a default linear modeling approach. The evidence demonstrates the biological implausibility of any relationship between formaldehyde and leukemia, a threshold mode of action for any potential adverse health effects, and the importance of mode of action information for understanding potential impacts. We are encouraged by the Agency's proposed rule's recognition that there is growing empirical evidence of nonlinearity and that the use of default models without consideration of alternatives can obscure the scientific justification for EPA actions. This acknowledgement by EPA is especially relevant to

formaldehyde given the several decades of published literature illustrating preserved thresholds for both noncancerous and cancerous status.

In addition to the significant research and the development of a biologically-based dose response model for formaldehyde that also integrates the available science and provides results inconsistent with default linear dose response modeling approaches typically apply for carcinogenic end points. The importance of using nonlinear and biologically based dose response modeling, when the published data supports it, cannot be overstated. In this review of a 2010 draft IRIS formaldehyde assessment, the National Academy of Sciences noted the development of several models to evaluate the risks associated with formaldehyde exposure and recommended that alternatives to EPA's default linear low-dose extrapolation approach be considered.

In addition to incorporating modern scientific knowledge, we also recognize the importance of

adequate transparency in data access and ensuring regulatory decisions are based on high quality and reproducible data. For more than a decade, the panel has conducted scientific research engaged directly with EPA's IRIS program to understand the scientific information being relied on to draw conclusions regarding potential for health effects. The panel has experienced considerable difficulty in understanding what data is being relied on and how the Agency has ensured the highest quality and most relevant science is informing its decisions. Importantly, in multiple instances, sometimes after years of requests, once the underlying data was made available, it was found to have significant methodological and quality issues. In several cases, the findings, when reevaluated, did not support the original study's conclusions. The issues identified were not minor and highlight the need for greater transparency and for EPA to have a mechanism in place to evaluate the quality and reproducibility of the data being relied upon for decisions.

One notable example involved over six years of repeated requests to access all the relevant data from a National Cancer Institute study which was relied upon by the IRIS program to draw conclusions regarding formaldehyde and leukemia. The data were requested from NCI for the purpose of validating the author's conclusions and the evaluation of that underlying data found that changes reported by the study authors were not exposure dependent and they did not follow their own stated protocol. As demonstrated by formaldehyde example, when the data access is limited and modern scientific approaches aren't used to move away from default assumptions, the results can be conclusions that lack scientific rigor and potentially provide the public with an inaccurate picture about everyday chemicals which have been used safely for years.

I hope that you find these comments useful and I will provide a detailed set of comments by the August deadline.

MR. RODAN: Thank you. I believe we have another

speaker.
MS. HALL: Right, I don't have any details on that yet.
MR. RODAN: What?
MS. HALL: I don't have any details on who it is or -- standby. Speaker 3, Walter Tsou, please come up to the speakers' table.
MR. RODAN: Around the far side. Take care of the wire. I think you provided a copy at the front desk, we'll take it here. Watch out for the cord there, we don't want you falling over. Okay, so, we went through some long instructions. You have five minutes.
MR. TSOU: Okay. I'll be less. My name is Dr. Walter Tsou. I serve as Executive Director of Philadelphia Physicians for Social Responsibility and a past president of the American Public Health Association. Thank you for this opportunity to testify on "Strengthening Transparency in Regulatory Science". As many of my colleagues have noted today, while the goal of transparency in how studies are conducted, and the ability to

reproduce scientific results are important, it can offer a politically motivated administration a convenient excuse for eliminating or ignoring scientific studies that may go against the wishes of a powerful industry group. All one has to do is demand that the data sets be handed over for "further scrutiny" or demand that the study be repeated before basing a regulation on the study in question.

The very nature of longitudinal public health studies where health and toxins intersect are, by design, large, expensive and require years or sometimes decades before results are found. Sample sizes can often number in the tens of thousands to millions of data points and may need to be collected over many years before a statistically significant finding is identified. For example, Curry, et al studied in Pennsylvania babies who lived within 1 kilometer of active fracking wells. She had to review over 1.1 million birth records before demonstrating the relationship between living close to gas wells and low birth weight

babies. Because these studies are so big, they are often too expensive to repeat. In our state of Pennsylvania, scientific research on fracking is actively stymied or suppressed. In a state where billions are made on gas drilling, only one part time contractor at the Health Department collects data on health complaints from fracking. Those who do have health complaints have to sign non-disclosure agreements and not cooperate with any research in order to get lifesaving water to drink. This I consider extortion and this practice is common in the industry in order to suppress any health studies on the dangers of fracking. If the transparency regulation was in place, all health studies on fracking would be simply not considered because the research could not be conducted due to non-disclosure agreements.

Today there is no reputable scientist that doesn't believe in the harmful effects of smoking. The health studies on smoking were 15 years in the making before the Surgeon General released his landmark 1964 report and except for a handful of

EPA administrators, there is no reputable scientist who doesn't believe that climate change is real and is man-made. The studies on climate change and health have been known since Exxon wrote about it in 1977. If these transparency rules were in place when the EPA was founded, smoking would still be in airplanes and no one would have heard of "greenhouse gases" or "global warming", the greatest threat to our planet's existence.

Since the founding of the EPA, independent scientific research has been the foundational basis of your mission. Science is the cross before the corporate devil. This Transparency Rule would destroy the confidential nature of research and make the burden of conducting research more difficult and expensive. Finally, the real purpose of these rules is to reverse regulations on industries who have been harmful to public health. We should let science speak for itself and speak the truth and the EPA should hear from all scientific studies, not just the ones the industry

wants you to listen to. Thank you for your time.
MR. RODAN: Thank you very much. So, do we have any other registered speakers waiting? So we'll have a short recess and we have a one hour clock ticking. The time now is 4:22.
[Off the record 4:22 p.m.]
[On the record 4:40 p.m.]
MR. RODAN: We are hereby reconvening this public hearing. Come up to the -- go to the right there, there's some steps.
MS. HALL: Speaker Number 4, Mark Mitchell.
MR. BRUCE RODAN: Thank you, you'll have five minutes of time and you'll get a green light for the first four, an orange light and then a red light when the five minutes is up.
MR. MITCHELL: Okay, thank you. Thank you for this hearing. My name is Mark Mitchell. I'm a public health trained environmental health physician. I am testifying on behalf of the National Medical Association which represents the interests of more than 30,000 African-American physicians and our patients. We are a member

society of the Medical Society Consortium on Climate and Health.

I got into environmental health because I was concerned about the health effects of environment on public health. As a public health official, I saw that a lot of the diseases that are common, particularly those that are common in communities of color, are associated with the environment. We are opposed to the misnamed proposed new rule on "Strengthening Transparency in Regulatory Science." The proposed rule prohibits the Agency from setting regulations that are supported in part or in whole by data that is not publically available for reanalysis or that cannot be replicated. This rule, if enacted would limit the consideration of perfectly good science in the EPA regulatory process. What's more, it's retroactive so the current regulations that are based on previous studies that can no longer be replicated for ethical or other reasons, could then be voided. As physicians, we are particularly concerned about our legal and ethical obligation

to protect patient privacy under the Health Insurance Portability and Accountability Act of 1996, otherwise known as HIPAA. We believe that patient health data should be considered in EPA regulations because it's necessary to consider the health effects of environmental exposures in order to protect human health, and that we should also be able to guarantee patient privacy that should be protected.

Currently, we do this in research publications through the peer review process. The peer review process has worked well to ensure an adequate level of transparency while allowing science to advance unencumbered. We do not need to reduce the health protection that environmental regulations provide in the name of so-called "transparency." Thank you for this opportunity to testify.

MR. RODAN: Thank you. So, we'll go into another short recess, or maybe an hour, at 4:44. Thank you.

[Off the record 4:44 p.m.]

[Off the record 5:44 p.m.]

MR. RODAN: It's 5:44. I'll read the closing statement. Thank you for taking the time today to share your comments on the EPA proposed rule. The time is now 5:45 p.m. No additional members of the public have registered or are waiting to speak. Therefore, this hearing is now officially closed. Thank you.

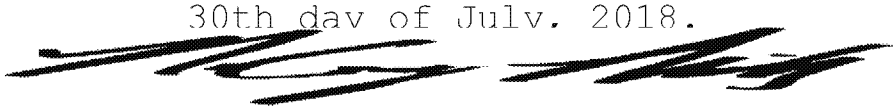
[Off the record 5:45 p.m.]

Whereupon, the above-entitled matter is concluded.

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, NaCorey Nichols, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.



My commission expires:

October 14, 2021

NOTARY PUBLIC IN AND FOR THE

DISTRICT OF COLUMBIA

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Gary Euell, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that the witness was duly sworn by me; that said testimony was taken by me electronically and thereafter reduced to typewriting under my direction; and that I am neither counsel for, related to, nor employed by any of the parties to this case, and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 30th day of July, 2018.

My commission expires:

March 14, 2023

NOTARY PUBLIC IN AND FOR THE

DISTRICT OF COLUMBIA

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Comments of Daniel Greenbaum, President
Health Effects Institute (HEI)
July 17, 2018

HEI Comments on Proposed Rule EPA–HQ–OA–2018–0259; FRL–9977–40–ORD

HEI is pleased to have the opportunity to present these brief oral comments. We are preparing and will submit more detailed written comments

1. HEI has a longstanding commitment to the principles being addressed by this proposal: producing science of the highest integrity and quality, with special attention to issues of reproducibility and transparency. This includes:

    - Rigorous research and statistical design – Subject to competition, continuous oversight, data quality assurance audits, and more
    - Extensive efforts to test all findings against a wide range of different statistical techniques and assumptions
    - Intensive and independent peer review, with *all* results published
    - An active *Data Access Policy* for nearly 20 years to ensure access to underlying data for all HEI-funded studies.

2. Reproducibility is a critical challenge for science: can the results of an important study be reproduced? In HEI's view the most effective way to test the reproducibility and validity of scientific results is not necessarily to simply reproduce the same results in the same data sets -- because that also reproduces all the weaknesses and limitations of the original study. Rather, it is most important to answer the question: *Are the results consistent when tested in other independent studies*:

    - That use new and different data not affiliated with the original studies?
    - Have different investigators applying the same and/or alternative statistical techniques?
    - And test the sensitivity of the results against a wide range of possible other explanations, e.g. smoking behavior, socioeconomic status, access to medical care, and more.

3. In a limited number of cases, where there are not comparable studies in other datasets, it may be useful to gain access to the original study data and analytic codes to allow for independent evaluation: *Can the original results be replicated? And are they robust to a wide range of alternative assumptions, models and potential confounders?*

- This is the approach that HEI applied in its independent, rigorous reanalysis of the Harvard Six Cities and American Cancer Society Studies (see attached description of the Reanalysis):
- This approach can – and did – provide comprehensive assurance of the quality, integrity, and validity of the original results
- However, this is a highly cost-intensive and time-consuming endeavor which should only be applied in cases where there are one or just a few studies in a given area.

4. HEI also agrees with the continuing need to enhance transparency and data access, but would note that these issues are not new, and have been addressed now for over 15 years by administrations from both parties and by the scientific community:

    - This has included Guidelines for the Information Quality Act adopted by the Office of Information and Regulatory Affairs (OIRA) in 2002, numerous actions by the scientific community and journals to enhance access, and most recently the requirements for enhanced data access across the Federal Government promulgated by the Office of Science and Technology Policy (OSTP) in February 2013
    - We would strongly urge EPA to review the progress already made under these several major initiatives, and to carefully consider whether or not there are additional efforts that could further enhance transparency, *before* proceeding with a final rule.

5. Finally, access to private medical information is essential to conducting high quality and reproducible air quality and health research:

    - There are of course longstanding federal rules for protecting the privacy of individual medical information of the subjects of studies (HIPPA, Common Rule, etc.)

    - Gaining access to data from older studies may be difficult, given the privacy commitments that were made to study subjects in the past.

    - However, there *are* today several means to make such data available to investigators with appropriate privacy protections (e.g. Medicare, Federal Research Data Centers) and many investigators have been taking advantage of these.

    - Although it is possible, as some have suggested, to create a "depersonalized" data set by stripping all personal identifiers, such as address, date of birth, etc.
        - *It is not possible to conduct a high-quality air pollution and health study without knowing the locations of those being studied*, i.e. where they live, and what are the sources and levels of their air pollution exposure?

Thank you for this opportunity to testify – we look forward to submitting our detailed written comments and would welcome the opportunity to further assist EPA in these efforts to ensure the widest array of quality science is available for decisions.

ATTACHMENT: The HEI Reanalysis Statement

HEALTH EFFECTS INSTITUTE

STATEMENT

Synopsis of the Particle Epidemiology Reanalysis Project

BACKGROUND

Epidemiologic work conducted over several decades has suggested that long-term residence in cities with elevated ambient levels of air pollution from combustion sources is associated with increased mortality. Subsequently, two prospective cohort studies, the Six Cities Study (as reported in Dockery et al 1993) and the American Cancer Society (ACS) Study (as reported in Pope et al 1995) estimated that annual average all-cause mortality increased in association with an increase in fine particles (all particles less than 2.5 μm in median aerodynamic diameter [$PM_{2.5}$]).

As part of the Six Cities Study, Dockery and colleagues (1993) had prospectively followed a cohort of 8,111 adult subjects in northeast and midwest United States for 14 to 16 years beginning in the mid-1970s. The authors found that higher ambient levels of fine particles and sulfate (SO_4^{2-}) were associated with a 26% increase in mortality from all causes when comparing the most polluted to the least polluted city, and that an increase in fine particles was also associated with increased mortality from cardiopulmonary disease. The relative risks in all-cause mortality were associated with a difference (or range) in ambient fine particle concentrations of 18.6 μg/m^3 and a difference of ambient sulfate concentrations of 8.0 μg/m^3, comparing the least polluted city to the most polluted city.

In the much larger ACS Study, Pope and colleagues (1995) followed 552,138 adult subjects in 154 US cities beginning in 1982 and ending in 1989 (3 cities did not overlap between the 151 and 50 cities studied, resulting in a total of 154 cities). Again, higher ambient levels of fine particles were associated with increased mortality from all causes and from cardiopulmonary disease in the 50 cities for which fine particle data were available (sampled from 1979 to 1983). Higher ambient sulfate levels were associated with increased mortality from all causes, cardiopulmonary disease, and lung cancer in the 151 cities for which sulfate data were available (sampled from 1980 to 1982). The difference between all-cause mortality in the most-polluted city and the least-polluted city was 17% and 15% for fine particles and sulfate, respectively (with a range of 24.5 μg/m^3 for fine particles and of 19.9 μg/m^3 for sulfate).

Both of these studies came under intense scrutiny in 1997 when the EPA used the results to support new National Ambient Air Quality Standards for fine particles and to maintain the standards for particles less than 10 μm in median aerodynamic diameter (PM_{10}) already in effect. Members of Congress and industry, the scientific community and others interested in regulation of air quality scrutinized the studies' methods and their results. Some insisted that any data generated using federal funding should be made public. Others argued that these data had been gathered with assurances of confidentiality for the individuals who had agreed to participate and that the concept of public access to federally funded data did not take into account the intellectual property rights of the investigators and their supporting institutions. To address the public controversy, Harvard University and the ACS requested that the Health Effects Institute organize an independent reanalysis of the data from these studies. Both institutions agreed to provide access to their data to a team of analysts to be selected by HEI through a competitive process.

APPROACH

To conduct the reanalysis, the HEI Board of Directors, with support from the EPA, industry, Congress, and other stakeholders, appointed an Expert Panel chaired by Dr Arthur Upton from the University of Medicine and Dentistry of New Jersey and former Director of the National Cancer

This Statement, prepared by the Health Effects Institute, is a summary of a research project conducted by the Reanalysis Team, led by Dr Daniel Krewski at the University of Ottawa. The following Special Report contains the detailed Investigators' Report (Summary, Introduction, and Parts I and II), Commentary on the project prepared by a special panel of the Institute's Health Review Committee, and Comments on the Reanalysis Project by the Original Investigators (Drs Douglas W Dockery, C Arden Pope III et al).

Institute. The Expert Panel selected competitively a Reanalysis Team—led by Dr Daniel Krewski of the University of Ottawa—and oversaw all aspects of the team's work. They were assisted in their oversight efforts by a broad-based Advisory Board of knowledgeable stakeholders and scientists who, in the project's early stages, provided extensive advice to the Expert Panel on the key questions to be analyzed. The final results of the Reanalysis Team were intensively and independently peer reviewed by a Special Panel of the HEI Health Review Committee, which was chaired by Dr Millicent Higgins of the University of Michigan.

The overall objective of what became the Particle Epidemiology Reanalysis Project was to conduct a rigorous and independent assessment of the findings of the Six Cities and ACS Studies of air pollution and mortality. This objective was met in two parts. In *Part I: Replication and Validation*, the Reanalysis Team sought to replicate the original studies via a quality assurance audit of a sample of the original data and to validate the original numeric results. In *Part II: Sensitivity Analyses*, they tested the robustness of the original analyses to alternate risk models and analytic approaches.

RESULTS AND IMPLICATIONS

PART I: REPLICATION AND VALIDATION

- An extensive audit of the study population data for both the Six Cities and ACS Studies and of the air quality data in the Six Cities Study revealed the data to be of generally high quality with a few exceptions. In both studies, a few errors were found in the coding and inclusion of certain subjects; when those subjects were included in the analyses, they did not materially change the results as originally reported. Because the air quality data used in the ACS Study could not be audited, a separate air quality database was constructed for the sensitivity analyses described in Part II.
- The Reanalysis Team was able to replicate the original results in both studies using the same data and statistical methods as used by the Original Investigators. The Reanalysis Team confirmed the original point estimates: For the Six Cities Study, they reported the relative risk of mortality from all causes associated with an increase in fine particles of 18.6 $\mu g/m^3$ as 1.28, close to the 1.26 reported by the Original Investigators. For the ACS Study, the relative risk of mortality from all causes associated with an increase in fine particles of 24.5 $\mu g/m^3$ was 1.18 in the reanalysis, close to the 1.17 reported by the Original Investigators.

PART II: SENSITIVITY ANALYSES

Once the original results of the studies had been validated, the Reanalysis Team sought to test an array of different models and variables to determine whether the original results would remain robust to different analytic assumptions.

- First, the Reanalysis Team used the standard Cox model used by the Original Investigators and included variables in the model for which data were available from both original studies but had not been used in the published analyses (eg, physical activity, lung function, marital status). The Reanalysis Team also designed models to include interactions between variables. None of these alternative models produced results that materially altered the original findings.
- Next, for both the Six Cities and ACS Studies, the Reanalysis Team sought to test the possible effects of fine particles and sulfate on a range of potentially susceptible subgroups of the population. Although different subgroups did show some variation in their estimated effects, the results were not statistically significant with one exception. The estimated effects of fine particles did appear to vary with educational level; the association between an increase in fine particles and mortality tended to be higher for individuals without a high school education than for those who had completed high school or for those with more than a high school education.
- In the ACS study, the Reanalysis Team tested whether the relationship between ambient concentrations and mortality was linear. They found some indications of both linear and nonlinear relationships, depending upon the analytic technique used, suggesting that the

issue of concentration-response relationships deserves additional analysis.

- In the Six Cities Study where data were available, the Reanalysis Team tested whether effect estimates changed when certain key risk factors (smoking, body mass index, and air pollution) were allowed to vary over time. One of the criticisms of both original studies has been that neither analyzed the effects of change in pollutant levels over time. In general, the reanalysis results did not change when smoking and body mass index were allowed to vary over time. The Reanalysis Team did find for the Six Cities Study, however, that when the general decline in fine particle levels over the monitoring period was included as a time-dependent variable, the association between fine particles and all-cause mortality dropped substantially, but the effect continued to be positive and statistically significant.
- Using its own air quality dataset constructed from historical data to test the validity of the original ACS air quality data, the Reanalysis Team found essentially the same results.
- Any future analyses using the sulfate data should take into account the impact of artifactual sulfate. Sulfate levels with and without adjustment differed by about 10% for the Six Cities Study. Both the original ACS Study air quality data and the newly constructed dataset contained sulfate levels inflated by approximately 50% due to artifactual sulfate. For the Six Cities Study, the relative risks of mortality were essentially unchanged with adjusted or unadjusted sulfate. For the ACS Study, adjusting for artifactual sulfate resulted in slightly higher relative risks of mortality from all causes and cardiopulmonary disease compared with unadjusted data. The relative risk of mortality from lung cancer was lower after the data had been adjusted.
- Because of the limited statistical power to conduct most sensitivity analyses for the Six Cities Study, the Reanalysis Team conducted the majority of its sensitivity analyses using only the ACS Study dataset with 154 cities. In that dataset, when a range of city-level (ecologic) variables (eg, population change, measures of income, maximum temperature, number of hospital beds, water hardness) were included in the analyses, the results generally did not change. Two exceptions were that associations for both fine particles and sulfate were reduced when city-level measures of population change or sulfur dioxide were included in the model.
- A major contribution of the Reanalysis Project is the recognition that both pollutant variables and mortality appear to be spatially correlated in the ACS Study dataset. If not identified and modeled correctly, spatial correlation could cause substantial errors in both the regression coefficients and their standard errors. The Reanalysis Team identified several methods for dealing with this, all of which resulted in some reduction in the estimated regression coefficients. The full implications and interpretations of spatial correlations in these analyses have not been resolved and appear to be an important subject for future research.
- When the Reanalysis Team sought to take into account both the underlying variation from city to city (random effects) and the spatial correlation between cities, only sulfur dioxide as a city-level variable continued to decrease the originally reported associations between mortality and fine particles or sulfate. This effect was more pronounced for sulfate.
- When the Reanalysis Team conducted spatial analyses of sulfur dioxide, the association between sulfur dioxide and mortality persisted after adjusting for sulfate, fine particles, and other variables.
- As a result of these extensive analyses, the Reanalysis Team was able to explain much of the variation between cities, but some unexplained city-to-city variation remained.

CONCLUSIONS

The Reanalysis Team designed and implemented an extensive and sophisticated series of analyses that included a set of new variables, all the gaseous copollutants, and the first attempts to apply spatial analytic methods to test the validity of the data and the results from the Six Cities Study and the ACS Study. Overall, the reanalyses assured the quality of the original data, replicated

the original results, and tested those results against alternative risk models and analytic approaches without substantively altering the original findings of an association between indicators of particulate matter air pollution and mortality.

At the same time, the reanalyses did extend and challenge our understanding of the original results in several important ways.

- The Reanalysis Team identified a possible modifying effect of education on the relation between air quality and mortality in that estimated mortality effects increased in the subgroup with less than high school education.
- The use of spatial analytic methods suggested that, when the analyses controlled for correlations among cities located near one another, the associations between mortality and fine particles or sulfate remained but were diminished.
- An association between sulfur dioxide and mortality was observed and persisted when other possible confounding variables were included; furthermore, when sulfur dioxide was included in models with fine particles or sulfate, the associations between these pollutants (fine particles and sulfate) and mortality diminished.

In reviewing these results, the Special Panel of the HEI Health Review Committee identified the following factors to consider when interpreting the results from the Reanalysis Team.

- The inherent limitations of using only six cities, understood by the Original Investigators, should be taken into account when interpreting results of the Six Cities Study.
- The Reanalysis Team did not use data adjusted for artifactual sulfate for most alternative analyses. When they did use adjusted sulfate data, relative risks of mortality from all causes and cardiopulmonary disease increased. This result suggests that more analyses with adjusted sulfate might result in somewhat higher relative risks associated with sulfate.
- Findings from spatial analyses applied to the ACS Study data need to be interpreted with caution; the spatial adjustment may have overadjusted the estimated effect for regional pollutants such as fine particles and sulfate compared with the effect estimates for more local pollutants such as sulfur dioxide.
- After the Reanalysis Team completed its spatial analyses, residual spatial variation was still noticeable; this finding suggests that additional studies might further refine our understanding of the spatial patterns in both air pollution and mortality.
- No single epidemiologic study can be the basis for determining a causal relation between air pollution and mortality.

In conclusion, the Reanalysis Team interpreted their findings to suggest that increased relative risk of "mortality may be attributed to more than one component of the complex mix of ambient air pollutants in urban areas in the United States". The Review Panel concurs. In the alternative analyses of the ACS Study cohort data, the Reanalysis Team identified relatively robust associations of mortality with fine particles, sulfate, and sulfur dioxide, and they tested these associations in nearly every possible manner within the limitations of the datasets. Future investigations of these issues will enhance our understanding of the effect of combustion-source air pollutants (eg, fine particles, sulfate, and sulfur dioxide) on public health.

HEI

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August 27, 2013

Mr. Lek Kadeli
Principal Deputy Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Mr. Kadeli:

I am pleased to provide you with the response from the Health Effects Institute (HEI) to your letter of July 8, 2013, seeking HEI's advice and comment on the important questions of sharing the data underlying epidemiologic studies of air pollution and health.

As you know, HEI has a longstanding policy to make data underlying its studies available to the widest possible scientific audience. We accomplish this first by the publication of comprehensive, intensively peer-reviewed reports of all results of research we fund (not just those that investigators might select for publication in a peer-reviewed journal), and by making extensive additional details available on-line. We also endeavor, in cases where we have full ownership of and rights to data produced for our studies, to make those data widely available to other investigators, including publishing entire data sets and analytical programs on the web. While there are legitimate privacy concerns that must be addressed in making epidemiologic data with personal health and other information available to other scientific investigators, HEI has long believed that mechanisms can often be developed for doing so and it is the interest of science, and the public policy informed by such science, to find ways to do that.

It is in this spirit that we respond to your letter. We have both several general comments on the nature of the data, and observations on how data may be shared and results replicated, for the particular studies you cite which rely on the American Cancer Society Cancer Prevention Study II and Harvard Six Cities cohorts. We provide, as well, specific answers to your questions.

General Considerations on the Data

As you note in your letter, air pollution epidemiology studies normally rely on several types of data: air quality data, census-based covariate data (e.g. income levels within a zip code area where the study subject(s) reside), health event data (which in these studies are data from the National Death Index), and individual health and personal characteristics data (e.g. level of education, alcohol consumption, body mass index, and smoking behavior) which are gathered through detailed individual questionnaires and in some cases periodic health examinations. We have several general observations:

- Data sets that have been created from publicly available sources and contain no individual identifying information, such as air quality monitoring data and census-based covariate data, should be able to be made publicly available without tremendous difficulty or cost.

- Data from the National Death Index (NDI) – maintained by the Centers for Disease Control and Prevention – is generally made available to investigators upon certification on their part that they would not advertently or inadvertently release the identity or cause of death or any other identifying information of any individual. The NDI does make provisions for making its data available more broadly, but according to well-specified rules for aggregating the data and removing certain information (e.g. specific date of death), which would keep a third party from using the data to identify an individual.

- Data collected from individual subjects in a study which normally includes detailed personal, health status, and behavioral information, is critical to allowing for these studies to determine whether some other factor than air pollution (e.g. obesity or smoking behavior) may be responsible for any health effects that are observed. This data, which is normally collected through individual questionnaires and/or medical examinations, is collected with the *express commitment to the participants - from the organizations and the original investigators that collect the data - that the participants' personal information and identity will not be divulged.* Studies using this data are also subject to the Common Rule, under which investigators must apply to their respective Institutional Review Boards (IRBs) to ensure the protection of human subjects in biomedical and behavioral research.

Observations on Data Sharing and Full Replication of These Studies

The ACS and Harvard studies, at their root, attempt to determine whether persons living in higher pollution areas are more likely to have higher relative risks of premature mortality than those living in lower pollution areas, while attempting to control for a host of personal-level and community-level covariates that may also differ between the individuals and the communities. This by its nature requires knowing where the person lives, which can pose challenges for protecting the identity of an individual if s/he lives in a smaller or sparsely populated area. This challenge has been long recognized, and there are a number of protections in federal rules and scientific practice that address this (e.g. the Census Bureau will not release certain data at the block or even zip code level if they believe that would allow identification).

Since the goal should be to find ways to share data which enables full replication and sensitivity analysis of original studies, it is valuable to consider two aspects of these particular studies that have moved them towards using data at smaller spatial scales:

- First, in response to valid criticisms that the earlier versions of these studies relied only on central air quality monitoring data to estimate exposure, investigators have increasingly sought to better estimate exposure employing land use regression models and other methods that can account for the distance of a subject's home from roadways, industrial facilities, and other sources of air pollution. They have also applied increasingly finer-grained community-level covariates (e.g. at the zip code level). While in the largest locations the application of these finer-grained data would likely not allow

for identification of individual subjects, the national analyses in some of these studies include subjects from a wide range of community sizes, including smaller communities where identification could be possible.

It should be possible to produce a data set which uses techniques like land use regression to assign exposure levels to each subject in a study and to provide only that exposure value in a dataset made available to others. This would avoid the possibility of identification of an individual subject, and would allow for replication of the original results for a study that was analyzing a range of exposure across a specific metropolitan area, for example. But such a data set, absent location information for each participant, would not allow for sensitivity analyses applying different forms of exposure modeling nor full testing of the validity of the original study's exposure estimates.

- Second, as these studies have been reviewed intensively by the HEI Review Committee, the Committee has identified two potentially significant sources of uncertainty in their results: so-called "ecological confounding"[1] and "spatial autocorrelation."[2] This is detailed in the HEI Review Committee's Commentary on the most recent HEI Research Report of Extended Analyses in the American Cancer Society cohort (pp. 128-129 in Krewski 2009). To address both of these issues, one of the first steps that investigators have taken has been to use data at smaller scales, e.g. at the zip code level, which while enhancing their ability to test for these two sources of uncertainties, also poses the potential in smaller communities for individuals and their personal information to be identified.

Taken together, these characteristics – which have in general enhanced the quality and the sensitivity of the studies – increase the difficulty of providing a fully "de-identified" data set while *also* enabling a different investigator to conduct a full replication and sensitivity analysis of the original study results.

Options for Making Data Available – Answers to your Specific Questions

With these considerations in mind, we attempt to answer your specific questions below:

1) Who owns and/or holds the data necessary to replicate the relevant studies and what are the concerns, if any, associated with making such data publicly available?

The publicly available air quality and census covariate data are of course collected and owned by the government and are freely available. The air quality and census data sets created specifically by investigators for a particular study are generally the property of the investigators, but should be capable of being made available, especially in the case where they were created using public funds.

[1] Ecological confounding arises when some community-level variables, which are themselves risk factors for mortality, are also associated with air pollution levels

[2] Spatial autocorrelation is the tendency for variables to have similar values for people or areas that are geographically close, which can suggest that there are other mortality causes which are unaccounted for in the analysis, or can distort the precision of risk estimates.

As to the ownership of the detailed participant data in the ACS and Harvard Six Cities cohort studies, HEI will leave the answers to the other two recipients of your letter – Harvard University and the American Cancer Society – who created these data sets, maintain them, and would have the most current information on others who may be holding these datasets in whole or in part. Those organizations also provided study participants with express commitments that their personal identity and information would not be divulged and have the responsibility to ensure that this commitment is not compromised during any data sharing.

2) What are the technical options for making these data publicly available, taking into account any concerns about the release of confidential personal health information or other confidential data? What are the implications of these options for replicating these studies? What level of effort in terms of time and resources would be required for these options?

3) If there are no feasible options for making all of the data publicly available, how would a researcher gain access to the full set of underlying data in order to replicate these studies? Please provide any documentation you believe would be helpful in understanding this process.

We see a range of options for making such data available, in different formats and with different procedures, so we are answering the questions jointly. In our view, it is feasible to share data in one of three ways (which have been used in many instances) and to do so while protecting the privacy of the individual subjects. The options range, however, from those that offer the most detailed access to study data to those that offer significantly less access:

A. **Collaboration with original investigators to obtain full access to data in order to conduct joint analyses**

This process is the most common practice in the scientific community for sharing personal data. It normally involves either formal or informal application processes for a scientific researcher to ask the original organizations and investigators who created the data set to gain access to the data to allow for collaborative analyses of an important research question. The American Cancer Society, for example, provides explicit instructions on their website on how to collaborate with them, and many other investigators have conducted more informal collaborations of a similar type. Such collaborations have, of course, to be conducted in full compliance with the Common Rule and any federal or other requirements for protecting the privacy of the participants.

The *advantage* of this process is that it can provide investigators with the fullest access to the data sets and with the benefits of regular consultation with the original investigators whenever there are questions about data structure or content. The *disadvantages* include that the original investigators may not choose to collaborate with all who request access, and a fully independent replication and sensitivity analysis of the original studies may not be possible or broadly accepted, given the collaborative relationship.

B. **Application to obtain independent access to analytic data sets sufficient to allow for replication and sensitivity analysis of the original results**

This process involves the request by a researcher to the original investigators, or to agencies and organizations, who created the data set to gain access to the data sets underlying a particular study. This normally would involve the development of a protocol for such analysis by the researcher, the review and approval of the protocol by the submitting scientists' IRB, explicit signed commitments by the researchers that they will not disclose personal information (on pain of penalty in the case of federally owned data sets), and usually other protections (e.g. prohibition of the publication of any results presenting data for groups of fewer than a certain number of subjects, and review by the original investigators before publication to ensure that no such information is inadvertently disclosed). Such a process is currently used within the US Department of Health and Human Services.

One relevant example of such data sharing is the detailed data sharing procedures established for the Multi-Ethnic Study of Atherosclerosis (MESA) which can be viewed at https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000403.v1.p3. In addition, MESA has created several "Limited Access Data Sets" in which personal identifying information has been removed and which can be accessed more readily, but which would not allow for full replication of original studies (see https://biolincc.nhlbi.nih.gov/studies/mesa/?q=MESA).

The *advantage* to this approach is that it can provide access to a substantial portion of the relevant data and allow for fully independent replication and sensitivity analyses of the original results. The major *disadvantage* is that this approach normally does not provide access to the full data set, but rather only to the detailed analytic data set or summary tables used in specific studies, thus precluding full replication.

A similar albeit much more intensive process enabled HEI and its independent investigators to gain access to the full data which we reanalyzed from the Harvard Six Cities Study and the American Cancer Society Study (HEI 2000). This process was structured to allow intensive efforts to replicate and test the robustness and sensitivity of the originally reported results. It was undertaken with the full agreement of, but not collaboration with, the original investigators, and provided full access to the data in accordance with a specifically developed data use agreement which ensured protection of privacy. The analyses were also informed by expert advisors from industry, academia, and other stakeholders.

C. **Provision of a "de-identified" disk (or other electronic medium) to provide a more limited data set that would not under any circumstances allow for identification of individuals**

In some cases, the simplest mechanism for providing access to study data would be through the provision of a fully de-identified data set in electronic form that can be readily shared with all parties without the possibility of an individual and his or her personal characteristics to be divulged. This has the *advantage* that it may allow independent replication and sensitivity analyses of some of the results of the original investigators. The most significant *disadvantage* is that, as noted above, the most recent analyses in the ACS populations have applied increasingly finer-grained community level data analysis; the release of a fully "de-identified" dataset will not allow full replication and sensitivity analysis of these most recent results, e.g. the testing of

alternative models for estimating exposure among the study subjects, and the inability to test whether ecological confounding and spatial autocorrelation could be affecting the results.

Overall, HEI believes that the opportunity for other scientific investigators to have access to and conduct additional analyses in these epidemiologic data sets is of tremendous scientific value, and can provide additional understanding of important scientific questions that can in turn inform air quality policy decisions. As we have described, there are well-established processes for making such data available; however, not all processes provide the fullest access to the data required while still protecting the privacy of individual information that is essential to the studies.

We would be pleased to provide additional consultation on these important questions and to answer any questions you might have. Please let us know if you have further questions or need additional assistance in this effort. You may feel free to contact me or HEI Science Director Dr. Rashid Shaikh at rshaikh@healtheffects.org or (617) 488-2301 for any follow-up questions

Sincerely,

Daniel S. Greenbaum
President

cc: Dr. Rashid Shaikh
Dr. Susan Gapstur, American Cancer Society
Dr. Douglas Dockery, Harvard University

Health Effects Institute. 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality: A Special Report of the Institute's Particle Epidemiology Reanalysis Project. Health Effects Institute, Cambridge MA.

Krewski D, Jerrett M, Burnett RT, Ma R, Hughes E, Shi Y, Turner MC, Pope CA III, Thurston G, Calle EE, Thun MJ. 2009. Extended Follow-Up and Spatial Analysis of the American Cancer Society Study Linking Particulate Air Pollution and Mortality. HEI Research Report 140. Health Effects Institute, Boston, MA.

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/29/2018 12:33:15 PM
To: Lowit, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d3428a2c0b84d5099124a0460babd53-Anna B. Lowit]
CC: Anand Mudambi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a94638932b49af8a6cf581262d5059-Mudambi, Anand]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Pope, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41baa5adcd7045d3872762b9cae6478f-Pope, Danielle]; Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]
Subject: RE: FYI

Great question. I haven't thought about this and will get back to you. It can't hurt to register.

From: Lowit, Anna
Sent: Friday, May 25, 2018 3:05 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: FW: FYI

Hey Tom

Quick question…. To attend in person to listen to the comments, do we need to register?

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: + Personal Matters / Ex. 6

From: Vogel, Dana
Sent: Thursday, May 24, 2018 3:41 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: FW: FYI

From: Sinks, Tom
Sent: Thursday, May 24, 2018 3:40 PM
To: Burden, Susan <Burden.Susan@epa.gov>; STPC_SSP <STPC_SSP@epa.gov>
Subject: FYI

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

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WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/24/2018 7:27:02 PM
To: Evalenko, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd595e1baa9640a296313941e77ebdf0-SEvalenk]; Watkins, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5af4e987140b40e5bf3d1cb8cc09b97a-Watkins, Stephen]
CC: Lousberg, Macara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e589fdabe6374c5987d0184b43fb5c57-MLousber]
Subject: RE: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule

Thanks – we placed it into the docket when we got it. I also sent Katie Foreman the following information today ….

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

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While we have taken steps to ensure the accuracy of this internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

From: Evalenko, Sandy
Sent: Thursday, May 24, 2018 3:13 PM
To: Watkins, Stephen <watkins.stephen@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Lousberg, Macara <Lousberg.Macara@epa.gov>
Subject: FYI: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule

Stephen and Tom: Dave Ross, OW AA, was copied on this public comment from several of OW's stakeholders. I would have sent this to the docket but it looks like it would have been a duplicate.

Heads-up: OW has three workgroup members on this action Transparency in Science. Our DAA is interested in the public comments submitted on the action.

Sandy

Sandy Evalenko
Water Policy Staff
Office of Water (4101M)
3226K WJC East
(202) 564-0264 telephone

From: Julia Anastasio [mailto:janastasio@acwa-us.org]
Sent: Wednesday, May 23, 2018 12:03 PM
To: Campbell, Ann <Campbell.Ann@epa.gov>
Subject: Fwd: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule

FYI. This letter was just sent to Dave as a cc.

Sent from my iPhone

Begin forwarded message:

> **From:** Katie Foreman <kforeman@acwa-us.org>
> **Date:** May 23, 2018 at 11:44:13 AM EDT
> **To:** "staff_osa@epa.gov" <staff_osa@epa.gov>, "Sinks.tom@Epa.gov" <Sinks.tom@Epa.gov>
> **Cc:** Julia Anastasio <janastasio@acwa-us.org>, "chanson@ecos.org" <chanson@ecos.org>, "ssankar@ecos.org" <ssankar@ecos.org>, "jsloan@csg.org" <jsloan@csg.org>, "daniar@astswmo.org" <daniar@astswmo.org>, "ASchaefer@NGA.ORG" <ASchaefer@NGA.ORG>, "aroberson@asdwa.org" <aroberson@asdwa.org>, "ross.davidp@epa.gov" <ross.davidp@epa.gov>
> **Subject: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule**
>
> Good Afternoon,

Please see the attached letter outlining a comment deadline extension request for the Strengthening Transparency in Regulatory Science Proposed Rule from seven associations, on behalf of the states. Should you have questions regarding this request, please feel free to contact Julia Anastasio (janastasio@acwa-us.org, 202-756-0600).

Thank you,

Katie Foreman
Environmental Program Associate
Association of Clean Water Administrators
1634 I Street NW, Suite 750
Washington, DC 20006
kforeman@acwa-us.org

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/24/2018 3:35:33 PM
To: Carpenter, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c286cf1692fa46dc9636a7c49c0925b8-Carpenter, Thomas]
Subject: FW: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

FYI

From: EPA Press Office [mailto:press=epa.gov@cmail20.com] **On Behalf Of** EPA Press Office
Sent: Thursday, May 24, 2018 8:00 AM
To: Kuhn, Kevin <Kuhn.Kevin@epa.gov>
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

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While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

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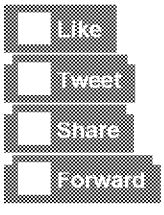


U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/17/2018 5:58:38 PM
To: Grifo, Francesca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c4870bfab004fa0ac47bc8659d9903b-Grifo, Fran]; Otto, Martha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bb74ccb24aa444097dc5a63b976269b-Otto, Martha]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; D'Arcy, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0344e54c7b1648bfa5672c497b4fddf8-D'Arcy, Dan]
Subject: FW: EPA Research News Clips 4/16/2018

From: McGuinness, Moira
Sent: Monday, April 16, 2018 4:21 PM
Subject: EPA Research News Clips 4/16/2018

EPA General/ Administrator Pruitt

OIRA Working With EPA To Develop 'Best Practices' On Scientific Data Inside EPA

White House regulatory chief Neomi Rao says her staff is working with EPA on developing a policy on the use of scientific data that underlies its rules, suggesting that the agency may take a softer approach than Administrator Scott Pruitt had signaled when he said he would require the agency to rely only on publicly available data to justify its rules.

During an April 12 hearing before the Senate subcommittee on regulatory affairs and federal management, Rao said under questioning from Sen. Maggie Hassan (D-NH) that EPA was seeking to find a "balance" between using the "best available" data and publicly available data.

Hassan pressed Rao on whether federal agencies should use the best available science to make decisions regardless of whether that information is available to the public as Pruitt has suggested.

"Questions on information quality are very important to us. That is something my staff has been working with EPA on to develop best practices in that area," Rao said after Hassan asked whether the White House Office of Information and Regulatory Affairs (OIRA) has provided any input to Pruitt on his proposal.

Hassan asked Rao whether Pruitt's policy as described makes sense. "We want to make sure we have the best available evidence," Rao replied. "It's also important for the public to have notice and information about the types of studies that are being used . . . by agencies for decisionmaking. There is a balance to be struck there, and I think that is something that the EPA is working towards."

Rao's characterization of the issue appears to offer an eased approach to the data transparency policy that Pruitt floated last month, when he said he planned to require the agency to justify its regulations based on scientific data that is publicly available on the internet.

"We need to make sure their data and methodology are published as part of the record," Pruitt said. "Otherwise, it's not transparent. It's not objectively measured, and that's important."

He said the policy will mirror legislation offered by Rep. Lamar Smith (R-TX), chairman of the House science committee. It directs the agency to use the "best available science" in all its actions, but bars the agency from using any studies that cannot be released publicly online "in a manner that is sufficient for independent analysis and substantial reproduction of research results."

But the planned approach drew widespread criticisms, with many environmentalists and Democrats warning it would undermine development of many regulations.

Many observers also charged that such a policy would face legal and implementation controversies, including potential violations of medical privacy protections, trade secret information and other data that form the basis for air quality standards, pesticide and chemical approvals and other rules.

One knowledgeable source said late last month that an early version of the policy had been drafted several weeks earlier, though the first draft was "pretty sketchy. The first cut was fully [Smith's bill], but there were a lot of questions about what it would mean," and how it would be implemented.

Maintain Procedures

Since Pruitt's public discussion of the issue, EPA has yet to publicly release any version of the policy.

But Rao indicated that her staff was working with the issue as the agency sought to find a "balance" between using the "best" data and data that is publicly available.

And in response to Hassan, Rao said she would not support agencies changing their procedures in ways that prevent them from using the best available evidence when making these decisions.

"I'm very glad to hear that," Hassan replied. "One of the reasons I am very concerned about the EPA proposal, it seems like common sense to use the best evidence to make decisions. But what we are looking at is the agency really describing a move away from the scientific process. There isn't perfect data or perfect science. Scientific evaluation and data and analysis is an ongoing process." -- *Maria Hegstad* (mhegstad@iwpnews.com)

As Scientists March, Federal Researchers Weather Trump Storm WIRED

Scott Pruitt Isn't Anti-Science National Review

FOIA WHAT IT'S WORTH: Politico's Morning Energy

The Center for Public Integrity says it has filed a lawsuit Friday against EPA, seeking public records after the agency failed to respond in a timely fashion to 25 Freedom of Information Act requests filed in 2017 and early 2018. The complaint says EPA's online system "does not list realistic estimated dates of completion for FOIA requests it receives and does not update estimated dates of completion after the listed dates have passed." The Center says EPA did not respond to requests for an updated schedule.

Center for Public Integrity sues EPA over public-records delays - Center for Public Integrity

EPA: Watchdog group calls for investigation of IG E&E News PM

Citizens for Responsibility and Ethics in Washington has requested a review of the EPA inspector general's head of investigations.

The ethics watchdog group today sent a **letter** to the Council of the Inspectors General on Integrity and Efficiency requesting its Integrity Committee "investigate whether EPA Assistant Inspector General for Investigations Patrick Sullivan engaged in conduct that undermined his independence or integrity."

The council, or CIGIE, is part of the executive branch and oversees IGs across the federal government.

One of its duties is to review complaints against the agencies' internal watchdogs, which are adjudicated by its Integrity Committee. Labor Department Inspector General Scott Dahl and Deborah Jeffrey, the Corporation for National and Community Service's inspector general, are the panel's members.

CREW's letter comes after a *New York Times* **report** yesterday that Sullivan is considered close with Pasquale "Nino" Perrotta, chief of Administrator Scott Pruitt's security team. Perrotta has emerged as a central figure in some of the ethics allegations surrounding Pruitt, specifically the purchase of potentially unwarranted security measures for the EPA chief.

The EPA IG has an open audit of agency spending on Pruitt's personal security, which is expected to be released this summer. IG spokesman Jeff Lagda would neither confirm nor deny the existence of an investigation into Perrotta.

Sullivan and Perrotta both served in the Secret Service before coming to EPA, and Perrotta first worked in the IG office before heading elsewhere in the agency. They have been spotted drinking together across the street from EPA headquarters in Washington, D.C., according to the *Times'* story.

"It appears that the information set forth in the Times article merits review by the Integrity Committee as conduct that may undermine the independence or integrity reasonably expected of Mr. Sullivan, and so critically important investigation or investigations currently being undertaken by the EPA Inspector General," said the letter, which was signed by CREW Executive Director Noah Bookbinder and Norm Eisen, CREW's board chairman.

Lagda disputed the reporting in the *Times*' story.

He said Sullivan never worked with Perrotta in the past and didn't know him until Sullivan came to the IG office in 2011.

"They have worked together since 2011 on issues related to their official duties, such as threat investigations. They are professional colleagues and friendly, but do not socialize out of work," Lagda said.

The IG spokesman said Sullivan has never had drinks with Perrotta "anywhere or at any time" and has never been to the Elephant and Castle with Perrotta — the bar where the *Times* said Sullivan was seen with Pruitt's security chief.

Lagda said, "The OIG welcomes a CIGIE IC review regarding CREW's concerns."

Watchdog requests probe into relationship between top EPA aide and man investigating him The Hill

Ethics and the EPA: How one government office helped turn up the heat on Scott Pruitt The Washington Post

Democrats ask EPA's Pruitt for details on weapons, security buys - Reuters

GAO finds Pruitt phone booth violated spending laws Inside EPA

The first in a series of expected watchdog reports into EPA Administrator Scott Pruitt's spending and ethics practices has found that the administrator's installation of $43,000 sound-proof privacy booth in his office violated several legislative requirements, ensuring continued criticism and scrutiny.

In an April 16 decision, the Government Accountability Office (GAO) says installation of the booth broke a fiscal year 2017 spending law that required advance notification of major upgrades to offices for presidential appointees.

Further, GAO says that "because EPA obligated appropriated funds in a manner specifically prohibited by law, we conclude that EPA violated the Antideficiency Act," which prohibits agencies from spending money in excess of appropriations.

The sound-proof booth has been one issue in a raft of ongoing allegations about Pruitt's spending and ethics problems, with critics citing it as an example of the administrator's willingness to flout spending constraints to address what he sees as pressing security challenges.

Even some Republicans, like Rep. Trey Gowdy (R-SC), have charged that some of Pruitt's explanations are not "credible."

GAO inquired into the issue at the request of Sens. Tom Carper (D-DE) and Tom Udall (D-NM), as well as Reps. Peter DeFazio (D-OR) and Betty McCollum (D-MN).

Udall, the ranking Democrat on the Senate appropriations panel that oversees EPA, last month urged the agency to cooperate with GAO's inquiry, charging that the agency had not provided any information to the watchdog office even though it sought responses to a series of questions by late January.

In its report, GAO says the booth and related installation cost $43,238, which included $24,500 for the booth itself, $3,400 for concrete floor leveling, $3,350 for wall preparation and painting, $7,900 for removal of closed caption TV equipment and $500 for cables and wires.

It cites an agency explanation for the booth as allowing Pruitt "to make and receive phone calls to discuss sensitive information," while also allowing him to "make and receive classified telephone calls (up to the top secret level) for the purpose of conducting agency business."

But GAO says the expenditure violates section 710 of the FY17 appropriations law, which requires agencies to notify the House and Senate when spending more than $5,000 to furnish or redecorate an office of an agency head that has been appointed by the president.

While EPA argued the spending law provision did not apply because the booth was to be used to advance the agency's mission, GAO found the expense falls "squarely" within the statutory definition of "furnish."

Because the expense contradicted the FY17 law, GAO says the funds were not "legally available" and thus EPA also violated the Antideficiency Act and must report the violation.

"We draw no conclusions regarding whether the installation of the privacy booth was the only, or the best, way for EPA to provide a secure telephone line for the Administrator," GAO writes.

EPA: Agency's handling of Pruitt phone booth broke law — GAO

This story was updated at 1:55 p.m. EDT.

The Government Accountability Office said today that EPA violated federal law by failing to tell lawmakers when it installed a secure phone booth in Administrator Scott Pruitt's office.

The deal cost EPA about $43,000, including a nearly $25,000 **contract** with a specialty acoustics company for the soundproof booth's purchase, delivery and assembly.

In an eight-page **decision**, the congressional watchdog concluded that EPA breached appropriations law — specifically the governmentwide $5,000 spending cap on office redecoration for political appointees — by not giving advance notice to Congress' appropriations committees. In addition, GAO found that since EPA spent its appropriated funds in a way banned by the law, it also broke the Antideficiency Act and needs to report its violation to Congress and the president.

The GAO decision quotes often from an EPA March 23 **letter** by Kevin Minoli, the agency's principal deputy general counsel, that pushes back on its ruling.

EPA argued Pruitt's phone booth "serves a functional purpose" by allowing the administrator to carry out agency business and compared it to other office supplies, like high-speed copiers or computers. Thus, the booth was a practical addition to the administrator's office and did not violate the specific appropriations law provision since it was not "an aesthetic improvement" contemplated by that measure, according to the agency.

GAO disagreed with EPA's interpretation of the law. The agency will be sending the required information to lawmakers this week related to Pruitt's phone booth.

"The GAO letter 'recognized the … need for employees to have access to a secure telephone line' when handling sensitive information. EPA is addressing GAO's concern, with regard to congressional notification about this expense and will be sending Congress the necessary information this week," EPA spokeswoman Liz Bowman said.

Without advance notice to lawmakers, EPA obligated $43,239 from its fiscal 2017 environmental programs and management account to install the soundproof privacy booth in Pruitt's office, according to the GAO decision. Along with the $24,570 contract for the actual booth, that sum included $7,978 to remove closed-circuit television cameras, $3,470 for concrete floor leveling, $3,360.97 to install a drop ceiling, $3,350 for patchwork and painting, and $509.71 for cabling and wiring.

EPA told GAO the booth is located in a former storage closet in Pruitt's office.

The agency also said that under its guidelines, a classified phone cannot be put on an office desk or in a conference room. In Minoli's letter, EPA told GAO that the booth "not only enables the Administrator to make and receive phone calls to discuss sensitive information, but it also enables him to use this area to make and receive classified telephone calls (up to the top secret level) for the purpose of conducting agency business."

In a congressional hearing last December, Pruitt described the booth as "a secure phone line" that he uses for sensitive talks, including with the White House (***E&E News PM***, Dec. 7, 2017).

But GAO noted the agency didn't say whether the booth was certified as a sensitive compartmented information facility, or SCIF. Former EPA officials told E&E News that the agency already has a SCIF in the basement of its Washington headquarters, which sees little use given the agency doesn't deal often with classified information (***Greenwire***, Sept. 27, 2017).

GAO stressed it was not ruling on whether Pruitt's phone booth itself broke the law, rather that EPA's failure to notify Congress about its spending above the $5,000 limit was the breach.

"GAO recognizes the requirement to protect classified material and draws no conclusions regarding whether the installation of the privacy booth was the only, or the best way for EPA to provide a secure telephone line for the Administrator. EPA's failure to comply with a governmentwide statutory requirement that an agency notify the appropriations committees before it spends more than $5,000 for the office of a Presidential appointee is the only legal issue addressed in this opinion," said Julie Matta, GAO's managing associate general counsel, in a statement.

'An illegal privacy booth'

Democrats on Capitol Hill had requested the legal opinion from GAO on Pruitt's phone. They blasted the EPA chief after the decision was released today.

"Scott Pruitt likes to talk about returning the EPA to the rule of law, but it turns out he's better at breaking it than following it. ... An illegal privacy booth to conduct secret discussions with his polluter friends does nothing to help our health or environment," said Sen. Tom Udall (D-N.M.), ranking member on the Senate Appropriations subcommittee that oversees EPA.

Statements from environmental groups also poured in, with several calling on Pruitt to leave the agency.

"With each passing day, Pruitt has created more headaches for Donald Trump with his mounting list of ethical and now legal violations. Donald Trump shouldn't wait to see what ethical norm or law Pruitt breaks next. He must fire him immediately," said Sierra Club Executive Director Michael Brune.

Republicans also expressed concerns in response to the GAO ruling released today. Senate Environment and Public Works Chairman John Barrasso (R-Wyo.) said EPA needs to make "a full public accounting" of its spending on Pruitt's phone booth.

"It is critical that EPA and all federal agencies comply with notification requirements to Congress before spending taxpayer dollars. EPA must give a full public accounting of this expenditure and explain why the agency thinks it was complying with the law," Barrasso said.

EPA in the past has run up against GAO legal opinions.

In December 2015, the congressional watchdog found that the agency had violated federal restrictions on lobbying and propaganda in its social media campaign on behalf of the Waters of the U.S. rule (***E&E News PM***, Dec. 14, 2015). Pruitt has since sought to roll back that regulation at the agency.

COMING TODAY - IG REPORT ON PRUITT HIRING: Politico's Morning Energy

Amid new and ongoing investigations into EPA Administrator Scott Pruitt, the agency's inspector general will shed some new light on his unorthodox hiring practices. The internal watchdog is releasing an interim report today on Pruitt's decision to hire several political aides using special authority he has under the Safe Drinking Water Act - part of a probe that began before recent reports that the administrator had relied on that same provision to get big raises for two top aides despite objections from the White House. (Pruitt has denied those reports and said the raises have been reversed.)

More than a dozen political appointees at EPA have been hired under the SDWA authority, which allowed them to avoid being subject to typical federal hiring restrictions or the Trump administration's ethics pledge, Pro's Alex Guillén reports . Among those hires: Nancy Beck, a former expert for the American Chemistry Council who is the new deputy assistant administrator in EPA's chemical office, and Lee Forsgren, the deputy in EPA's water office, and several public affairs staffers. Beck, for one, has made a number of controversial changes relating to implementation of the Toxic Substances Control Act. The agency's senior ethics counsel told POLITICO last summer that she did not need an ethics recusal to do so, even though she had been heavily involved with the issue in her previous job.

The IG audit began in January, and while the scope of today's report remains unclear, it could include urgent information the IG thinks Pruitt needs to know about before the audit is completely finished. Whether the IG has expanded that existing probe to include Pruitt's recent controversy is also unclear.

EPA watchdog to release report Monday on Pruitt hiring controversy Washington Examiner

GOWDY TO PRUITT: BECOME A MONK? Politico's Morning Energy

Two days after expanding his probe into Pruitt's travel and security costs, House Oversight Committee Trey Gowdy offered the EPA administrator some advice in a "Fox News Sunday" appearance. "The notion that I've got to fly first class because I don't want people to be mean to me, you need to go into another line of work if you don't want people to be mean to you," the South Carolina Republican said. "Like maybe a monk, where you don't come in contact with anyone." Gowdy said Pruitt's fate rested with President Donald Trump - "I don't know how much trouble he's in" - but defended his expanding probe into the embattled EPA chief.

Ewire: Gowdy says Pruitt travel explanation not 'credible' Inside EPA

The Republican chairman of the House oversight committee says Scott Pruitt's explanation for why he needed to fly first class does not appear not "credible," arguing that the EPA administrator did not need the pricey tickets to avoid unpleasant interactions with fellow passengers over security concerns.

"I'd be shocked if that many people knew who Scott Pruitt was," Rep. Trey Gowdy (R-SC) told Fox News Sunday. "So the notion that I've got to fly first class because I don't want people to be mean to me -- you need to go into another line of work if you don't want people to be mean to you. Like maybe a monk, where you don't come in contact with anyone."

Gowdy late last week sent a letter to Pruitt demanding interviews with five close EPA aides, according to the Associated Press. The oversight chairman is also seeking a raft of documents related to Pruitt's travel spending and "unprecedented" security measures.

The letter seeks interviews with Pruitt security chief Pasquale "Nino" Perrotta -- who has emerged as a central figure in many of the swirling headlines about Pruitt's alleged ethical lapses -- as well as agency Chief of Staff Ryan Jackson.

Gowdy also hopes to interview former agency political aide Kevin Chmielewski -- who confirmed many details of news reports about the ethics scandals in a prior interview with Democratic lawmakers -- and two Pruitt aides who worked with him when he was attorney general of Oklahoma, and who are the subject of a separate investigation into whether Pruitt bypassed the White House to give them hefty pay raises.

If nothing else, the latest developments in the lawmaker's ongoing investigation continues to keep Pruitt's ethical troubles in the news, despite President Donald Trump's stated support for the agency chief.

In addition, it comes as EPA's inspector general (IG) is slated to release an "interim" report today that will look at Pruitt's use of the Safe Drinking Water Act to fill "administratively designated" positions.

Pruitt reportedly used that provision in the law to give the controversial raises to the two aides identified in Gowdy's letter, though it is not clear whether the forthcoming IG report will address that issue or more broadly address Pruitt's use of the drinking water law's hiring provisions.

Gowdy sent Pruitt a letter Friday, Politico's Morning Energy
...demanding additional documents and interviews with several of his top aides. He asked Pruitt to provide documentation related to his round-the-clock security protection, contracts to sweep Pruitt's office for electronic surveillance, his trips to Italy and Morocco, the hiring of an Italian security firm, and travel by Pasquale "Nino" Perrotta. The oversight committee chairman also demanded interviews with five of Pruitt's aides: chief of staff Ryan Jackson; Perrotta, the head of Pruitt's security detail; Kevin Chmielewski, a former Trump campaign aide who was Pruitt's deputy chief of staff; senior legal counsel Sarah Greenwalt and scheduling director Millan Hupp, both of whom received significant raises under the SWDA. Gowdy's letter arrived one day after his staff met for several hours with Chmielewski, who is being treated as a whistle blower.

Former EPA political aide who clashed with Pruitt faces ethics charge Inside EPA
A former top EPA political appointee who has recently spoken out on Administrator Scott Pruitt's ethics and spending scandals is himself facing accusations that he violated ethics laws, with the possibility of a criminal indictment if the charges prove true.

ProPublica reports that Kevin Chmielewski, Pruitt's former deputy chief of staff for operations, never filed a financial disclosure form that would have identified potential conflicts of interest in his work at EPA.

"EPA officials say Chmielewski has not been granted any extensions, and he's still obligated to provide a financial disclosure even though he has left the agency," says the article, which notes that in the past officials have been criminally charged for failure to file a report as required by the Ethics in Government Act.

Previous violations of the law have led to four-figure fines, but Chmielewski could face a stiffer penalty because he never filed a disclosure at all. *ProPublica* reports that the prior officials failed to file a final report upon leaving their government posts, and calls an official neglecting to fill out the initial report "unprecedented."

Chmielewski recently spoke to Democratic lawmakers about Pruitt's spending and alleged unethical conduct, providing details that formed the basis for an April 12 letter to President Donald Trump calling for Pruitt's ouster.

That letter cites Pruitt's effort to "marginalize" his chief of staff, Ryan Jackson, in favor of a pair of close aides who worked with Pruitt in Oklahoma. Both aides are themselves subjects of an investigation over claims that Pruitt gave them significant raises despite the White House denying his request, using Safe Drinking Water Act authority for emergency personnel moves.

"[I]f you speak with knowledgeable parties like Mr. Chmielewski and examine relevant documents, it will become clear that the right course of action in this case is to hold Administrator Pruitt accountable for his serious ethical lapses and to restore honest, competent leadership to EPA so that this important agency may fulfill its critical mission," the letter says.

But if Chmielewski becomes embroiled in his own ethics scandal, it could become more difficult for Pruitt opponents to use him as a centerpiece of their claims against the administrator.

YOU DON'T GOT A FRIEND IN ME: Politico's Morning Energy
Patrick Sullivan, the assistant IG in charge of investigations at EPA, is disputing a New York Times report that says he is friends with the head of Pruitt's protective detail, according to a spokeswoman for the internal watchdog. The Times report became the basis Friday of a request from the watchdog group Citizens for Responsibility and Ethics for an investigation from a council of federal inspectors general. But Sullivan disputed claims that he had drinks with Perrotta, "anywhere or at any time," IG spokeswoman Tia Elbaum said in an email Friday. A Times spokesperson said the paper stands by its story. Alex has more here.

EPA'S KELLY ADDRESSES BANKING BAN: Politico's Morning Energy
Albert Kelly, Pruitt's senior adviser on Superfund issues - who joined the agency after agreeing to be banned from working in the banking industry - recently spoke to The Montana Standard and addressed the Federal Deposit Insurance Corp. controversy for the first time. Kelly's bank, SpiritBank of Tulsa, made several loans to Pruitt, which he addressed. "There are no questionable loans by my bank to the administrator. If you go back and look at any loans to the administrator, without going into his privacy, they were very solid," Kelly said. "They were done in a very positive way and were paid off."

His problem with the FDIC, he said, involved a particular transaction in 2010. "They didn't like it," Kelly said, dodging on the root cause of his ban. "The bank didn't lose any money. The bank made money. There was nothing untoward about it." The former banker also told the Standard Pruitt is still planning on visiting Butte, Mont. in August. More here.

How Conservative Activists Saved Scott Pruitt's Job—for Now Bloomberg Environment & Energy Report
During the first week of April, as scandals piled on top of Environmental Protection Agency Administrator Scott Pruitt, it looked like his job was in jeopardy.

A handful of lawmakers, including two Republicans, called for him to resign after reports surfaced that he'd rented a Capitol Hill condo on unusually agreeable terms from the wife of a prominent energy lobbyist with business before the

EPA. Top administration officials distanced themselves from Pruitt as the White House launched a review of his actions, and Chief of Staff John Kelly told President Trump it was time for the EPA chief to go.

Pruitt was already controversial.

The former Oklahoma attorney general, who made a name for himself suing the agency he now runs, had drawn fire for his enlarged security detail, his habit of flying first class, and the $43,000 installation of a soundproof booth in his office, not to mention his disregard for climate science.

But this time it felt like a line had been crossed, especially as damaging revelations kept coming, seemingly every hour. Reports surfaced of staff being reassigned or demoted for challenging him and of Pruitt using an obscure law to give two close aides hefty raises over White House objections.

#StandWithScottPruitt

When the EPA's general counsel walked back his initial assessment that the rental deal didn't violate federal ethics laws, Pruitt looked like a goner.

What happened next is a testament to the EPA administrator's ties to the business community and how crucial he is to the conservative antiregulation agenda. By the evening of April 5, an aggressive advocacy campaign to save his job had kicked into gear as activists, business executives, and Republican politicians came to his defense.

The campaign went public when FreedomWorks, a powerful right-wing advocacy group, blasted out a call for help to its online community of 5.7 million conservatives, including on Facebook, Twitter, and by email, reminding them of Pruitt's record on rolling back regulations and asking them to call the White House and Congress to support him. The group also promoted a #StandWithScottPruitt hashtag on social media, highlighting it in multiple tweets, including one asserting that he was the victim of a "smear campaign" by the "radical left."

Among those responding was Dallas investor Doug Deason, whose family has given millions to right-wing candidates. He texted and emailed contacts at the White House to make clear he wanted Pruitt to stay. As reports surfaced that Trump's chief of staff had suggested the EPA chief needed to go, Deason got angry. "If that's true, I think Kelly needs to go because he has no spine," he says. "We need to get on the offense."

Back in Washington, conservative leaders including Myron Ebell of the Competitive Enterprise Institute and Tom Pyle of the American Energy Alliance scrambled to find ways to show support, resulting in an open letter from dozens of Republicans hailing Pruitt's work.

'A Conservative Hero'

Soon, what started as an email effort morphed into a full-throated #SaveScott campaign, with prominent Republicans and leaders of the Tea Party movement such as Steve Forbes and Kentucky Sen. Rand Paul penning op-eds, posting on Twitter, and picking up the phone to lobby the president against firing the man they see as a champion of deregulation and for whose confirmation they fought.

"He's a conservative hero," Deason says. "We burned a lot of chits to get him into that position." They couldn't afford to lose him now.

By the end of the week, Trump had heard from billionaire Oklahoma oilman Harold Hamm and confidant Chris Ruddy, chief executive officer of Newsmax Media Inc., voicing their support. By the night of April 7 it looked like Pruitt was safe when Trump tweeted that, despite the issues surrounding the security detail and rental agreement, "Scott is doing a great job!"

One factor working in Pruitt's favor is that Trump is unlikely to get anyone like him through the confirmation process again. Senate Republicans warned it would be tough—if not impossible—to confirm a replacement.

Given three bruising confirmation battles expected for the president's picks to lead the CIA, the Department of Veterans Affairs, and the State Department, there isn't much appetite for a fourth.

Trump "will be forced to nominate someone who is more moderate on the environment, or he will get tattooed in the Senate," says Dan Eberhart, CEO of Canary LLC, a Colorado-based drilling-services company, and a major GOP donor.

Deregulation Star

Pruitt has emerged as the deregulation star of Trump's cabinet, methodically dismantling rules meant to protect the environment. He's proposed scrapping President Obama's signature plan to cut carbon emissions, is rewriting a water pollution rule, and has quashed an effort to put new limits on methane leaks from oil wells.

"Pruitt is the most conservative member of the cabinet, both in temperament and action," says Republican strategist Mike McKenna. "He's also the guy who has done the most for the president's agenda."

His support among Senate Republicans isn't absolute. In a series of interviews, some voiced concerns over his spending habits and the potential blowback. "He needs to stop leading with his chin," says Republican Sen. John Kennedy of Louisiana. "This is taxpayer money he is spending, and he needs to treat it like the precious commodity it is. I can support his policies without supporting his behavior."

Environmental groups are stepping up opposition research and a "boot Pruitt" campaign on Twitter.

The Sierra Club broadcast a critical ad on Fox News Channel's Fox & Friends, which the president watches faithfully. The Sierra Club has received funding from Bloomberg Philanthropies, the charitable organization founded by Michael Bloomberg, the ultimate owner of Bloomberg Environment.

Activists are scouring Pruitt's real estate transactions, records from his tenure as Oklahoma's attorney general, and documentation of his travel for any tantalizing detail.

"The environmental movement in total is all in for the removal of Scott Pruitt," says Lukas Ross, a campaigner with the group Friends of the Earth. "You are going to see escalating pressure in the coming days, especially on the Senate side, to get members to commit publicly that Pruitt should be fired."

The government's top ethics official, David Apol, is urging the EPA to investigate Pruitt.

Series of Investigations

At least four probes are under way, and the agency's inspector general's office has been asked to open other investigations into his condo agreement.

Another conflict may relate to the man behind some of Pruitt's most controversial security upgrades, including biometric locks in his office and his round-the-clock bodyguards. Pasquale "Nino" Perrotta is a former Secret Service agent who got the job protecting the administrator last year after the previous security head questioned some decisions and was reassigned, according to a person familiar with the change.

At issue is an EPA security move that may have enriched one of Perrotta's business partners, Edwin Steinmetz, the vice president for technical surveillance countermeasures at Perrotta's Maryland-based company, Sequoia Security Group Inc. Perrotta is the company's principal, and the EPA's $3,000 contract to search for bugs in Pruitt's office was awarded to Edwin Steinmetz Associates LLC. Perrotta didn't respond to messages seeking comment.

Perrotta played a key role in the agency's decision to guard Pruitt 24 hours a day, a major shift from the typical approach giving administrators only "door-to-door" protection. Now at least 19 agents guard the EPA chief day and night, and the number may be higher depending on travel and other needs.

"Perrotta is at the center of these decisions to spend money in ridiculous ways," says Austin Evers, the executive director of American Oversight, a government watchdog group probing the EPA's security decisions. "The administrator has gone out of his way to pick someone to lead his detail who will say 'yes' to everything and give him the entourage he apparently dreamed of."

EPA: Skeptics who aided Pruitt see a chief with nothing to lose Climatewire

Scott Pruitt could be poised to adopt a more aggressive approach against climate science after conservatives rallied around the embattled EPA chief.

Media scrutiny on the ethical lapses dogging Pruitt seem to have strengthened his bond with President Trump, according to those familiar with the president's thinking. Trump sees much of himself in Pruitt — a renegade Washington outsider perceived as being under siege by Democrats and the press.

Conservatives who have championed Trump's policies from the outside have mounted an effective campaign to defend Pruitt. Those organizations are influential in today's administration and see Pruitt as a dyed-in-the-wool defender of their core beliefs, from property rights to Christian values.

"[Trump] has actually referenced it in meetings, that people have been weighing in on Pruitt's behalf," said an industry source who talks with "industrialists and movement conservatives" in Trump's inner circle.

Conservatives have launched a media blitz to buoy Pruitt. On Wednesday, 22 conservative movement leaders — led by climate skeptic group the Heartland Institute — sent Trump a letter defending Pruitt's "record of leadership" that said "radical environmentalists and the biased media are trying to force him out of office" in an "example of selective outrage by those you defeated in your election" (***E&E News PM***, April 11).

That support has buttressed Pruitt against rumors that some White House aides, including chief of staff John Kelly, want him gone. Trump has stuck by him. He now knows who his friends are, and his friends are Trump's friends.

"Whatever was on their wish list as a 'possible' is moving to the 'more likely' column because he has nothing to lose," said Marc Morano, a former staffer for Sen. Jim Inhofe (R-Okla.) on the Environment and Public Works Committee.

Morano stressed an important caveat — Pruitt's ability to act stridently depends on whether he can escape further embarrassment or scandal. Those odds are growing murkier in the wake of a widening probe by House Oversight and Government Reform Chairman Trey Gowdy (R-S.C.). House investigators requested a trove of documents and recorded interviews with Pruitt aides.

The investigation increases Pruitt's potential exposure to new revelations. So far, he's survived scrutiny around his deal to rent a condo for $50 per night from the wife of an energy lobbyist, spending on lavish travel and security, reassigning staff that questioned those decisions, and approving large pay bumps for two aides despite White House disapproval. Some of those claims were brought to light by Kevin Chmielewski, an EPA aide and former Trump campaign hand, in conversations with congressional Republicans and Democrats.

For those wondering how Pruitt may operate going forward, a meeting last week at the Heritage Foundation offered clues. Casting aside criticism that he's embraced fringe voices on environmental issues, he sat down with a whole roster of them for a policy discussion, attendees said.

Most of the participants are interested in policies aimed at dismantling greenhouse gas regulation. Attendees included Myron Ebell of the Competitive Enterprise Institute; Patrick Michaels of the Cato Institute; Kenny Stein of the Institute for Energy Research; and Steve Milloy, a former EPA transition member under Trump (***E&E News PM***, April 11).

"While [the] meeting was off-the-record, I can safely say that it was evolutionary and consistent with previous briefings he has held," Michaels said in an email.

To be sure, Pruitt has huddled often with that set. Some have been frustrated that Pruitt hasn't challenged the endangerment finding, which provides the legal underpinning for regulating greenhouse gases. It's a tall task, they acknowledge, and one that legal scholars and scientists argue is doomed to fail. To be successful, Pruitt and his team would need to rebut peer-reviewed climate science with evidence that humans are not warming the planet.

Pruitt also has promised the same audience a "red team, blue team" exercise to debate climate science. The White House reportedly nixed that idea, but it's unclear whether Pruitt has given up the push.

Those who participated in last week's meeting at the Heritage Foundation left with the feeling that bolder steps are on the way. They viewed the sit-down as a thank you for standing by Pruitt in a time of turmoil, but also as a rallying point.

"For people who are climate bedwetters, they're going to need a whole lot of extra diapers coming up," Milloy said.

But not everyone is convinced Pruitt is safe.

The White House has said it's conducting a review of the allegations against the EPA chief. But it hasn't said what exactly is under investigation or given a timeline for completion. The White House did not respond to a request for comment.

Trump's personnel decisions are "unpredictable," Ebell said. He said EPA has been increasingly cautious in its response to recent headlines, rather than taking the combative tone it used during earlier scrutiny regarding Pruitt's expensive travel and expanded security detail.

"I don't think they're trying to speed up the big announcements," Ebell said. "I'm not making a bet on how this turns out."

Still, Ebell said significant policy news is in the offing. But he's measured in assessing Pruitt's confidence about his own job security. Ebell noted the flurry of bad news already pushed one major policy development to the end of this month, though he declined to describe what it was.

A notice of proposed rulemaking that appeared on the Office of Management and Budget's Office of Information and Regulatory Affairs website last week said EPA is considering regulations to "increase consistency ... reliability to affected stakeholders, and increase transparency during the development of regulatory actions." *The Daily Caller* reported EPA will cease accounting for health co-benefits associated with greenhouse gas emissions reductions, such as decreases in fine particulate matter that are linked to heart and lung ailments.

Pruitt's team has tried to "keep a low profile" so as not to "feed this story," which isn't necessarily the marker of someone ready to take up the battle ax, Ebell said.

One thing giving Ebell confidence is Trump's April 7 tweet that defended Pruitt. The president hasn't said anything publicly to distance himself from Pruitt since then.

To Pruitt's champions, those are good signs. And it's a reminder to them that in the Trump administration, only one person's opinion matters — Trump's. As long as that's the case, they're confident Pruitt will outlast the current storm.

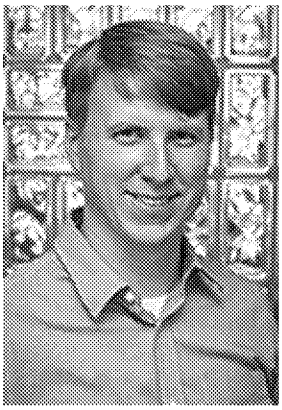
"His once-a-month rallies in Pennsylvania, Ohio, West Virginia to 10,000 and 20,000 — one of his big applause lines is mocking the environmental regulations and the U.N. climate treaty, and the crowd goes wild," Morano said. "Who loves him and who does he interact with? Those crowds. That's who he's loyal to. You have no idea how refreshing Donald Trump is. We're as happy as Roseanne that Donald Trump is president."

A-E

AIR POLLUTION: Pruitt's grant ban hits advisory panel at critical time Greenwire

As an EPA scientific advisory panel inches toward a key juncture in its high-stakes review of Clean Air Act standards for particulate matter, some members are facing a now-familiar dilemma: Give up agency funding or leave the group.

At least four panel members have been presented with that choice, according to court papers and interviews. While that's a relatively small percentage of the review panel's 27 members, it points to the continuing impact of the policy put in place last October by EPA Administrator Scott Pruitt.



Peter Adams. Carnegie Mellon University

For researchers caught in the middle, that policy continues to rankle.

"I feel like this new rule is kind of quote unquote 'solving' a problem that doesn't exist," said Peter Adams, a civil and environmental engineering professor at Carnegie Mellon University. Late last month, Adams was told that he was off the review panel after declining to relinquish an EPA grant.

The panel is in effect a work group for the seven-member Clean Air Scientific Advisory Committee (CASAC), which offers outside expertise to EPA during regularly required reviews of the air quality standards for particulate matter, ozone and four other "criteria" pollutants identified in the Clean Air Act.

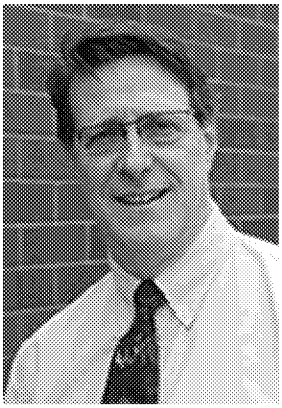
EPA is now in the early stages of re-examining the particular matter standards, which were last strengthened in 2012. With recent studies suggesting current limits for so-called fine particulates still may not be tight enough to protect public health, the agency is tentatively expected to release a draft roundup of available research — known as an "integrated science assessment" — this summer. Traditionally, CASAC and the review panel would then provide feedback as a prelude to a second, revised draft.

Dr. Rob McConnell. USC

While EPA had replaced several members of the main CASAC around the time that Pruitt announced the new policy last fall, the agency has only recently begun to extend the grants prohibition to review panel members.

Also out is Dr. Rob McConnell, a professor of preventive medicine at the University of Southern California. Late last month, McConnell told EPA that he had chosen "grant-funded research over continued service" on the panel, according to a recent court filing in one of three lawsuits challenging Pruitt's policy. McConnell could not be reached for comment.

A third member, Dr. Joel Kaufman, interim dean at the University of Washington's School of Public Health, said in an email last week to E&E News that he, too, had been contacted by EPA. Kaufman didn't reply to a follow-up message asking what he intended to do.



Dr. Joel Kaufman.University of Washington

But Jeremy Sarnat, an associate professor of environmental health at Emory University, said he was ending an EPA grant related to climate change three months ahead of schedule in order to stay on the panel. In an email, Sarnat said he felt strongly that the strength of EPA's advisory committees rested in their "diverse representation" across academic and governmental lines.

"I see this new policy as a means of hindering this diversity, by making it difficult for people (like me) with careers conducting air pollution and health research in academic institutions to participate in CASAC," Sarnat said. "So, for this reason, I want to do what I can to ensure that the policy fails."

As of this morning, the particulate review panel's **website** had not been updated to reflect any membership changes.

Jeremy Sarnat. Emory University

Tom Brennan, acting head of EPA's Science Advisory Board staff office, which has been contacting review panel members about their status, referred questions to the agency's press office, where spokespeople did not reply to emailed questions. Also not responding to queries last week was Richard Yamada, a Pruitt appointee who has taken a lead role in implementing the policy as deputy head of EPA's Office of Research and Development.

But the turnover was welcomed by Steve Milloy, a senior policy fellow at the Energy and Environmental Legal Institute, an anti-regulatory group that unsuccessfully sued two years ago to force the dissolution of the entire panel on the grounds that most members had received EPA grant money at some point and were "inappropriately influenced" in favor of the agency's alleged predisposition toward stricter regulations (***Greenwire***, Aug. 2, 2016).

Milloy's only objection in this instance was that EPA didn't move faster.

"I would have gotten rid of them right away," he said in an interview last week. "I think Pruitt has taken the humane way out."

Echoes of 'secret science' bill

It's unclear whether departing review panel members will be replaced. In rolling out the new policy last fall, Pruitt described it as a way of ensuring researchers' "objectivity."

"There is a question that arises over independence," Pruitt said at the time. "They have to choose: either the grant or service. But not both" (***E&E News PM***, Oct. 31, 2017).

Detractors have noted that Pruitt appears to have no such worries about the industry ties of some of his own advisory panel appointees.

"Focusing on non-existent conflicts of interest related to EPA funding while overlooking much larger conflicts of interest in industry is clearly a losing proposition for the nation," Adams wrote to Brennan in an email last month after being told he was no longer on the review panel. Adams provided a copy of the exchange to E&E News.

The ban on participation by EPA grant recipients isn't the only uncertainty hovering over the particulate standards review, which is set to wrap up in 2022.

In a **presidential memorandum** last week, the White House instructed Pruitt to come up with criteria for all reviews of ambient air quality standards "to ensure transparency in the evaluation, assessment and characterization of scientific evidence."

To some observers, that language is reminiscent of the "secret science" legislation repeatedly introduced by House Science, Space and Technology Chairman Lamar Smith (R-Texas) to bar the use of research in the development of new EPA regulations that is not "transparent or reproducible." The latest version of the bill, **H.R. 1430**, is awaiting action by a Senate committee after winning House approval more than a year ago.

Among the legislation's backers has been Tony Cox, a Colorado consultant whose clients have included the American Petroleum Institute.

Named last fall by Pruitt as CASAC chairman, Cox is also expected to lead the particulate matter review panel. In an email late last week, Cox said he disagreed with critics who view the legislation as a backhanded way of excluding studies that would suggest the need for stronger limits on fine particulates.

"To the contrary, I believe that we should shine a bright light on available data, independent of whether it suggests or opposes any particular policy conclusion and should follow where the data lead," Cox said in response to questions from E&E News, adding that he had not yet reached a conclusion on whether the fine particulate standards should be revised.

"This will be important for all of the members of CASAC to deliberate about, and I expect that final conclusions will be informed by careful consideration of available evidence," Cox wrote. "Much of that process will take place later this year."

EPA 'Secret' Biofuel Waivers Undercut Trump's Pledge to Farmers Bloomberg Environment & Energy Report

Even as President Donald Trump floats the idea of more ethanol sales, critics says moves by his Environmental Protection Agency would undercut the support to corn farmers.

Trump said April 12 the government probably would allow the year-round sale of gasoline containing as much as 15 percent ethanol, a blend known as E-15. But some lawmakers and ethanol producers say the change is undermined as the EPA continues its longstanding practice of issuing hardship waivers to some oil refineries.

At the heart of the matter is demand for ethanol, usually made from corn. A federal mandate requires a certain amount of biofuel blending, a regulation that oil refineries have long complained is too expensive and burdensome. The EPA's waivers allow some of them to skirt the requirements.

The "EPA's practice of giving away secret hardship waivers to the country's biggest oil refining companies needs to stop," four Republican senators from top corn-producing states including Chuck Grassley and Joni Ernst of Iowa said in a joint statement late April 12. The waivers are "effectively gutting" national biofuel quotas and are "another backdoor attempt" to destroy ethanol regulation, they said.

Trump has held a series of meetings in recent months to carve out a biofuels deal that satisfies the agriculture and oil lobbies, which also happen to represent two of his most important constituencies: farmers in the rural Midwest and blue-collar workers in industrial areas. The two sides have clashed repeatedly over the Renewable Fuel Standard, a complicated policy that crosses political lines.

On April 12, farmers cheered as Trump said the government would probably allow year-round sales of E15, a change from current policy that restricts its sale during the summer in areas where smog is a problem.

But in a meeting with farm-state lawmakers and governors, Trump also indicated there would be a two-year transition for the change, with "no guarantee" it would happen, and he stressed that he would be "helping the refineries" who have complained about the biofuel mandate.

EPA Encouraging Waivers

Trump's EPA already is doing just that. It has encouraged some 38 eligible oil refineries to apply for waivers and granted more than two dozen of them. A federal law allows exemptions for facilities that use no more than 75,000 barrels of crude per day, and a court ruling last year made winning waivers easier.

"The court basically said that, under the statute, EPA is required to give small refinery exemptions more liberally," Jeff Holmstead, the former assistant EPA administrator, said in an emailed statement April 12. What's more, the law "does not

make a distinction between small refineries owned by small parent companies and small refineries owned by a large ones."

Exxon Mobil Corp. has applied for at least one waiver, according to people familiar with the process who asked for anonymity to discuss the confidential program. Its 61,500 barrel-a-day facility in Billings, Mont., would qualify based on capacity. Suann Guthrie, an Exxon spokeswoman, declined to comment.

Billionaire Carl Icahn's CVR Energy Inc.'s Wynnewood, Okla., refinery, has a capacity below the 75,000-barrel threshold and could also qualify for the exemption.

Brandee Stephens, a spokeswoman for CVR, declined to comment on whether the company sought a waiver. Icahn, a former special adviser to Trump on regulations who has advocated for changes to the program, didn't respond to several messages requesting comment.

The EPA's waiver decisions "are based on refinery-specific information" and Department of Energy analyses, EPA spokesperson Liz Bowman said by email. "We continue to work through petitions received for 2017."

GOP Touts High-Octane Standard In RFS Reform Package But Faces Hurdles Inside EPA

Top House Republicans are expressing confidence about enacting a nationwide high-octane fuel standard as part of a broader package to "reform" or scale back the renewable fuel standard (RFS), arguing the move could satisfy a range of fuel stakeholders while also giving automakers a relatively cheap compliance option for fuel economy limits.

However, ethanol groups are expressing concern about key details of such a standard, arguing that it may not expand biofuels' market share much beyond current RFS blending mandates and could even reduce that share.

In addition, both Democrats and Republicans, during an April 13 House hearing on the concept, raised a number of questions ranging from the policy's impact on the fuel supply's greenhouse gas emissions, the potential for mis-fueling a range of vehicles and potential increases in consumer costs.

Yet some top GOP lawmakers during the House Energy & Commerce environment subcommittee hearing touted the concept as providing benefits to multiple groups.

A high-octane standard is a "relatively low-cost way to increase miles per gallon," said panel Chairman John Shimkus (R-IL), adding it could offer a "pathway to use as much if not more" ethanol than is currently required by the RFS.

Similarly, Energy & Commerce Committee Chairman Greg Walden (R-OR) said the concept "seems like an elegant way to make both the RFS and the [corporate average fuel economy (CAFE)] standards work together."

While lawmakers must still "kick the proverbial tires of this idea," he said the topic is a priority for the committee and "we intend to move forward one way or the other."

Some Republicans have long embraced the notion of a high-octane standard, as the Trump administration and GOP lawmakers have struggled to develop consensus fixes to the RFS.

Octane is a measure of fuel's ability to resist engine "knock," or incorrect ignition. Fuels with higher octane ratings enable higher engine efficiency and lower emissions of GHGs and other pollutants.

As a result, some have urged California officials to exercise little-used federal authority to require gasoline sold in the state to have a higher octane level as a way to reduce vehicle GHGs, an issue that is not preempted by federal law -- unless and until Congress or EPA enacts federal octane limits.

At the same time, Shimkus has been involved in a months-long attempt to craft legislation reforming EPA's biofuel blending program, though some sources see the effort as unlikely to bear fruit in the near term given the looming November midterms.

Rep. Paul Tonko (D-NY), ranking Democrat on the subcommittee, told the hearing that he doubts that a high-octane standard by itself would do a better job than the RFS of encouraging lower-carbon advanced and cellulosic ethanol, though he said he is "open to hearing otherwise."

He noted that a standard expressed as 95 research octane number (RON) -- a proposal floated by many lawmakers and witnesses at the hearing -- is not guaranteed to be achieved by using ethanol or other low-carbon fuels, and could "increase the carbon intensity of the fuel supply."

Further, he charged that any octane standard should not be issued "without the certainty that these [CAFE] standards will continue and continue to be strengthened into the future."

RFS 'Sunset'

Though they broadly endorsed the concept of requiring higher octane, key stakeholder groups at the hearing were divided on important details.

For instance, American Fuel & Petrochemical Manufacturers (AFPM) President Chet Thompson testified that his group endorses a "performance-based" octane standard of 95 RON, provided it is accompanied with a "sunset" of the RFS, adequate lead time and measures to prevent mis-fueling.

In contrast, Growth Energy CEO Emily Skor said a high-octane standard is laudable but is a "different conversation" when coupled with an end to the RFS. She added that any standard must specify that a portion of the octane be achieved by "renewable fuels," as opposed to chemical additives.

Skor and a representative of gasoline retailers also urged EPA to grant a waiver allowing year-round sales of 15 percent ethanol (E15) blends. But Thompson said he is group is only willing to entertain such a step "as part of a comprehensive RFS solution." His members "would not be too keen to the idea in exchange for nothing."

To allow year-round sales, EPA would have to lift Reid vapor pressure (RVP) restrictions that currently limit sales in the summer. Ethanol advocates argue that the prohibition is outdated and that the air emissions profile of E15 is if anything better than the 10 percent blend (E10) that is the national standard.

President Donald Trump on April 12 endorsed the concept of year-round E15 sales, comments that prompted ethanol critics to charge that EPA lacks Clean Air Act authority for such a waiver.

Despite the apparent differences at the hearing, Shimkus claimed, "I believe that we are closer than people think" to agreement on the policy.

'Cost-Effective' Compliance

For their part, automakers are embracing a national high-octane standard, which would allow them to craft a new generation of turbo-charged engines designed to run on such fuel and achieve up to a 3 percent fuel economy gain.

Dan Nicholson, a global propulsion official with General Motors testifying on behalf of the United States Council for Automotive Research, said that combining high-octane fuels with advanced engines is "the most cost-effective thing that we can do" to comply with increasingly stringent CAFE and vehicle GHG requirements.

Such an effort could entail billions of dollars in investments to redesign engines over the next four-plus years, but "other things we can do will cost even more."

If Congress passed legislation with a high-octane standard this year, he said, automakers could deploy advanced engines designed for the fuel by model year 2023 at the earliest.

AFPM's Thompson said that if a high-octane standard is phased in, it might not cost his members much in the early years to comply but would ultimately require "tens of billions of dollars." Even so, he said refiners are willing to embrace the policy as a "compromise solution to a bad status quo: How do we help autos comply with CAFE and how do we make the RFS better?"

Thompson also claimed that a 95 RON standard would be good for the ethanol sector because ethanol is currently the cheapest way to boost octane levels in fuel. "It would provide them with every bit as much ethanol demand as they get under the RFS and likely more," he said.

He opposed requiring a certain level of ethanol to be used to achieve octane gains, noting that California and five other states currently ban E15 blends.

But Skor countered that a "performance" standard could allow oil refiners to use other petroleum products to boost octane, even if ethanol is a cheaper option, in order to crowd out ethanol's market share. As such, she called for the RFS to continue to provide "guard rails" that ensure ethanol has a place in the fuel market.

She noted that a 95 RON fuel is similar to premium fuel available today, which she said refiners make without significantly higher ethanol than regular gasoline.

Timothy Columbus, representing two trade associations of retail gas stations, said his members are mainly seeking "peace in the valley" regarding fuel policy. He backed a waiver allowing year-round sales of E15, while noting that the concept of a high-octane standard creates "substantial opportunity" for the ethanol sector.

He also backed a "performance" standard, arguing that would ultimately drive down consumer costs. Further, he urged Congress to allow sufficient lead time for retailers to upgrade underground storage tanks to ensure they can store higher ethanol blends, in order to avoid liability under the Resource Conservation and Recovery Act. -- *Lee Logan* (llogan@iwpnews.com)

The EPA's push for dirtier cars is based on old data The Verge
Pruitt tells climate deniers he'll stop counting value of lives saved for new rules - ThinkProgress

CSS

Chemical List From EPA to Help Companies Meet October Deadline Bloomberg Environment & Energy Report

A list of chemicals that the EPA released April 12 should help paint, cleaning, and other companies that combine chemicals know if they need to notify the agency by Oct. 5 of the components of their mixtures.

The Toxic Substances Control Act amendments of 2016 require the EPA to divide its official inventory of chemicals into two parts: a list of chemicals that are active in commerce and a list of those that once were, but are now dormant.

The agency April 12 released information that will help companies that mix compounds comply with TSCA. The first registry is of particular interest to chemical processors—companies that make mixtures of chemicals such as cleaning products, car polish, and paint.

Live and in Commerce

That registry lists chemicals the agency believes to be active in commerce based on information chemical manufacturers provided earlier this year.

Chemical processors can check that list to make sure the chemicals they use are on it. If they are, no further action is required.

But if the chemicals these companies need are not on the provisional list, processors have until Oct. 5 to let the agency know they use the compound. The agency would then add the chemical to a final active-in-commerce list it is expected to release in 2019.

Under TSCA, only chemicals that are on the final active list can continue to be sold, used, or imported into the U.S.

The second chemical list the agency released is an update of its TSCA inventory, which lists all chemicals that have been made in or imported into the U.S. since the early 1980s. This larger inventory includes many chemicals that are no longer made or used.

House Farm Bill Seeks To Scrap Inter-Agency ESA Pesticide Consultations Inside EPA

House Republicans in the recently introduced Farm Bill are proposing to amend federal pesticide law to strip a requirement that EPA consult with federal wildlife agencies on pesticides' risks to endangered species, a provision environmentalists say could make it more difficult to move the bill through the Senate and would speed extinctions.

The bill, H.R. 2, introduced April 12, would amend the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to allow EPA to deem a pesticide "not likely" to adversely affect listed species or critical habitat, stripping the agency of an obligation under the Endangered Species Act (ESA) to consult with wildlife officials whenever a pesticide "may affect" a listed species, although the language does allow for registrants to petition the agency to consult.

"The Administrator shall not be required to consult or communicate with the Secretary of the Interior or the Secretary of Commerce when making such determination, unless otherwise petitioned to by the registrant of the pesticide," a House Agriculture Committee summary of the provision says.

Environmental groups that have long pressed EPA through federal lawsuits to consult on pesticides' risks to endangered species, are calling the bill language a pesticide industry handout that along with other "poison pill" provisions could preclude the Farm Bill from passing the Senate.

"This is one of many things that might sink the Farm Bill," a source with the Center for Biological Diversity (CBD) tells *Inside EPA*, characterizing the practical affect of the provision as allowing pesticide users to kill listed species provided they follow product label directions.

"It's going to make passing the Farm Bill exceptionally harder."

In an April 12 statement, CBD argues that the bill would seek to essentially codify an April 2017 request from Dow AgroSciences and other pesticide producers for EPA to scrap an Obama-era process for assessing pesticides risks under the ESA, that advocates say would allow EPA to ignore species' risks.

"Without question, this will accelerate extinctions for some of our most vulnerable species," CBD's Lori Ann Burd says in the statement. "Companies like Dow that have dumped millions into congressional campaigns are now calling all the shots in D.C. on dangerous pesticides."

The pesticide producers association CropLife America is backing the language as bringing needed changes. "The language included in the Farm Bill would streamline the administrative process, avoiding duplication, delay and procedural litigation," CropLife America President and CEO Jay Vroom says in a statement to *Inside EPA*.

"This is not a change in the safety standard, nor does the Farm Bill language change provisions for citizen suits."

A second pesticide industry official who supports the provision says that inter-agency consultation process for pesticide reviews is broken and that a new solution is needed to address the conflicting mandates of FIFRA and the ESA.

ESA Consultations

During the Obama administration, EPA, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (NMFS) crafted an inter-agency process for correcting EPA's long-standing failure to assess pesticides' risks to listed species as required under the ESA.

EPA officials have acknowledged that early iterations of the Obama-era process relied on highly conservative assumptions, and said they were working to improve the process.

In January, EPA Administrator Scott Pruitt and Trump officials overseeing federal wildlife agencies formed a working group to review and potentially revise the process that Pruitt described as broken.

But prospects for an agreement are "gloomy," according to Bill Jordan, a former deputy director of EPA's pesticides office. "Each side has to make some serious compromises," he said during an April 10 webinar.

EPA is seeking comment through May 22 on the first biological opinion (BiOp) finalized under the Obama-era process, including on the scientific approaches and data underlying the analysis. EPA has said the input is needed because a federal court late last year rejected NMFS' request to delay finalizing the BiOp, precluding the wildlife service from seeking public input, including from pesticide producers.

The language in the House Farm Bill mirrors language in draft legislative text that several environmental groups, including the CBD, Center for Food Safety, and Defenders of Wildlife, charged that pesticide industry officials were shopping on Capitol Hill and that they said "would eliminate all requirements for the EPA to consult with agencies that have the most expertise on endangered species."

Now CBD officials say the pesticide industry has succeeded in getting similar language in the farm bill.

The CBD source says advocates have been meeting with Senate Democrats for months to oppose pesticide industry efforts to strip the requirement for EPA to consult with wildlife officials on pesticides risks to endangered species.

"If the rider remains in place, consideration for impacts on endangered species would be written out of the process of registering pesticides," Burd says in an April 13 op-ed in *Environmental Health News*.

"If we don't stop it, it could not only directly fuel the extinction of many of our most endangered plants and animals -- it could eliminate one of the most important shields we have to protect all species, including humans, against highly toxic pesticides poisoning the waterways and landscapes we all depend on."

In addition to the consultation provision, section 9111 of the bill would also amend FIFRA to require that EPA use "best scientific and commercial data available" when registering pesticides, and to consider any use restrictions when assessing pesticides' risks, according to the summary.

The bill would set a schedule for EPA to make determinations on whether a pesticide is likely to jeopardize species or alter critical habit. EPA would have until Oct. 1, 2026 to assess ESA risks of pesticides initially registered before Oct. 1, 2007, and until Oct. 1, 2033 for those registered after that date and before enactment of the law. -- *Dave Reynolds*(dreynolds@iwpnews.com)

HHRA

NAS advice on IRIS disappoints chemical industry Inside EPA

The American Chemistry Council (ACC) says it is disappointed with the results of a National Academy of Sciences (NAS) report that largely backed reforms EPA is making to its Integrated Risk Information System (IRIS), saying the report did not go far enough in calling for reforms the group believes the program needs to ensure adequate assessments.

In an April 13 statement, ACC, the leading chemical sector trade association, charged that EPA provided the NAS panel with only limited information about its activities to reform the program.

"ACC had little expectation the committee would be able to properly evaluate the progress the agency has made to address past NAS recommendations," the statement says.

"NAS was tasked with reviewing proposed IRIS changes based on what EPA presented in a 1.5-day workshop. Unfortunately, EPA staff elected to provide only PowerPoint presentations that offered few details on the specific practices being used and did not include the review of any actual examples of completed assessments reflecting all the changes IRIS has made," it adds.

ACC's statement responds to a NAS's panel's April 11 report that praised EPA's efforts to improve its influential but controversial risk analysis program, and even backed supporters' efforts to keep Republicans from consolidating the program with EPA's toxics office, underscoring steps Congress took in EPA's recent budget bill.

"Overall, the committee was impressed with the changes being instituted in the IRIS program since" NAS' last IRIS review, published in 2014, the report said.

"The committee views the transformation of the IRIS program as a work in progress, recognizes that this review assesses one moment in time in a still-evolving program, and acknowledges that the IRIS program will (and should) continue to evolve as it adapts and applies new scientific approaches and knowledge," NAS' April 11 report states.

The findings mark a significant change for the program in the Trump administration as IRIS has faced years of critical reviews from NAS and others, and more recently, calls from industry representatives and GOP lawmakers to scale back the program.

While the NAS committee called for continued improvements in the program, ACC says the panel still fell short and pledges to continue to work with the administration and Congress to ensure additional reforms.

"While the report commends IRIS staff on the progress to implement systematic review as presented in its PowerPoint slides, the fact remains the agency has yet to produce any meaningful products (e.g., a finalized IRIS handbook, a draft IRIS assessment that reflects the new systematic review approach) based on the changes it says it has made. The absence of these critical pieces of information, after years of opportunity by EPA to address the 2011 and 2014 NAS recommendations, clearly indicates that much work still remains before IRIS assessments meet the benchmark of a gold standard review expected by the scientific community."

"We look forward to working with Congress and EPA to improve the IRIS program so that it will one day be able to produce high-quality, scientifically sound chemical assessments," ACC added.

SHC

Chesapeake Bay grass resurgence is first big conservation success tied to humans, scientists say Norfolk Virginian-Pilot

SSWR

Chemical in Fayetteville's tap water may cause cancer The Fayetteville Observer

North Carolina cracks down on Chemours's fluoroether air pollution Chemical & Engineering News

Science and Science Communication

SEE IT: Politico's Morning Energy

Marchers hit D.C. and other cities around the country for a second year to protest the Trump administration and politicians who thwart efforts to address climate change, as part of the March for Science. See POLITICO's photo gallery here.

Moira

Moira McGuinness
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202-564-1507—desk (T, Th, F)
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Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/23/2018 3:47:00 PM
To: Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]
Subject: FW: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule
Attachments: Science Comment Extension v2.pdf

Another

From: Katie Foreman [mailto:kforeman@acwa-us.org]
Sent: Wednesday, May 23, 2018 11:44 AM
To: Staff_OSA <Staff_OSA@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Julia Anastasio <janastasio@acwa-us.org>; chanson@ecos.org; Sam Sankar <ssankar@ecos.org>; jsloan@csg.org; Dania Rodriguez <DaniaR@astswmo.org>; ASchaefer@NGA.ORG; aroberson@asdwa.org; Ross, David P <ross.davidp@epa.gov>
Subject: Comment Deadline Extension Request on Proposed "Strengthening Transparency in Regulatory Science" Rule

Good Afternoon,

Please see the attached letter outlining a comment deadline extension request for the Strengthening Transparency in Regulatory Science Proposed Rule from seven associations, on behalf of the states. Should you have questions regarding this request, please feel free to contact Julia Anastasio (janastasio@acwa-us.org, 202-756-0600).

Thank you,

Katie Foreman
Environmental Program Associate
Association of Clean Water Administrators
1634 I Street NW, Suite 750
Washington, DC 20006
kforeman@acwa-us.org

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/5/2018 6:34:39 PM
To: McGartland, Al [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5fe25fc1df634f9798675527e0070429-AMcGartl]
Subject: FW: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT
Attachments: Barnes Cert of Confidentiality 21-Century-Cures-Act Bloomberg Law 10-4-2017.pdf

Al – here is the language from the 21st Century Cures Act and a journal article related to it. Also here is the website for NIH re this …
https://humansubjects.nih.gov/coc/index

From: Sinks, Tom
Sent: Tuesday, March 20, 2018 4:19 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Teichman, Kevin <Teichman.Kevin@epa.gov>
Subject: RE: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT

Language passed in the 21st Century Cures Act states the following …. https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

''(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

''(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

''(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

''(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

''(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

''(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

''(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

''(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

''(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

''(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).
''(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used

for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.
''(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.
''(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.
''(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.
''(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.
''(4) For purposes of this subsection, the term 'identifiable, sensitive information' means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—
''(A) through which an individual is identified; or
''(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.''.
(b) APPLICABILITY.—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:
''(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—
''(A) an individual is identified; or
''(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.
''(2)(A) Each determination of the Secretary under paragraph

(1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.
''(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.
42 USC 241 note.

PUBLIC LAW 114–255—DEC. 13, 2016 130 STAT. 1051
''(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.''.
SEC. 2014. DATA SHARING.
(a) IN GENERAL.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—
(1) in paragraph (23), by striking ''and'' at the end;
(2) in paragraph (24), by striking the period and inserting ''; and''; and
(3) by inserting after paragraph (24) the following:
''(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—
''(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and
''(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.''.
(b) CONFIDENTIALITY.—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information.

From: Sinks, Tom
Sent: Monday, March 19, 2018 2:26 PM
To: Shoaff, John <Shoaff.John@epa.gov>
Subject: new NIH position on certificates of confidentiality is also relevant to the HONEST ACT

Certificates of Confidentiality for NIH Funded Research

NIH awardees no longer have to apply for a CoC.

Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC. Compliance requirements are outlined in the NIH Grants Policy Statement, which is a term and condition of all NIH awards.

This policy applies to NIH funded:

- Grants
- Cooperative Agreements
- R&D Contracts
- Other Transaction Awards
- NIH's own intramural research

How do I know if my NIH funded research project is covered by a CoC?

Research in which identifiable, sensitive information is collected or used, including research that

- Meets the definition of human subjects research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that might identify a person

If your research meets any of the above criteria then your research data or information is automatically protected by a CoC from NIH.

What does having a CoC mean I need to do?

1. **Researchers with a CoC may ONLY disclose identifiable, sensitive information in the following circumstances:**
    - if required by other Federal, State, or local laws, such as for reporting of communicable diseases
    - if the subject consents; or
    - for the purposes of scientific research that is compliant with human subjects regulations
2. **AND you must ensure that anyone who is conducting research as a subawardee or receives a copy of identifiable sensitive information protected by the policy understand they are they are also subject to the disclosure restrictions, even if they are not funded directly by NIH.**

How do I document that I have a CoC for my NIH funded Research?

NIH will no longer issue a physical certificate. You may point to your Notice of Award and the NIH Grants Policy Statement as documentation of the CoC protection.

Will I ever need to extend or amend my CoC?

If your NIH-funding will or has ended but the collection of new data from research participants will continue without NIH-funding you will need to apply for a CoC for continuity of protections using the CoC application system. If your NIH funding will or has ended but your study has completed all enrollment and data collection, there is no need to extend the Certificate. Sensitive, identifiable research information maintained by investigators during any time a Certificate is in effect, is protected permanently.

Where can I learn more?

Read the 2017 NIH Certificates of Confidentiality Policy.

Have a CoC Question?

Please address your inquiries to: NIH Office of Extramural Research: NIH-CoC-Coordinator@mail.nih.gov

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
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Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 2/13/2018 2:51:40 PM
To: Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]
Subject: Re: Are you participating...

No

Sent from my iPhone

On Feb 13, 2018, at 9:31 AM, Teichman, Kevin <Teichman.Kevin@epa.gov> wrote:

> ...in the meeting I see on Richard's calendar today with Aaron Ringel re the HONEST Act?
>
> Kevin Teichman
> Senior Science Advisor
> Office of Research and Development (8101R)
> U.S. Environmental Protection Agency
> 1200 Pennsylvania Ave., NW
> Washington, DC 20460
>
> Phone: (301) 975-6421
> Fax: (301) 975-4409

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/23/2018 2:58:25 PM
To: kelleyscanlon3@gmail.com
Subject: secret science

News clips from Friday

REGULATIONS: EPA sends 'secret science' plan to White House Greenwire

EPA yesterday sent a proposed rule to the White House Office of Management and Budget with the announced purpose of "strengthening transparency and validity in regulatory science," according to the RegInfo.gov site.

The proposal appears to be a concrete step toward restricting the types of scientific research that EPA officials can use in crafting new regulations. The proposal was not listed on EPA's latest semiannual regulatory agenda, and agency press aides did not respond to an emailed request for more information this morning.

"We need to make sure their [scientists'] data and methodology are published as part of the record," EPA Administrator Scott Pruitt told *The Daily Caller*, a conservative news outlet last month, in an article that the agency later distributed as a news release. "Otherwise, it's not transparent. It's not objectively measured, and that's important."

House Science, Space and Technology Chairman Lamar Smith (R-Texas) has repeatedly introduced "secret science reform" legislation that would bar EPA from using scientific data that are not "transparent or reproducible."

Smith has promoted the bill as a good government measure. Critics argue, however, that it's intended to prevent the agency from using the best available science and could have steep implementation costs (***E&E News PM***, April 13, 2017).

While the House has passed various versions of the legislation several times, Smith has been unable to get the bill through the Senate. Newly released emails show that Pruitt and Smith met in January to discuss the issue. But the emails, obtained by the Union of Concerned Scientists, an advocacy group opposed to Smith's legislation, also show that a top political appointee raised concerns about the potential impact on pesticide registration and on chemical regulation under the Toxic Substances Control Act (***Climatewire***, April 20).

OMB's Office of Information and Regulatory Affairs is now supposed to complete a standard interagency review of the proposed rule within 90 days but can seek more time if needed.

At a hearing last week, Sen. Maggie Hassan (D-N.H.) had pressed OIRA Administrator Neomi Rao for her stance on the issue (***E&E Daily***, April 13). Asked by Hassan whether she would "generally support agencies changing their procedures in ways that prevent them from using the best available evidence in making these decisions," Rao responded, "No, I would not."

If Rao "stays true" to that commitment, then "secret science has no business seeing the light of day," Yogin Kothari, senior Washington representative for the Union of Concerned Scientists, said in an interview today.

Pruitt Moving Again to Change the Way EPA Uses Science (1) Bloomberg Environment & Energy Report

EPA Administrator Scott Pruitt is taking another step toward changing how the agency uses science.

The White House Office of Management and Budget is reviewing a proposal that aims to strengthen the “transparency and validity” of the science the Environmental Protection Agency uses to support its regulatory decisions, according to the office’s website. OMB’s review, typically one of the final steps before a proposal is released for public review, started April 19.

There are no details on what’s included in the proposal, but Pruitt told Bloomberg News in March that the EPA should rely on science that is “very objective, very transparent, and very open.” He raised concern about third-party research where the underlying data isn’t public.

“That’s not right,” Pruitt said in March. “The methodology and data need to be a part of the official record—the rulemaking—so that you and others can look at it and say, ‘Was it wisely done?’”

Researchers and environmental advocates told Bloomberg Environment that such a policy could severely limit the data the agency considers when it regulates everything from drinking water and air quality to pesticides. Some EPA staff agree: The agency in 2017 told the Congressional Budget Office that similar open data requirements would limit usable studies by 95 percent.

"The policy is still being developed," EPA spokesperson Liz Bowman said in an April 20 statement emailed to Bloomberg Environment. "It's important to recognize that Administrator Pruitt believes all Americans deserve transparency, with regard to the science and data that's underpinning regulatory decisions being made by this Agency."

Pruitt's goal is similar to that in legislation (H.R. 1430) that House Science and Technology Committee Chairman Lamar Smith (R-Texas) introduced, which would require the EPA to base its regulatory decisions on data that's publicly available and substantially reproducible.

Last year, Pruitt barred scientists who receive EPA grants from serving on agency advisory panels, citing conflicts of interest. That policy affected many members of the EPA's advisory panels, including a panel that reviews the science backing national air quality standards, who either left or had to relinquish their grants.

Emails between EPA officials ... Politico's Morning Energy

Emails between EPA officials obtained by the Union of Concerned Scientists show that Nancy Beck, the top political official in the agency's chemicals office, voiced concerns after she received a draft of the not-yet-released policy on Jan. 31. The directive in question has origins in legislation introduced by Rep. Lamar Smith during the Obama administration, but its requirements would exclude a great deal of data about pesticides and toxic chemicals that Beck's office considers when determining whether a substance is safe or must be restricted. "These data will be extremely valuable, extremely high quality, and NOT published," Beck wrote in an email to an official in EPA's office of research and development. "The directive needs to be revised."

EPA Smith pitched Pruitt on 'secret science.' Now it's happening Climatewire

EPA coordinated with House Republicans about their plans to restrict the science used in crafting regulations, newly released emails show.

In early January, EPA chief Scott Pruitt met with Rep. Lamar Smith (R-Texas), chairman of the House Science, Space and Technology Committee, to discuss one of Smith's pet projects — overhauling how EPA uses science. Smith hasn't been able to get legislation to do so through Congress, so he pitched Pruitt to do so internally, according to **emails** obtained through a Freedom of Information Act request. The emails were obtained by the Union of Concerned Scientists and shared with E&E News.

In March, Pruitt announced that he would follow through. He said EPA plans to require that data and methodology from studies used to craft regulations be made public (***Climatewire***, March 16). The topic has long been contentious. Smith and others describe the effort as a way to ensure science used to craft regulations can be properly scrutinized. Critics have said it is an effort to limit air pollution research and other studies that have been cited as reasons for regulations.

EPA has said little about its plans to make science more transparent, other than Pruitt's brief interview with a conservative news outlet to say the plan was coming at some point.

The new emails reveal how Pruitt's staffers have worked behind the scenes with Smith's office.

On Jan. 16, a few days after Pruitt met with Smith at EPA headquarters, a Smith staffer followed up with Pruitt's shop.

"It was great to see you last week and appreciate the Administrator's time. Chairman Smith is very keen for our staff to get together to discuss further transparent science-based regulations at the EPA," Smith's aide Joe Brazauskas wrote to EPA congressional affairs staffer Aaron Ringel. "We can meet at your earliest convenience with the appropriate EPA staff to discuss this matter further."

Within an hour of receiving Brazauskas' email, Ringel circulated the message to colleagues at EPA.

"All, see below follow up from Chairman Smith's meeting with the administrator," he wrote. "Want to check on who would be the most appropriate [for] them to speak to. In short, this is in regards to his pitch that EPA internally implement the HONEST Act (no regulation can go into effect unless the scientific data is publicly available for review)."

One of the aides copied on Ringel's email was Richard Yamada, the deputy assistant administrator of EPA's Office of Research and Development. Yamada previously worked for years on the Republican staff of the House Science Committee led by Smith.

The emails also show that EPA staffers wanted to have the program rolled out by the end of February.

Brittany Bolen, who works in EPA's policy office, sent an email dated Feb. 12 saying that Pruitt's chief of staff Ryan Jackson "asked to have this rolled out by the end of the month."

Timing for the rollout of the policy is still unclear.

EPA spokeswoman Liz Bowman said yesterday, "These discussions are part of the deliberative process; the policy is still being developed."

The Union of Concerned Scientists said the emails show the plan was crafted by political staff with little input from scientists. They also show that EPA's political appointees are mostly concerned about industry, rather than environmental or health protections, said USC spokesman Yogin Kothari.

"This idea to restrict the use of science at EPA was hatched solely and worked on almost exclusively by political appointees who are doing everything they can to ensure that independent science doesn't get in the way of policy decisions at the agency," he said. "It's an effort to stack the deck in favor of industry that EPA is supposed to regulate."

'This directive needs to be revised'

The emails also reveal that an EPA political appointee — a former chemical industry executive — raised concerns about the science overhaul.

Nancy Beck, deputy assistant administrator of EPA's chemicals office, raised pointed concerns about what a secret science policy would mean for both pesticide registration and for chemical companies and regulating chemicals under the Toxic Substances Control Act (TSCA).

In an email sent on Jan. 31, Beck warned Yamada; Erik Baptist, EPA's senior deputy general counsel; and Justin Schwab, deputy general counsel, that requiring underlying data to be public would affect pesticide registrations and TSCA implementation.

"This directive needs to be revised. Without change it will jeopardize our entire pesticide registration/re-registration review process and likely all TSCA risk evaluations," she wrote. "Let me know what more you may need from me to facilitate a change."

Beck noted that under EPA regulations, pesticide registration requires companies to submit studies that include a "huge amount of data" and cost the companies millions of dollars to conduct. "Guideline studies of this type are never put in journal publications — there is no audience for them, thus in IARC's eyes they are not published," she wrote.

The World Health Organization's International Agency for Research on Cancer, or IARC, develops an international database of chemicals that could potentially cause cancer. Beck notes that most of the data in this process are considered confidential business information, but the "CBI" tag can be waived to make the data available in many instances.

"Making data available is very different than requiring a publication requirement. Such a requirement would be incredibly burdensome, not practical and you would need to create a whole new arm of the publishing industry to publish these types of studies that nobody is interested in," she wrote.

Beck added that there would be a similar problem under TSCA, where data for many existing chemicals aren't published because there is "no incentive for anyone, anywhere to publish them."

"Yes, thanks this is helpful — didn't know about the intricacies of CBI — ok, we will need to thread this one real tight! Thanks Nancy!" Yamada wrote in response to Beck's warning.

Richard Denison, a senior scientist at the Environmental Defense Fund, noted that EPA staff and members of Congress had previously objected to Smith's "Honest and Open New EPA Science Treatment Act" — the basis for the potential EPA policy — for the data collection burden it would put on researchers, who would have to go back and identify which data could be made public.

Critics also warned at the time that the impact would be to significantly reduce the number of studies that could be used to develop research, and many suspected this was the real purpose of the bill.

"What Nancy Beck is ironically pointing to is the same set of issues would fall on the industry, because it is not only whether the information would be made public or not, it's the cost and burden associated with doing so," Denison said.

EPA spokeswoman Bowman did not comment on whether EPA planned to follow Beck's suggestion to revise its proposal. "It's important to understand, however, that any standards for protecting CBI would be the same for all stakeholders," she said.

At least one "secret science" policy proponent said he was open to requiring researchers and companies to make data available when they are requested by "legitimate researchers" rather than publishing all underlying data.

"This data has to be somewhere, and if someone needs to see it then arrangements have to be made," said Steve Milloy, former EPA transition team member. "You can't attack this stuff with a broad brush."

In another email from March, months after the process had started, Beck found a passage from documents the agency's pesticide program released in December 2016 saying EPA "does not believe that it is appropriate to refuse to consider published studies in the absence of the underlying data."

The document Beck referred to also said, "The EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies."

Beck wrote in the email, "I'm sharing for awareness, particularly regarding court cases that are cited."

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/27/2018 2:13:24 PM
To: Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]
Subject: Fwd: SIGNED: Strengthening Transparency in Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Sinks, Tom" <Sinks.Tom@epa.gov>
To: "ORD-OSA" <ord-osa@epa.gov>
Cc: "Cawiezell, Thomas" <cawiezell.thomas@epa.gov>, "Teichman, Kevin" <Teichman.Kevin@epa.gov>, "Nelson, Daniel K." <Nelson.Daniel@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

Folks – today Administrator Pruitt announced this proposed rule. Many of you have heard about this in the media. The proposal likely touches upon three aspects of OSA work – public access to EPA funded research, human subjects research protection, and scientific integrity. Even though OSA and I have not participated in the development of this document and I just this moment obtained it (have yet to read it), I am listed as the point of contact on this NPRM.

I expect a high volume of emails and telephone calls coming into OSA. Tom Cawiezell's phone number is listed in the NPRM as is an STPC staff email. No doubt we will all have a lots of questions re this – but I wanted you to be aware of this and encourage you to read about it.

From: Orme-Zavaleta, Jennifer
Sent: Tuesday, April 24, 2018 4:01 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; ORD-Exec-Council-Directors <Execcouncildirectors@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy

<Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 1/26/2018 5:29:08 PM
To: Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]
Subject: Personal Matters / Ex. 6 questions about today

Didn't know about the 10:30. I will call in for the 2.

Sent from my iPhone

> On Jan 26, 2018, at 10:06 AM, Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov> wrote:
>
> Hi Tom
>
> Personal Matters / Ex. 6
>
> Are you planning to call into the 10:30 SI phone briefing?
>
> What about the 2 pm Honest Act discussion?
>
> Thanks
>
> Liz
>
> Liz Blackburn
> Chief of Staff
> EPA Office of Research and Development
> 202-564-2192
> Cell : Personal Matters / Ex. 6
>
> Sent from my iPhone

Appointment

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 1/26/2018 1:39:18 PM
To: Gomez, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=575ba24fc19d429c8302a05102353238-lgomez]

Subject: Accepted: CONFIRMED: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
Location: Personal Matters / Ex. 6

Start: 1/26/2018 7:00:00 PM
End: 1/26/2018 8:30:00 PM
Show Time As: Busy

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/16/2018 11:54:30 AM
To: Kelley.Scanlon@fns.usda.gov
Subject: FW: FYI - SAB workgroup Pans Pruitt's Science Transparency Rule, Seek SAB Review - memo attached
Attachments: epa2018_0856.pdf

Personal Matters / Ex. 6

From: Flowers, Lynn
Sent: Wednesday, May 16, 2018 7:41 AM
To: Kuhn, Kevin <Kuhn.Kevin@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Teichman, Kevin <Teichman.Kevin@epa.gov>; Blancato, Jerry <Blancato.Jerry@epa.gov>; Christian, Megan <Christian.Megan@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Grifo, Francesca <Grifo.Francesca@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>
Subject: FYI - SAB workgroup Pans Pruitt's Science Transparency Rule, Seek SAB Review - memo attached

DAILY NEWS

Top Advisors Pan Pruitt's Science Transparency Rule, Seek SAB Review

May 15, 2018
Top EPA science advisors, including Administrator Scott Pruitt's hand-picked chair of the agency's Science Advisory Board (SAB), are strongly criticizing the administrator's controversial plan to require only publicly available research to justify its regulations, charging it will undermine rules' integrity and was developed without adequate review.
"The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits," an SAB work group said in a May 12 memo recommending the full SAB review the measure.
The work group even warns that the proposed rule "could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts," and suggests several steps to ease the rule's limits to allow for the use of confidential data.
And echoing concerns from EPA staff, environmentalists, states and Democratic lawmakers, the memo warns that the measure was developed without adequate review from the public, the scientific community and others and calls for the full SAB to review the measure.
"Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community," the memo says.
"The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts," the memo says. "As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from [SAB]," it adds.
The work group's May 12 memo is scheduled to be considered by the chartered SAB at its next meeting, slated for May 31-June 1 in Washington, D.C. The board is already scheduled to consider an earlier work group report that calls for the SAB to review Trump EPA plans to roll back three Obama-era climate rules -- for new and existing power plants, as well as new and modified oil and gas sources -- because they concluded EPA may not use adequately peer-reviewed science to justify the plans.
Historically, SAB work groups reviewing EPA regulatory agendas rarely find actions that meet their strict criteria to merit further review, but such calls appear to have become more common.
The latest recommendation for SAB review was issued quickly, weeks after Pruitt signed the measure April 24.
The full board -- with its slate of new members selected by Pruitt -- could reject the work group's advice, but the recommendation still raises the heat on an already controversial proposal.
And while SAB's earlier work group recommending review of the three climate rules contained few Pruitt appointees, the updated membership of the work group recommending full SAB action on the science transparency rule includes its new chairman, Michael Honeycutt, a top Texas state risk assessor, who Pruitt appointed to the post late last year.
The work group also includes John Graham, another Pruitt appointee who led the Bush administration's White House Office of Information and Regulatory Affairs. Graham was instrumental in advancing a controversial risk assessment guidance for federal agencies until it was forced into a critical National Academy of Sciences (NAS) review, which in 2007 recommended that it be dropped.

In a statement to *Inside EPA* the agency replied, SAB "plays an important role in informing EPA actions on policy and regulatory matters. We value the Board's expertise, and we welcome feedback from the chartered panel on areas in which they are interested in getting additional scientific information that is relevant to the rulemaking process."

Proposed Rule

The proposed rule generally bars EPA staff from basing regulatory actions on any science where the underlying data and modeling is not publicly available, though the plan allows the administrator to waive the requirements. The concept is based on controversial legislation long championed by House science committee chairman Lamar Smith (R-TX), which twice passed the House but has failed to advance in the Senate.

Critics charge it is intended largely to block the use of long-standing confidential medical studies that the agency has relied on when setting strict air quality and other health-based standards, though the chemical and pesticide industries have also raised concerns it could affect the use of confidential business information.

Environmentalists are especially concerned that the proposal targets the agency's long-time use of strict, default linear dose-response models, which Republicans and industry groups say result in stricter rules than are needed.

Many observers have warned the measure faces significant legal hurdles, including vague or undefined terminology, statutory mandates likely at odds with the rule and potential violations of administrative law.

The proposal was published in the *Federal Register* April 30 for a 30-day public comment period, though environmentalists, states and Democratic senators have urged the agency to withdraw the proposed rule to consult with the National Academy of Sciences and to extend the comment period by as much as 150 days to allow for such NAS consultation.

EPA staff has also warned that the measure was rushed through intra-agency review without the usual staff and program office input that such significant measures usually receive. As a result, they say it is unclear whether the agency will be able to finalize the proposal in its current form because officials did not create an agency-wide group that would be able to review and respond to the thousands of comments the agency is likely to receive.

The SAB work group memo echoes much of the criticisms, noting that the proposed rule "would limit the use of science based on human subject data and would impose requirements for the analysis of dose-response relationships widely used in risk assessments across a wide range of agency programs."

While acknowledging the value of transparency in underlying data, modeling and approaches, as well as the efforts in multiple science fields to advance transparency, the work group adds that it is not always possible, especially for studies published in the past. "There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate," the work group writes.

The work group adds that the proposed rule "fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods" and "oversimplifies" its argument that it is easy to address confidentiality concerns through existing methods, such as redaction.

And, the memo criticizes the draft rule's efforts to make transparent "the dose response data and models that underlie what we are calling 'pivotal regulatory science'." Rule language on dose-response modeling appears to target EPA's longstanding cancer risk assessment guidance, which as a default directs agency risk assessors to use linear modeling -- assuming no safe exposure -- unless there is biological information directing otherwise.

The work group says that the proposed rule's "requirement of the consideration of multiple dose-response models should explicitly state that this consideration is based on information relevant to the selection of the most scientifically-appropriate model(s) such as biological plausibility, mode of action, or mechanism of action. Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data."

The work group also suggests several other steps EPA take to soften the proposal, including limiting its application to future studies rather than those already designed or published.

"It might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish."

"It might also be easier if the rule took into account reasonable areas for accommodation or exception in situations for which it is not possible to release a data set publicly either entirely, or without revision, for legitimate reasons pertaining to the use, for example, of human subject data," the memo adds. -- *Maria Hegstad*(mhegstad@iwpnews.com)

-----Original Appointment-----

From: Kuhn, Kevin

Sent: Thursday, May 10, 2018 3:19 PM

To: Kuhn, Kevin; Vandenberg, John; Bussard, David; Teichman, Kevin; Blancato, Jerry; Flowers, Lynn; Christian, Megan; Bahadori, Tina; Sinks, Tom; Grifo, Francesca; Hauchman, Fred; D'Amico, Louis; Doa, Maria

Subject: General Discussion - small group

When: Tuesday, May 15, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41107-1; DCRoomRRB41107-2; Call in: 202-991-0477; code: 3335473

Please find relevant materials for the conversation at the following SharePoint site:
https://usepa.sharepoint.com/sites/ORD_Work/io_small_workgroup/SitePages/Home.aspx

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/26/2018 12:54:43 PM
To: Leopard, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c7e250715234083a7a99796d2543127-Leopard, Matthew]
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

This is the PDF of the NPRM

From: Orme-Zavaleta, Jennifer
Sent: Tuesday, April 24, 2018 4:01 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; ORD-Exec-Council-Directors <Execcouncildirectors@epa.gov>
Subject: FW: SIGNED: Strengthening Transparency in Regulatory Science

From: Johnson, Laura-S
Sent: Tuesday, April 24, 2018 3:10 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

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In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/25/2018 5:47:01 PM
To: Personal Matters / Ex. 6
Subject: FW: Data access and Regulatory Science
Attachments: Strenthening Transparency in Regulatory Science 04-24-2018.pdf

In case your UW email no longer works

From: Sinks, Tom
Sent: Wednesday, April 25, 2018 8:23 AM
To: Falk, Henry (CDC/ONDIEH/OD) (CTR) <hxf1@cdc.gov>; Jackson, Richard J. < Personal Matters / Ex. 6 Howard Frumkin (frumkin@uw.edu) <frumkin@uw.edu>; Chris Portier < Personal Matters / Ex. 6 >; Burke, Thomas <Burke.Thomas@epa.gov>
Cc: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: Data access and Regulatory Science

Former Boss Colleagues:

Yesterday, Administrator Pruitt signed the attached Proposed rule which should appear in the Federal Register shortly. While it was developed as the Administrator's response to a proposed law passed last year by the House but not taken up by the Senate (HONEST ACT), it is not identical. Please feel free to consider it and distribute it to those who would wish to comment.

Thomas Sinks, Ph.D.
Director, Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Room 41251 RRB, MC 8105 R
Washington DC, 20460
office: (202) 564-3099 mobile: (404) 226-6288
email: sinks.tom@epa.gov

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 4/25/2018 1:04:20 PM
To: O'Farrell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4af53b2f4a4b43c8b5013a26c430d5d8-O'Farrell, Thomas]
CC: Arling, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d34c279dcae9457facbeae51c602af4e-Arling, Michelle]; Nelson, Daniel K. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9bd641d949d4a96b2d6c307be288afa-Nelson, Dan]
Subject: Re: SIGNED: Strengthening Transparency in Regulatory Science

Possibly.

Sent from my iPhone

On Apr 25, 2018, at 9:02 AM, O'Farrell, Thomas <OFarrell.Thomas@epa.gov> wrote:

> Yes so just thinking for a second. Will this affect OPP's ability to make decisions based on human subjects research? Or maybe I'm missing something.
>
> Tom
>
> **From:** Sinks, Tom
> **Sent:** Wednesday, April 25, 2018 8:10 AM
> **To:** STPC Members <STPC_Members@epa.gov>; STPC_SSP <STPC_SSP@epa.gov>
> **Cc:** Sinks, Tom <Sinks.Tom@epa.gov>
> **Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science
>
> Yesterday today Administrator Pruitt announced this proposed rule. The proposed rule touches upon three aspects of OSA work – public access to EPA funded research, human subjects research protection, and scientific integrity. It has highly significant implications for EPA programs and regions in defining how access to research data is used in rulemaking.
>
> I presume it will be released in the Federal Register shortly. The proposed rule seeks comments and I suspect your state, local, academic, industry, and NGO partners will be interested. Please feel free to distribute it to them.
>
> **From:** Orme-Zavaleta, Jennifer
> **Sent:** Tuesday, April 24, 2018 4:01 PM
> **To:** Sinks, Tom <Sinks.Tom@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; Robbins, Chris <Robbins.Chris@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Hauchman, Fred <hauchman.fred@epa.gov>; ORD-Exec-Council-Directors <Execcouncildirectors@epa.gov>
> **Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science
>
> **From:** Johnson, Laura-S
> **Sent:** Tuesday, April 24, 2018 3:10 PM
> **To:** Jackson, Ryan <jackson.ryan@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Lyons, Troy

<lyons.troy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; White, Elizabeth <white.elizabeth@epa.gov>; Bodine, Susan <bodine.susan@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Leopold, Matt <Leopold.Matt@epa.gov>; Bowman, Liz <Bowman.Liz@epa.gov>; Wheeler, Andrew <wheeler.andrew@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Wooden-Aguilar, Helena <Wooden-Aguilar.Helena@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>; Hope, Brian <Hope.Brian@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>; Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Gaines, Cynthia <Gaines.Cynthia@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Maguire, Kelly <Maguire.Kelly@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: SIGNED: Strengthening Transparency in Regulatory Science

Good afternoon
Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,
Laura

Laura S. Johnson | U.S. Environmental Protection Agency
Special Assistant, Office of the Administrator | Cell (202) 819-4941
Office (202) 566-1273 | johnson.laura-s@epa.gov

August 16, 2018

The Honorable Andrew Wheeler
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Strengthening Transparency in Regulatory Science, Proposed Rule published April 30, 2018; Agency Docket Numbers EPA-HQ-OA-2018-0259; FRL-9977-40-ORD; FRL-9978-31-ORD

Dear Administrator Wheeler:

As leaders at the University of Washington with particular expertise in environmental policy, we are writing to comment on the proposed rule on "Strengthening Transparency in Regulatory Science." The University of Washington is a leading research-intensive institution of higher learning, and is proud to conduct scientific research that has lasting impact and can contribute to the public good. Our institution has a history of conducting research that informs regulatory decision-making, termed as "pivotal regulatory science" in this proposed rule. We find that the proposed rule places substantial and unreasonable restrictions on what research EPA can consider in its decision-making for regulating important environmental factors including air pollution, water pollution, toxic chemicals, and agents with climate impacts. This rule would negate the use, application, and impact of existing and future valid research and hence threaten public health. The University of Washington recommends that the EPA withdraw this proposed rule, for the reasons discussed below.

The proposed rule would limit consideration of science in decision-making in a manner that is unjustified and arbitrary, and would lead to inadequate regulatory protections, inconsistent with federal law. Existing law and precedent dictates that the EPA take action based on the weight of scientific evidence even in the face of some uncertainty. This requires that the agency considers all available scientific evidence in its decision-making and not make arbitrary exclusions of research. The principal focus of the proposed rule is to require full access to original data for scientific studies in order for those studies to be used for regulatory decision-making. While the preamble to the rule indicates that this could be done while maintaining the protection of privacy and confidentiality of research participants, the proposed rule does not include specific provisions to make these protections possible. A substantial amount of pivotal regulatory science includes epidemiological research in which the maintenance of privacy and confidentiality of research participants is essential to conducting the research. As examples, we can note two papers from the University of Washington that involved studies that ensure confidentiality of the participants (Miller KA et al, Long-term exposure to fine particulate matter air pollution and cardiovascular events in women. New England Journal of Medicine 2007; 356:447-58; and Kaufman JD et al, Association between air pollution and coronary artery calcification within six metropolitan areas in the USA [The Multi-Ethnic Study of Atherosclerosis and Air Pollution]: a longitudinal cohort study. The Lancet 2016; 388:696-704). Both studies contain dose response data and models as anticipated in the proposed rule, and for which the proposed rule creates an

expectation that data required to replicate the analysis be made available. In each case, the underlying studies are conducted with strict rules under the auspices of the National Institutes of Health (National Heart, Lung, and Blood Institute), that preclude any potential identification of subject identity or confidential information. The NIH and the approving institutional review boards would not permit release of the data in a way that would adhere to the letter of the rule. It is possible that limited datasets could be created for replication analysis that would protect participant identity and confidential information, but funds are not available to create these datasets, and the rule is not clear that such a limited dataset would be acceptable. As a result, the rule would lead to arbitrary exclusion of pertinent scientific evidence.

Existing processes for evaluating the quality of scientific data are adequate. The current state of scientific practice permits decision-makers to consider all peer-reviewed science and make decisions based on the weight of evidence. The proposed rule suggests that there is a crisis to be addressed, in that scientific data to support environmental decision-making cannot be replicated. The rule cites examples primarily related to replication issues in the pharmaceutical industry. Such issues are not documented to be prevalent in the environmental research area. The studies which are frequently noted to be problematic since raw data was not available for replication—the Harvard Six Cities Study and American Cancer Society CPS II cohorts studies which demonstrated the effect of particulate matter on cardiovascular disease—have not only been independently confirmed by reanalysis by the independent Health Effects Institute, but also replicated by dozens of subsequent research studies [see the two papers cited above as well as Hoek et al Environmental Health 213; 12:43]. The scientific peer review process, along with the ability to weigh the entire extent of published data, is entirely adequate to determine the state of the evidence regarding environmental effects of agents considered for regulation. The solution to an inadequate research database for regulatory decision-making is not to exclude research from consideration as proposed in this rule, but rather to provide funding and incentives for more and better research to answer important environmental questions. The proposed rule cites policies from several leading journals as justifying the need for the proposed rule, however, the editors of all of those journals (Science, Nature, PLOS, PNAS, and Cell) wrote to indicate this rule is not justified.

We recommend that the EPA withdraw the proposed rule and focus on: 1) implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies; and 2) encouraging development of high-quality research that can be used to provide pivotal regulatory science, through funding of important research topics and through processes to establish datasets which can be used for replication of key findings.

Sincerely,

Hilary Godwin, PhD Dean and Professor UW School of Public Health	Lisa J. Graumlich, PhD Mary Laird Wood Professor & Dean UW College of the Environment	Joel Kaufman, MD, MPH Acting Associate Dean and Professor UW School of Public Health

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 8/29/2018 3:17:22 PM
To: Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Kumar, Manisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497133a6697a45f9bea221a07f4359f6-Kumar, Mani]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
CC: Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]
Subject: RE: OSA website

I don't know what we had on the intranet. This was from the internet

From: Greene, Mary
Sent: Wednesday, August 29, 2018 11:15 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Kumar, Manisha <Kumar.Manisha@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Cc: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>
Subject: RE: OSA website

Will this need to be posted on both the inter and intranet?

From: Sinks, Tom
Sent: Wednesday, August 29, 2018 11:00 AM
To: Kumar, Manisha <Kumar.Manisha@epa.gov>; Greene, Mary <greene.mary@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Cc: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>
Subject: OSA website

Suggested edits to the OSA page … https://www.epa.gov/osa/strengthening-transparency-regulatory-science Please coordinate so we only change the webpage once. We should make the change once OSP has established an email box and the transcripts are posted on regulations.gov

Strengthening Transparency in Regulatory Science

A Proposed Rule by the Environmental Protection Agency on 04/30/2018

This action provides that EPA will ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation. Where available and appropriate, EPA will use peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments. This action is consistent with the principles underlying the Administrative Procedure Act and programmatic statutes that EPA administers to disclose to the public the bases for agency rules and to rationally execute and adequately explain agency actions. This action is also consistent with Executive Orders 13777 and 13783, and the focus on transparency in

OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies (the Guidelines) and OMB Memorandum 13-13: Open Data Policy – Managing Information as an Asset. It builds upon prior EPA actions in response to government-wide data access and sharing policies, as well as the experience of other federal agencies in this space.

The comment period on the proposed rule was open from April 30, 2018 to August 16, 2018. A public hearing for the proposed rule was held on July 17, 2018 in Washington, DC.

EPA has started reviewing the more than 500,000 comments received. EPA will be reviewing these comments through the fall. EPA will determine a timeline for a decision after it has more fully assessed the comments.

Final Federal Register Notice: Strengthening Transparency in Regulatory Science-- Extension of Comment Period and Notice of Public Hearing

To read written comments posted to the docket, please visit Regulations.gov: Docket ID No. EPA-HQ-OA-2018-0259.

The transcripts of the public hearing have been posted on the docket as supplemental information.

You may need a PDF reader to view some of the files on this page. See EPA's About PDF page to learn more.

- List of Speakers for Public Hearing (PDF)(4 pp, 59 K)
- Strengthening Transparency in Regulatory Science-- Extension of Comment Period and Notice of Public Hearing (PDF)(6 pp, 55 K)

Related Documents

Federal Register Notice: Strengthening Transparency in Regulatory Science

News Release: EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations

Contact Us to ask a question, provide feedback, or report a problem.

Thomas Sinks, Ph.D.
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email: sinks.tom@epa.gov

COMMENTS OF ATTORNEYS GENERAL OF NEW YORK, NEW JERSEY, CALIFORNIA, CONNECTICUT, DELAWARE, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NORTH CAROLINA, OREGON, PENNSYLVANIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION, AND THE ATTORNEYS OF KING COUNTY, WASHINGTON AND THE CITIES OF CHICAGO, LOS ANGELES, NEW YORK, OAKLAND, PHILADEPHIA AND SAN FRANCISCO

August 16, 2018

By Electronic Submission to www.regulations.gov

Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OA-2018-0259, Proposal to Limit Use of Scientific Evidence in Rulemaking, 83 Fed. Reg. 18,768 (April 30, 2018).

Dear Acting Administrator Wheeler:

The undersigned twenty-three State Attorneys General and County and City Attorneys respectfully submit the following comments on the U.S. Environmental Protection Agency's (EPA) April 30, 2018 proposal to limit the use of scientific evidence in rulemaking, 83 Fed. Reg. 18,768. The proposed rule would severely limit the scientific evidence that EPA can consider when adopting rules and standards to protect human health and the environment. It violates controlling federal law, is arbitrary and capricious, and contains clear errors in reasoning. The proposed rule was also issued without adequate review, most notably without *any* review from EPA's own science advisors. It will not "improve" the science relied upon by EPA, but will instead exclude much, if not most, of the science underpinning EPA action to protect the environment and our citizens from harm. Coupled with the former Administrator's directive prohibiting EPA grant recipients from serving on scientific advisory panels, the proposal reflects an effort to subvert well-founded agency practices for developing science-based regulations. This proposal is particularly troubling given EPA's critical mission and its significant responsibilities to the American people. EPA's change in leadership provides a unique opportunity to hit the reset button; we urge you to withdraw this harmful and deeply flawed proposal.

EXECUTIVE SUMMARY

While the proposal is worded vaguely, the intent is clear—in developing future regulations to protect human health and the environment, EPA would be precluded from considering relevant, probative scientific studies, models, or other information that have been

validated through peer review, on the sole basis that the underlying data are not publicly available.

It is equally clear that the proposed rule would violate the very federal laws EPA is required to uphold. To cite just a few examples, in performing its duties, EPA must rely on "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices," 42 U.S.C. § 300g-1(b)(3)(A)(i) (Safe Drinking Water Act); on the "best available science," 15 U.S.C. § 2625(h) (Toxic Substances Control Act); on "the latest scientific knowledge," 33 U.S.C. § 1314(a)(1) (Clean Water Act) and 42 U.S.C. § 7408(a)(2) (Clean Air Act); and on "generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies," 42 U.S.C. § 11023(d)(2) (Emergency Planning and Community Right-to-Know Act). Indeed, no federal environmental law so much as suggests that, in setting standards, EPA can ignore the "latest" or "best" or "appropriately designed and conducted" scientific studies whenever any portion of the underlying data is not public—which is often the case for important privacy reasons. The scientific community has made clear that such a limitation is *not* in accordance with best practices. This anti-science approach has stalled in Congress and been rejected by the courts; it has no place at EPA. Indeed, in rejecting an industry effort to impose the same strictures imposed here, the D.C. Circuit was persuaded by EPA's position that "requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary,'" and agreed with EPA that such a requirement would mean "'much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment.'" *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

EPA's proposal would also violate the Administrative Procedure Act (APA), 5 U.S.C. § 501 *et seq.*, both because it is arbitrary and capricious, and because it flouts that Act's important procedural requirements. EPA claims that the entire basis for the proposed rule is to ensure that the "pivotal regulatory science" underlying EPA regulations is transparent. But EPA ignores existing laws and policies that already do exactly that and which also take into account the need to protect medical data and other confidential information. This proposed rule would promote transparency in name only; in truth, it would mean that EPA's important decisions would no longer be informed by the latest, best available, and generally accepted science. Disturbingly, the proposed rule's only failsafe is the EPA Administrator's sole discretion to determine on a case-by-case basis that compliance is "impracticable" when making data publicly available is "not feasible." But the proposal provides no standards to govern the Administrator's exercise of discretion in determining "impracticability or "feasibility"—a recipe for the very arbitrariness that the APA prohibits.

With respect to EPA's process, this proposal has been rushed, is vague, and creates more questions than it answers: it does not clearly state the actual parameters of the proposed rule, it is open-ended in terms of alternatives under consideration, and it fails to provide critical information such as projected costs. It is also completely unclear—or worse, contradictory—whether and how this proposed rule would apply to EPA's cost-benefit analyses. Still more troubling, EPA has failed to consult its own Science Advisory Board (SAB) about this proposed rule despite the SAB's assessment that "this rule deals with a myriad of scientific issues for

which the Agency should seek expert advice."[1] Proposing a rule that limits the use of scientific data without even notifying, let alone consulting, the Agency's own expert scientific advisors is a text book example of an arbitrary and capricious failure to consider "relevant factors." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983).

In light of these substantive and procedural infirmities, it is unsurprising that the proposed rule also makes little sense as a matter of science. Although EPA now claims that science is "better" only when both the underlying information is publicly available and the results reproducible, that position is contrary to the scientific consensus, and EPA provides no support for its assertion. The downsides of this proposal are significant: critical studies already designed and published on virtually all aspects of public health and environmental protection have relied on information for which complete disclosure is impossible for various reasons, including legally mandated confidentiality protections. This is particularly true of seminal and long-standing epidemiological studies that EPA has relied upon in setting air and other health-based standards. Therefore, the proposal would force EPA to ignore important peer-reviewed studies of health effects in future regulatory efforts. As our nation's leading scientists at the National Academies of Sciences, Engineering, and Medicine (NAS) warned in a July 16, 2018 letter to EPA, the proposal's overly stringent transparency requirements "pose a threat to the credibility of regulatory science."[2]

Although EPA stated in its proposal that this rule would not affect any states, and therefore has no federalism implications, nothing could be further from the truth. The adoption of this proposed rule would very likely affect the protectiveness of the standards that EPA sets, which would significantly impact federal and state efforts to protect the quality of our air, water, and land, and the health and welfare of the American people. Some states' environmental laws and regulations explicitly adopt EPA standards in all or some instances, or at the very least require an express justification for any deviation. So it is clear that a fundamental change in how EPA develops standards would most certainly affect state standards, and therefore would affect the health of our residents and our natural resources.

---

[1] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science to Members of the Chartered SAB and SAB Liaisons, *Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)* 2 (May 12, 2018) [hereinafter SAB Work Group Memo], *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf.

[2] Letter from Marcia McNutt, President, Nat'l Acad. of Sciences, C.D. Mote, Jr., President, Nat'l Acad. of Eng. & Victor J. Dzau, President, Nat'l Acad. of Med., to Andrew Wheeler, Acting Administrator, U.S. Envtl. Prot. Agency (July 16, 2018) [hereinafter NAS Letter], *available at* http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf.

For all these reasons, as discussed in detail below, we oppose this misguided proposal to limit the science on which EPA relies. EPA should withdraw this flawed proposal and return to its core mission of protecting human health and the environment.

LEGAL COMMENTS

I. EPA Lacks Statutory Authority to Promulgate the Proposed Rule, Which Conflicts with Statutory Requirements Regarding EPA's Consideration of Scientific Information

Agencies may not adopt or implement regulations that conflict with the statutes under which they are promulgated, and an agency's interpretation of those statutes must always at least be reasonable. *See Chevron, U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). Accordingly, an agency's regulations cannot be "arbitrary, capricious, or manifestly contrary to the statute," *id.*, or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706. Further, agencies may not rely on general statutory grants of rulemaking authority to promulgate regulations that are otherwise inconsistent with more specific statutory directives. *Global Van Lines, Inc. v. Interstate Commerce Comm'n*, 714 F.2d 1290, 1293-97 (5th Cir. 1983).

In this case, the proposed rule is at odds with provisions of multiple statutes EPA is charged with implementing. For example:

- The Clean Air Act (CAA) requires that air quality criteria "accurately reflect *the latest scientific knowledge* useful in indicating the kind and extent of *all identifiable effects on public health or welfare*." § 108(a)(2), 42 U.S.C. § 7408(a)(2) (emphases added).

- The Safe Drinking Water Act (SDWA) requires that findings which support a determination to regulate a contaminant "be based on *the best available public health information*," and that, in developing the National Primary Drinking Water Regulations, "to the degree that an Agency action is based on science, the Administrator shall use *the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices*." §§ 1412(b)(1)(B)(ii)(II), 1412(b)(3)(A)(i), 42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(3)(A)(i) (emphases added).

- The Clean Water Act (CWA) requires that water quality criteria "accurately reflect[] *the latest scientific knowledge*." § 304(a)(1), 33 U.S.C. § 1314(a)(1) (emphasis added).

- The Toxic Substances Control Act (TSCA) requires the Administrator, in decisions based on science, to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed *in a manner consistent with the best available science*," and, in carrying out certain sections of the Act, to "take into consideration information relating to a chemical substance or mixture . . . that is

reasonably available to [him or her]." § 26(h), (k), 15 U.S.C. § 2625(h), (k) (emphases added).

- The Emergency Planning and Community Right-to-Know Act (EPCRA) requires that a determination to add a chemical to the Toxics Release Inventory "be based on *generally accepted scientific principles or laboratory tests, or appropriately designed and conducted epidemiological or other population studies, available to the Administrator*." § 313(d)(2), 42 U.S.C. § 11023(d)(2) (emphasis added).

Even statutory provisions that EPA chose to cite as authority for the proposed action prohibit the Agency from promulgating the proposed rule. For example, CWA § 104(l) explicitly requires that "[t]he Administrator shall . . . develop and issue . . . *the latest scientific knowledge available* in indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in water." 33 U.S.C. § 1254(l) (emphasis added). It strains credulity to believe that a directive to issue the "latest scientific knowledge available" somehow imposes a requirement that the Administrator only issue knowledge based on publicly available data, and EPA has not supplied any substantive argument that it does. Similarly, although Section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) directs that regulations "take into account . . . *the appropriate data* for evaluating [] risk," 7 U.S.C. § 136w (emphasis added), it would be arbitrary and capricious to define "appropriate" to exclude from consideration relevant and valid scientific studies, as EPA proposes to do in this rulemaking. Requirements to review the "latest" and "appropriate" scientific data are not carte blanche to impose new, unscientific limits on that data.

Because the proposed rule would run afoul of these provisions and potentially others,[3] EPA's citation to general rulemaking authorities such as CAA § 301(a), 42 U.S.C. § 7601(a), and CWA § 501, 33 U.S.C. § 1361, is unavailing. Such general provisions of rulemaking authority cannot override more specific statutory directives. *Global Van Lines*, 714 F.2d at 1293-97. Nor can EPA's reliance on 5 U.S.C. § 301 in the notice extending the comment period save its *ultra vires* proposal. 83 Fed. Reg. at 24,256. Known as the "housekeeping statute," 5 U.S.C. § 301 is "simply a grant of authority to the agency to regulate its own affairs," not a general, independent basis for deviating from a specific statutory directive or limiting the scope of other statutes. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 308-12 (1979).

Thus, as a general matter, EPA's obligation is clear: it must base its decisions on such criteria as the latest scientific knowledge, the best available, peer-reviewed science, and/or generally accepted scientific principles or laboratory tests. No statute suggests that EPA, in setting standards, can reject scientific evidence that meets those criteria solely because the underlying data are not public or because the evidence is based on models that otherwise follow long-accepted scientific guidelines. In short, EPA lacks sufficient legal authority to either adopt or implement the proposed rule, and its proposed action conflicts with the statutes it must follow.

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[3] For example, CAA § 184(d), 42 U.S.C. § 7511c(d), "require[s] that the best available air quality monitoring and modeling techniques be used" in setting the criteria for determining ozone contributions in nonattainment areas.

II. The Proposal Does Not Meet Baseline Rulemaking Requirements and Should Be Withdrawn

a. EPA Failed to Obtain Input from Scientists in Developing a Proposal with Sweeping Impacts on Agency Use of Science

Common sense, good government, and the APA's fundamental requirement for informed decision-making all dictate that an agency developing a proposed rule should consult with persons having expertise regarding the subject matter of the proposal. EPA's Scientific Integrity Policy makes clear that these principles apply with great force here: "it is essential that the EPA's policymakers involve science experts on scientific issues and that the scientific information and processes relied upon in policymaking manifest scientific integrity, quality, rigor, and objectivity."[4] Indeed, Congress mandated in the Environmental Research, Development and Demonstration Authorization Act of 1978 that when EPA provides a proposed rule such as the one at issue here to another federal agency for formal review and comment, it must also provide that same proposal to the SAB: "the Administrator . . . shall make available to the [SAB] such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based." 42 U.S.C. § 4365(c)(1). Yet, as revealed in a June 28, 2018 letter from the SAB Chair to former Administrator Pruitt, EPA violated this fundamental requirement: although EPA provided the proposed rule to the Office of Management and Budget (OMB) for review on April 18, 2018, the SAB never had the opportunity to review it and instead learned of the proposal only from subsequent news reports and the April 30, 2018 *Federal Register* notice.[5]

Nor did EPA obtain input from the NAS or any other external science organizations or experts in developing the proposal. As the SAB work group noted: "Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community." SAB Work Group Memo at 3.

EPA offers no explanation for its inexplicable failure to consult with science experts, including the SAB, on this proposal, and it is beyond question that this highly consequential proposal demanded such consultation. Not only is this statutorily required, *see* 42 U.S.C. § 4365(c)(1), but as the SAB Work Group Memo states, "[t]he proposed rule deals with issues of scientific practice and proposes constraints that the [A]gency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for

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[4] U.S. Envtl. Prot. Agency, *Scientific Integrity Policy* 3, *available at* https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.

[5] Letter from Michael Honeycutt, Chair, Science Advisory Bd., to E. Scott Pruitt, Administrator, U.S. Envtl. Prot. Agency 2 (June 28, 2018) [hereinafter SAB June 28 Letter], *available at* https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf

which the Agency should seek expert advice from the [SAB]." SAB Work Group Memo at 2. Underscoring the importance of the issue, the full 44-member SAB followed up on the Work Group's Memo with a unanimous vote to review the proposal and urged EPA to proceed no further until EPA does what it should have done in the first place: "request, receive and review scientific advice from the SAB." SAB June 28 Letter at 1.

Put simply, EPA's effort to rush this proposed rule out the door without any input from the SAB or other scientists violates basic principles of good government and policy-making as well as EPA's legal duty. We urge EPA to withdraw this ill-conceived proposal and to consult with the SAB, the National Academy of Sciences, and the broader scientific community before determining if any rule is needed.

b. The Proposal is Too Vague, Conclusory, and Conditional to Allow for Meaningful Public Participation

EPA's failure to solicit input from the SAB and other scientific groups is exacerbated by its failure to meet the fundamental legal requirements for a valid rulemaking proposal under the APA. The APA requires that "general notice of proposed rulemaking shall be published in the Federal Register," including the "terms or substance of the proposed rule." 5 U.S.C. § 553(b). The straightforward purpose of this requirement is to give the affected public an opportunity to provide meaningfully informed comment on an agency's proposal. *See Home Box Office, Inc. v. Fed. Commc'n Comm'n*, 567 F.2d 9, 35-36 (D.C. Cir. 1977). But here, EPA's notice of proposed rulemaking is vague as to the actual parameters of the proposed rule, is open-ended in terms of the alternatives under consideration, and fails to provide key information such as projected costs. Courts will not hesitate to strike down final rules based on proposals so lacking in specificity. *See, e.g.*, *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (noting that "general notice that a new standard will be adopted affords the parties scant opportunity for comment").

Far from meeting the requirement to "disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based," *Home Box Office*, 567 F.2d at 35–36, the proposal at issue here creates far more questions than it answers. Most fundamentally, the proposal fails to provide a rationale for EPA to act contrary to accepted scientific practice, i.e., to preclude consideration of probative scientific information that has been subject to rigorous peer review for the sole reason that underlying data are confidential and therefore not publicly available. The proposal states that "EPA believes the benefits of this proposed rule justify the costs," 83 Fed. Reg. at 18,772, but fails to provide any specific information, quantification, or analysis as to what EPA believes are the proposed rule's purported benefits or expected costs, including the significant costs from the loss of probative information that the proposed rule would work to exclude. For example, Section 30.7 of the proposed rule could be read to require EPA to undertake very costly independent review of "pivotal" science on which it relies, but Section 30.8, entitled "How is EPA to account for cost under this subpart?" states only that EPA will "minimize costs." *Id.* at 18,774. The absence of data and analysis in support of EPA's cost-benefit conclusion deprives the public of a meaningful opportunity to evaluate the proposal and thus violates EPA's duty under the APA.

Further, the proposal says the rule is intended to apply prospectively, but also states that EPA "should be guided by this policy to the maximum extent practicable during ongoing regulatory action." *Id.* at 18,771. Yet it never explains how or why ongoing EPA actions would be subject to the proposed rule and which existing scientific studies are implicated by the proposed rule. It also fails to acknowledge the costs from delays in rulemaking proceedings while EPA performs the additional review called for above and beyond the extensive scientific peer review to which scientific studies have already been subjected. Other open-ended aspects of the proposal similarly fail to provide commenters with a sufficient guide as to what any final rule would look like or how it would operate if adopted. For example:

- The proposal defines "pivotal regulatory science" as "the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions." *Id.* at 18,773. However, the proposal does not specify to what extent studies must support regulatory decisions to be considered a "driver," who will determine what qualifies as pivotal regulatory science, or at what stage of the rulemaking process such determinations will be made. The proposal is also unduly vague in its use of undefined terms that are subject to interpretation, such as the use of the term "uncertainty" in Section 30.6 of the proposed rule. *Id.* at 18,774.

- The proposal says EPA "should collaborate" with other agencies to identify strategies to protect private information (such as patient health records) when it is making information publicly available. *Id.* at 18,771. However, there is no timeframe for this process, no explanation of what will happen until such strategies are formed, and no indication of what these strategies will be.

- EPA asks "whether alternative or additional regulatory or other policy vehicles are appropriate to establish and implement these policies, and whether further regulatory or other policy vehicles on the programmatic or statutory level would be appropriate as alternative or additional steps." *Id.* It is EPA's job to identify and describe these alternatives, and to explain why it has put forward its particular proposal: it may not, at this late stage, ask amorphous questions on policy design.

- EPA seeks comment on criteria it should use to establish exemptions, whether case-by-case exemptions may be appropriate, whether the proposed rule should apply to a broader or narrower set of regulatory proceedings, and whether certain categories of regulatory actions should be exempt. *Id.* at 18,772. As written, the proposed rule would allow the Administrator to grant exemptions based solely on his or her own determination of what is "feasible" without offering any definition or bounds on that term. *Id.*

- EPA asserts that the proposed rule is generally consistent with a number of policies or reports by scientific groups or scientific journals, but it does not specify in what respects those documents support its proposal, nor does it identify any groups or reports that advocate precluding consideration of non-public data in regulatory decision-making. In fact, contrary to EPA's assertion, the Bipartisan Policy Center, a

group with which EPA claims consistency, clarified that the proposed rule "is not consistent" with the Center's position "in substance or intent."[6] EPA's false assertion of consistency with the policies and positions of leading science groups thus misleads the public and inhibits their informed participation.

- EPA seeks comment as to "whether the disclosure requirements . . . should be *expanded* to cover other types of data and information, such as, for example, economic and environmental impact *data and models that are designed to predict the costs, benefits*, market impacts and/or environmental impacts of specific regulatory interventions." 83 Fed. Reg. at 18,772 (emphasis added). However, EPA also states that the "pivotal regulatory science" to which the proposed rule would already apply includes "studies, models, and analyses that drive the magnitude of the benefit-cost calculation." *Id.* at 18,770. It is thus unclear whether and how EPA intends the proposed rule to apply to the cost-benefit determinations that it performs.

- The proposal provides no analysis of its environmental impacts and fails to explain how EPA has addressed the requirements of the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*

- The proposal fails to meet EPA's obligations under Executive Order 12898, which requires the Agency to address the proposal's "disproportionately high and adverse human health or environmental effects" on "minority and low-income populations." 59 Fed. Reg. 7629 (Feb. 16, 1994). Section IV.K of the proposal incorrectly asserts that Executive Order 12898 does not apply since the proposal "does not establish an environmental health or safety standard," 83 Fed. Reg. at 18,773. But the Executive Order by its own terms applies to the "effects of" all federal agency "programs, policies, and activities," 59 Fed. Reg. at 7629, and thus plainly applies here. While the proposal would jeopardize the health of all Americans, it would have increased impacts upon the nation's most sensitive populations—such as children, those with chronic illnesses, and environmental justice communities.

- The proposal likewise fails to meet EPA's obligations under Executive Order 13045, which requires the Agency to identify and assess environmental health risks that may disproportionately affect children. 62 Fed. Reg. 19,885 (Apr. 23, 1997). That Executive Order also requires each federal agency to "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks," *id.* at 19,885, and thus applies here.

- EPA states in conclusory fashion that the proposed rule "does not have federalism implications" and "will not have substantial direct effects on the states." 83 Fed. Reg. at 18,772-73. However, the proposal fails to explain whether or how the proposed rule would apply to EPA's review and approval of state standards, and, accordingly,

[6] Letter from Jason Grumet, President, Bipartisan Policy Center, to E. Scott Pruitt, Administrator, U.S. Envtl. Prot. Agency (May 22, 2018), *available at* https://www.eenews.net/assets/2018/05/31/document_gw_01.pdf.

deprives commenters of a full and fair opportunity to assess and comment on the proposal's federalism implications.

In sum, EPA's skeletal outline falls far short of the APA's notice requirements and fails entirely to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Natural Res. Defense Council, Inc. v. U.S. Envtl. Prot. Agency*, 859 F.2d 156, 209 (D.C. Cir. 1988). EPA should withdraw the proposal on these grounds alone.

c. EPA Failed to Identify Legal Authority for the Proposed Rule

The APA further requires that a notice of proposed rulemaking contain "reference to the legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2). "'[T]he required specification of legal authority must be done *with particularity*,'" and "'must be sufficiently precise to apprise interested persons of the agency's legal authority to issue the proposed rule.'" *Global Van Lines*, 714 F.2d at 1298 (quoting H.R. Rep. No. 1980, at 24 (1946) and U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 29 (1947)). EPA has also failed to meet this requirement.

In both the April 30, 2018 notice of proposed rulemaking and the May 25, 2018 notice extending the comment period, EPA discusses statutory authority for the proposed rule, citing to a number of provisions, largely from statutes it implements. 83 Fed. Reg. at 18,769; 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). In particular, EPA invokes the CAA, CWA, SDWA, EPCRA, FIFRA, TSCA, Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and Resource Conservation and Recovery Act (RCRA). 83 Fed. Reg. at 18,769.

But rather than identify legal authority with particularity, the cited statutory provisions mainly set forth EPA's broader authorities to conduct research and promulgate regulations. Few of the cited provisions actually address EPA's ability to pick and choose amongst valid scientific information, studies, and techniques in its formation of environmental standards and modeling, and none authorize the wholesale preclusion of probative, relevant studies, as EPA proposes here. Tellingly, in the proposal itself, EPA requests assistance to determine "whether additional or alternative sources of authority are appropriate bases for the proposed regulation." *Id.* at 18,771. EPA's inability to identify specific statutory authority for its proposed action falls far short of the APA's standard for notice and comment rulemaking, as would any ultimate reliance on statutory authority EPA has failed to cite. *See Global Van Lines,* 714 F.2d at 1297-99.

III. The Proposed Rule Arbitrarily and Capriciously Requires EPA to Exclude Relevant Studies and Models, and is not Saved by Exemption Provisions

The proposed rule opens the door for arbitrariness, bias, and selectivity in its application, in contravention of the factors that Congress has required EPA to consider in setting standards, such as the best available science or latest scientific knowledge.

The proposed rule disregards the APA's bedrock requirement that an agency's decision-making be based on a consideration of the relevant factors and data. *See Motor Vehicle*

Mfrs., 463 U.S. at 42-43 (articulating standard and citing numerous cases). An agency's action is arbitrary and capricious not only if the agency "entirely fail[s] to consider an important aspect of the problem," but also if it "relie[s] on factors which Congress has not intended it to consider." *Id.* at 43. The proposed rule would call for EPA to do both. First, in excluding studies and models from its consideration based only on whether the underlying data are publicly available or have been subject to additional independent review by EPA, EPA would be excluding studies and models that Congress has instructed it to consider by requiring it to use, for example, the "best available science" or "latest scientific knowledge." Second, because none of the statutes EPA administers specify that, in setting standards, it shall consider whether the studies and models it uses have publicly available data or have been independently reviewed by EPA, EPA would be using factors that Congress did not intend it to rely on in deciding to exclude studies and models based on the proposed rule. *See Am. Trucking*, 283 F.3d at 372 (finding that the CAA does not require EPA to "obtain and publicize the data underlying the studies on which the Agency relies"). EPA's failure to consider otherwise relevant studies and models that do not meet the proposed rule's requirements would therefore be arbitrary and capricious. *See Motor Vehicle Mfrs.*, 463 U.S. at 42-43.

In apparent recognition of the overly limiting nature of the proposed rule's requirements, the proposal also includes a provision that would allow the Administrator to grant case-by-case exemptions based on his or her subjective determination that compliance is "impracticable" because making data publicly available or conducting independent peer review is "not feasible." 83 Fed. Reg. at 18,774. However, allowing the Administrator to make ad-hoc exemptions for specific studies or models does not cure the proposed rule's fatal defect of requiring EPA to consider factors other than those specified by Congress. *See Alltel Corp. v. Fed. Commc'n Comm'n*, 838 F.2d 551, 561 (D.C. Cir. 1988) (holding that an agency "cannot save an irrational rule by tacking on a waiver procedure" because the "essence of waiver is the assumed validity of the general rule"). Rather, because the proposed rule contains no standards requiring the exemptions to be based on the relevance, importance, or scientific validity of the study or model at issue, the Administrator's ability to arbitrarily include certain studies at his or her discretion simply compounds the extent to which the proposed rule would allow EPA to deviate from the requirements of the statutes it is charged with implementing.

In addition, because the proposed rule offers no definition or standards to guide the Administrator's determination of what is "practicable" or "feasible," the exemption provision gives the Administrator broad discretion in making such determinations.[7] Without any

[7] The exception to the proposed rule's requirement of additional independent peer review, unlike the exception to the transparency requirement, does instruct the Administrator to look at Section IX of the OMB Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005), when making those determinations. *See* 83 Fed. Reg. at 18,774. However, this direction makes little sense because Section IX of the Bulletin primarily discusses situations in which peer review is not *needed* rather than not feasible. *See* 70 Fed. Reg. at 2667 (providing exceptions for individual adjudications, agency regulatory impact analyses, routine information, and accounting and other financial information). The use of Section IX as a guidepost is not only inappropriate but is also unhelpful because almost all of the situations described therein are outside the category of "pivotal regulatory science" that the proposed rule addresses. Notably, although

standardized and objective criteria, the exemption process could, for example, allow biased determinations by the Administrator that provide an exception for confidential business information in studies submitted by chemical and pesticide manufacturers, while excluding academic toxicology or epidemiology studies. The NAS also highlighted this concern, noting that "[d]ecisions about exemptions should be based on formal agency guidance and not according to criteria established by a single EPA employee." NAS Letter at 3. Given how severely the proposed rule would limit the scientific evidence available for EPA's use, the proposed exemption provisions could become the basis upon which *most* of the science relied on by EPA in its rulemaking is admitted. The exceptions could thus largely swallow the rule, resulting in greater arbitrariness in EPA regulatory actions rather than greater transparency.

IV. Existing Statutes, Policies, and Procedures Already Provide for Transparency and Ensure Scientific Reliability, Rendering the Proposed Rule Unnecessary

a. Existing Laws and Policies Promote Transparency

EPA's proposal is unnecessary because existing laws and policies already fulfill its stated purpose. EPA claims that the rule will ensure that the "pivotal regulatory science" underlying "significant" EPA regulations is fully transparent, and will ensure that underlying data and models are publicly available in a manner sufficient for independent validation. 83 Fed. Reg. at 18,770. Notwithstanding its stated purpose, the proposed rule would not add anything useful to the existing body of policies and laws already in place, which include mechanisms to provide for maximum transparency while taking into account the need to protect the privacy of medical data, confidential business information, and the like. These existing laws and policies include the following:

- A directive issued on February 22, 2013, by the White House Office of Science and Technology Policy directing federal agencies with more than $100 million in annual research and development expenditures (which includes EPA) to develop plans for increasing public access to the results of the research they support, specifically scholarly publications and digital data.[8]

- OMB Memorandum 13-13,[9] which mandates, among other things, broader public access to federal and federally funded data and information, and provides that

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there is an exemption for time-sensitive disseminations when the findings of a study have already been adequately peer-reviewed, there is no general exception for situations in which independent EPA review would be duplicative of external peer review that has already been performed.

[8] Memorandum from John P. Holden, Director, Executive Office of the President, Office of Science and Technology Policy, to Heads of Executive Departments and Agencies, *Increasing Access to the Results of Federally Funded Scientific Research* (Feb. 22, 2013), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

[9] Memorandum from Sylvia M. Burwell, Dir., Steve VanRoekel, Fed. Chief Info. Officer, Todd Park, U.S. Chief Tech. Officer &Dominic J. Mancini, Acting Administrator of the Office of Info.

information collection should be done in a way to support information dissemination. This includes building redaction, slicing, and exporting into how data are collected to reduce the cost of public access later on. The memorandum also requires agencies to create data catalogs to include datasets "that can be made publicly available but have not yet been released." *Id.*

- The Data Quality Act, also known as the Information Quality Act, which is designed to improve the quality, objectivity, utility, and integrity of data released by the federal government. 44 U.S.C. § 3501. Pursuant to this act, EPA issued *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*.[10] These Guidelines, which apply to rulemaking, among other things, provide that "EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. . . . [I]f access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken." *Id.* at 21.

- The Data Access Act (attached as a rider to the Omnibus Appropriations Act of fiscal year 1999, P.L. 105-277), which requires federal agencies, including EPA, to ensure that all research data produced under a federal award be made available to the public under the Freedom of Information Act. The law promotes public access while protecting privacy by excluding medical and business-related confidential data from disclosure. *See* 2 C.F.R. § 200.315 (which superseded OMB Circular A-110).

- EPA's November 2016 public access plan,[11] which covers publications and digital data and requires those seeking EPA research and development funding to develop data management plans that describe the data to be collected in their studies and approaches for preserving and providing access to that data. For publications, the plan requires researchers to make peer-reviewed journal articles resulting from federally funded research publicly accessible in designated repositories no later than a year after the official date of publication.

& Regulatory Affairs, Exec. Office of the President, Office of Mgmt. and Budget, *Open Data Policy—Managing Information as an Asset* (May 9, 2013), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2013/m-13-13.pdf.

[10] U.S. Envtl. Prot. Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (Oct. 2002) [hereinafter *Information Quality Guidelines*], *available at* https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf.

[11] U.S. Envtl. Prot. Agency, *Plan to Increase Access to Results of EPA-Funded Scientific Research* (Nov. 29, 2016), *available at* https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

In sum, while EPA should encourage making data available to researchers and the public where lawful and appropriate, existing laws and policies applicable to federal agencies already do that, while protecting the scientific integrity of the "pivotal regulatory science" considered by EPA in promulgating standards and weighing the various factors that impact those standards. EPA's proposal ignores these established transparency laws and policies in service of excluding relevant science, thereby undercutting the environmental laws that EPA enforces by limiting the use of best available science.

b. Existing Policies and Procedures Provide for a Robust and Transparent Peer Review Process That Ensures the Validity of Scientific Information Relied Upon by EPA, and EPA Provides No Explanation for Why an Additional Level of Review Is Required

EPA has a long history of peer review of scientific studies supporting its regulations, relying on independent analyses of studies while also giving respect to those privacy protections required by law or non-disclosure agreements. As the NAS has pointed out, the National Academies "have developed a long-standing body of work that demonstrates scientific literature can be evaluated in a transparent and objective manner without complete disclosure of the underlying data." NAS Letter at 2. And as several scientific journal editors have noted, scientists conducting peer review "are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results."[12] This peer review process ensures the reliability and validity of the scientific information relied upon by EPA in the regulatory process.

Existing policies and procedures for peer review include the following:

- EPA's *Peer Review Handbook* provides that if a regulation is supported by a scientific and technical work product, the underlying work product should be peer reviewed unless it meets listed exemption criteria.[13] The Handbook explains that a critical element in ensuring that decisions are based on sound and defensible science is to have an open and transparent peer review process. *Id.* at xiii.

- EPA vets scientific studies through several independent expert panels, including the SAB, the EPA Clean Air Scientific Advisory Committee, the EPA FIFRA Scientific Advisory Panel, and the EPA Chemical Assessment Advisory Committee. The Clean Air Scientific Advisory Committee routinely reviews and

[12] Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel & Deborah Sweet, *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Science, Apr. 30, 2018 [hereinafter *Joint Statement*], *available at* http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.full.pdf.

[13] U.S. Envtl. Prot. Agency, *Peer Review Handbook* 28, 44-45 (4th ed. 2015), *available at* https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf.

evaluates epidemiological and toxicological studies that are the basis for dose response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards (NAAQS); the Chemical Assessment Advisory Committee reviews toxicological assessments of various chemicals for inclusion in EPA's Integrated Risk Information System database;[14] and the NAS has reviewed EPA risk assessment practices numerous times.[15]

- Each of these independent committees or panels is required to be staffed by a "fairly balanced" mix of regulators, academics, and industry/consultant representatives who bring a well-balanced perspective to the process. *See* Federal Advisory Committee Act, 5 U.S.C. App. 2 § (5)(b)(2), (c).

- OMB bulletin entitled "Final Information Quality Bulletin for Peer Review," 70 Fed. Reg. 2664-02 (Jan. 14, 2005), is applicable to all federal agencies, including EPA, and establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. The bulletin was subject to extensive public and agency comment on two prior draft versions. It includes guidance to federal agencies on what information is subject to peer review, the selection of appropriate peer reviewers, opportunities for public participation, and related issues. The bulletin also defines a peer review planning process that provides for public participation whenever possible and permits the public and scientific societies to comment about which scientific reports and studies merit especially rigorous peer review.

The proposed rule ignores this existing robust peer review process and its role in independently validating scientific information and ensuring that published information meets the standards of the scientific community.

In addition, despite the existing peer review process, EPA apparently proposes to require that EPA itself conduct an additional "independent" review. *See* 83 Fed. Reg. at 18,774. Yet the proposal nowhere discusses how EPA would vet reviewers to identify persons who are purportedly more competent than those already used in past or current peer review processes, or the level of EPA staffing and associated costs that would be needed for additional review—only stating that EPA will implement the proposed rule in a manner "that minimizes costs." *Id.* at 18,774. But any requirement for EPA to conduct additional review would entail additional significant costs, contrary to the proposal's assertion. *Id.* at 18,772. The practical outcome of

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[14] *See, e.g.*, U.S. Envtl. Prot. Agency, *IRIS Assessment Development Process (2015), available at* https://www.epa.gov/sites/production/files/2015-09/iris_process_figure_2015.jpg (providing a graphical listing of all the rounds of review in the existing IRIS process, which includes internal review, intra-agency review, external review (public comments), and peer-review (SAB)).

[15] *See, e.g.*, Nat'l Research Council, *Science and Decisions: Advancing Risk Assessment* (2009), *available at* https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment.

the proposal is that EPA may end up relying on a much smaller number of studies and/or on a less robust subset of relevant available studies, thus undermining the regulatory decision-making process.

In sum, EPA fails to acknowledge the rigor of existing processes in statutes, policies and federal procedures, or to explain how its proposal would provide any added value and minimize costs. EPA should abandon this unnecessary and counterproductive exercise.

V. Obtaining Private Data May Not Be Practically Possible and, Even When it is Possible to Make Data Available, the Proposed Rule Would Unnecessarily Impose Substantial Costs to Do So

The proposal's suggestion that concerns about access to confidential or private data can simply be addressed through the application of tools used by other federal agencies, *id.* at 18,770-71, will be unworkable or impracticable for many past and even future studies. For example, the proposal cites to guidance regarding methods to de-identify protected health information under the privacy rules of the 1996 Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936. *Id.* at 18,771 n.17. That guidance document is 28 pages, contains detailed instructions for de-identification, including how experts are to assess the risk of identification of information, and emphasizes the importance of data-sorting systems to manage protected health information for the de-identification process, including use of a one-way cryptographic function to obscure personally identifiable information.[16] Among other things, the guidance provides that various identifiers of individuals—including all names, geographic subdivisions smaller than a state (with one exception), dates directly related to an individual, telephone numbers, biometric identifiers, and so forth—must be de-identified. *HIPAA Guidance* at 4-5. The guidance thus highlights that, in fact, it is not easy to address confidentiality concerns: the de-identification process is complex and must be designed into the overall study process, something that cannot be done for historic studies. Moreover, to the extent that one of the purposes of the proposal is to enable persons to replicate studies, this may not be possible where the de-identified data is critical to the studies' findings and conclusions.

And even if it were possible, EPA's proposal ignores the large costs that would be associated with the complex process of de-identifying data and fails to identify who would pay for these procedures. As scientists from the Union of Concerned Scientists have pointed out, redacting confidential data from large studies "isn't just blocking out a line," it is a huge job that can take thousands of hours, at commensurately high cost.[17] Similarly, a Work Group of the SAB, EPA's external scientific advisors charged with evaluating EPA's science and regulatory

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[16] *See* U.S. Dept. of Health & Human Servs., *Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule* 6 (Nov. 26, 2012) [hereinafter *HIPAA Guidance*], https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

[17] *See* Ed Yong, *The Transparency Bills That Would Gut the EPA*, The Atlantic, March 15, 2017, https://www.theatlantic.com/science/archive/2017/03/how-to-gut-the-epa-in-the-name-of-honesty/519462/.

actions, explained that there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board (IRB)[18] requirements, including the issue of who would be responsible for shouldering this burden. *See* SAB Work Group Memo at 3.

Indeed, those anticipated costs are well-documented, albeit not in EPA's proposal. In 2017, Congress proposed the Honest and Open New EPA Science Treatment Act, H.R. 1430, 115th Cong. (2017), which, like the proposed rule, provided that EPA could only rely on studies whose data were open and accessible. In assessing that legislation, the Congressional Budget Office (CBO) estimated that costs to EPA associated with redacting confidential information to comply with this act would be at least $100 million per year.[19] These costs would encompass obtaining the underlying data, review of the data to address confidentiality concerns, formatting the data for public access, providing computer codes and models used, and providing directions for accessibility of the data. And the CBO did not include in its cost estimate the additional costs related to the potential need for contractors due to EPA staffing issues to assist with this work. Similar costs can be expected with the proposal as drafted, undermining the proposal's assertion that it does not amount to an Executive Order 13771 regulatory action. *See* 83 Fed. Reg. at 18,772. Rather than acknowledging those costs, however, the only place where the proposed rule even mentions costs is in Section 30.8, which states that "EPA shall implement the provisions of this subpart in a manner that minimizes costs"—a misleading and fatally vague projection of the impacts of the proposed rule. 83 Fed. Reg. at 18,774.

Because EPA's existing processes, including peer review, already help ensure that studies used by EPA are scientifically sound, the proposed rule is not needed to add credibility or reliability to the development of EPA models and standards. Instead, it will burden EPA and the public with unnecessary delays and expense, and result in the unnecessary exclusion of important scientific evidence that is critical to the development of standards that are protective of human health and the environment.

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[18] An IRB is a committee that applies research ethics to review the methods proposed for research to make sure they are ethical. Membership generally consists of individuals with varying backgrounds and affiliations, knowledgeable not only about a specific research activity, but also applicable law, institutional regulations, and standards of professional conduct. *See, e.g.*, 45 C.F.R. § 46.107; 21 C.F.R. § 56.107.

[19] Cong. Budget Office, *Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017* 3 (Mar. 29, 2017), *available at* https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf. The predecessor to the HONEST Act was the so-called Secret Science Reform Act, H.R. 1030, 114th Cong. (2015). The CBO estimated that costs associated with redacting confidential information to comply with the latter act would be even higher--around $250 million per year initially. *See Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015* 1-3 (Mar. 11, 2015), *available at* https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

VI. EPA Has Not Considered the Substantial Direct Effects the Proposed Rule Would Have on the States

States, as sovereign entities, have an interest in protecting the natural resources within their borders, and the health and well-being of their residents. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). EPA states that the proposed rule "does not have federalism implications" and "will not have substantial direct effects on the states." 83 Fed. Reg. at 18,772-73. This is simply incorrect because states are often statutorily required to adopt EPA standards, sometimes lack resources to deviate from EPA standards, frequently are required to obtain EPA approval of state-set standards, and may feel the effects of EPA decisions far beyond the environmental sphere.

Most obviously, some states' environmental laws and regulations explicitly adopt the standards set by EPA or require an express justification for any deviation. For example, under state law, Pennsylvania's Department of Environmental Protection may not promulgate air quality control measures to implement a NAAQS if the control measures are more stringent than federal measures unless it demonstrates that the higher standard is necessary to attain or maintain a NAAQS, to satisfy related CAA requirements, to prevent assessment or imposition of CAA sanctions, or to comply with a final federal court decree. *See* 35 *Pa. Consol. Stat.* § 4004.2. Similarly, New Jersey's Department of Environmental Protection must justify any deviation from federal standards pursuant to Executive Order 27 (Whitman 1994). Changes to federal standards resulting from the application of an arbitrary subset of the available science will either change the standards applicable at the state level or require states to initiate proceedings to impose and justify the imposition of different standards based on rigorous, comprehensive science. Therefore, any change to EPA's process for developing its standards will necessarily impact state standards as well.

Even those states that are not statutorily required to apply federal standards may not have the institutional capacity to develop their own standards and therefore, for practical reasons, often rely on the standards set by EPA. For example, because of lack of institutional capacity, and in acknowledgement of EPA's expertise, Washington D.C. has traditionally relied on EPA to set air quality standards. Further, even more states rely on the publicly available models created by EPA in determining appropriate state standards. For all the reasons discussed in the technical comments that follow, the adoption of this proposed rule would very likely affect the protectiveness of the standards that EPA sets and limit the models that EPA makes available to the public. The regulatory programs of all states that rely on EPA standards or models, including all the signatories of this letter, would therefore be affected by the proposed rule, and states' ability to protect their environment and the health of their citizens would be undermined by its adoption.

Still more, under some programs, standards set by the states must be approved by EPA. *See, e.g.*, 40 C.F.R. §§ 131.20, 131.21 (Water Quality Standards). If the proposed rule were applied to EPA's review and approval of state standards (and it is unclear whether that would be so—another fatal flaw in the proposal), then the rule would also affect the states in this context—further altering the balance of cooperative federalism in the implementation of these programs. Needless to say, if the proposed rule applies to EPA's review and approval of state standards, the

federalism implications could not be any clearer—and EPA's failure to grapple with them or even recognize that they exist is arbitrary and capricious. The proposal's lack of clarity on this issue impairs the states' ability to provide meaningful comment.

Finally, the proposed rule would also impact the states through the incorporation of EPA standards into the regulations or programs of other federal agencies that rely on EPA standards and/or modeling. Should EPA adopt a deficient standard due to the arbitrary exclusion of available scientific information, other federal agencies relying on EPA standards as a basis for action would be affected, as would be the states that interface with those federal programs. As such, the impacts of the proposed rule are likely to impact states in areas far beyond the environmental field.

Based on EPA's complete failure to consider or discuss the effects of its action on state programs, the proposal should be withdrawn so that EPA can adequately consult with state officials to analyze these important impacts. *See* Exec. Order 13132 § 6(a) (instructing agencies to "ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications"); *Chem. Mfrs. Ass'n v. U.S. Envtl. Prot. Agency*, 870 F.2d 177, 203 (5th Cir. 1989).

TECHNICAL COMMENTS

I. Consideration of Valid Scientific Studies Most Relevant for Regulatory Standards Would Be Severely Limited

For reasons discussed below, the proposed rule would severely limit EPA's ability to consider valid and important scientific studies and data, including many that are most relevant for use as the basis for regulatory standards.

a. The Proposed Rule Would Exclude the Use of Studies That Were Based on Confidential Data

The proposed rule fails to recognize or acknowledge the existence of many studies already designed and published with terms that make complete transparency difficult or impossible because of IRB requirements and other important confidentiality protections. The proposal thus could have the effect of excluding important peer-reviewed studies of health effects from use as sources to support EPA's past and future regulatory efforts simply because they do not meet excessively rigid transparency standards. This is particularly true for long-standing confidential epidemiological studies that EPA has relied upon in setting air quality and other health-based standards.

In general, and specifically in EPA's 2005 *Guidelines for Carcinogen Risk Assessment*, human (i.e., epidemiology) data are preferred to animal data as the basis for risk assessment toxicity factors (e.g., cancer potency factors or reference doses for non-carcinogenic effects) when they are of sufficient quality and are amenable to dose response modeling.[20] This is

[20] U.S. Envtl. Prot. Agency, *Guidelines for Carcinogen Risk Assessment* 2-3 (Mar. 2005),

because animal data always carry inherent uncertainties in regard to their relevance to humans. *Id.* Epidemiology data collected over at least the last 40 years, however, have been generated under the auspices of IRBs working to protect the patient or participant information obtained by academic institutions, government entities, hospitals, and other organizations, and thus disclosure of that data would be difficult, if not impossible.

Generally accepted professional practice for the collection of human data requires IRB review and informed consent from the individuals from whom the data are collected. Although the proposal states that "concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government," 83 Fed. Reg. at 18,770, this will not be possible for many studies because IRBs dictate the specific terms of this informed consent, including that the conditions of collection and analysis of human data be specified *before* initiation of the study. These *a priori* conditions include the types of analyses that will be performed, how the data will be used, and whether and how the data can be shared. In general, *a priori* conditions preclude sharing raw data with entities not included in the original IRB approval and performing analyses not specified in the original IRB approval, even if portions of the data are redacted. Furthermore, clinical data collected from physicians, hospitals, clinics, etc., may also be subject to restrictions under HIPAA, over and above IRB restrictions.

These factors would all preclude EPA's or researchers' ability to provide raw, unpublished data for re-analysis as required under the proposed EPA rule. Thus, the provisions of the proposed rule would essentially prohibit the use of such epidemiology data in human health risk-based assessment despite their clear superiority over animal data for use in risk assessment. For older epidemiology data, such as data from studies on occupational exposures to workers in factories before the advent of strict IRB requirements, raw data are seldom if ever still available. Therefore, such data, including high quality data generated by major corporations in conjunction with academic institutions, would also not be available to EPA under the proposed rule. Thus, effectively, the proposed rule would restrict the epidemiology data available for use by EPA, even where the weight of the evidence clearly supports a finding of causality and risk.

Two examples of studies that could be impacted by EPA's proposed rule are the Harvard Six Cities Study and the American Cancer Society Cancer Prevention Study II.[21] These studies followed thousands of people over nearly two decades, and linked personal medical histories, occupational histories, and home locations to detailed air quality data to show that people exposed to more particulate matter are more likely to die prematurely. In order to collect all the

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available at https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

[21] Douglas W. Dockery, C. Arden Pope, Xiping Xu, John D. Spengler, James H. Ware, Martha E. Fay, Benjamin G. Ferris, Jr., and Frank E. Speizer, *An Association Between Air Pollution and Mortality in Six U.S. Cities*, 329 New Eng. J. Med. 1753, 1753-59 (1993), *available at* https://www.nejm.org/doi/10.1056/NEJM199312093292401; *Cancer Prevention Study II*, Am. Cancer Soc'y, https://www.cancer.org/research/we-conduct-cancer-research/epidemiology/cancer-prevention-study-2.html.

information, researchers entered into confidentiality agreements with the study participants, agreeing that their private information would not be made public. These promises of confidentiality (wholly apart from the difficulty and cost of redacting personal information) would render the studies "non-transparent" under the proposed rule, enabling or requiring EPA to ignore them. This is so even though the studies have been thoroughly peer-reviewed and their results have been re-analyzed by the Health Effects Institute, which confirmed the robustness of the studies' findings with respect to air pollution and mortality.[22] Under the proposed rule, EPA could ignore these two foundational studies and other peer-reviewed studies built upon them in setting health-based air quality standards for particulate matter and other pollutants.[23] The effect could be devastating and deadly, as these standards save lives. EPA estimates that reductions in ambient particulate matter under the 1990 Clean Air Act Amendments will prevent 230,000 adult deaths by 2020.[24]

b. The Proposed Rule Would Also Exclude Studies That Cannot Be Reproduced

"Reproducibility," "replication," and "validation" of scientific studies are mentioned throughout the proposed rule, but these terms are not defined. *See, e.g.*, 83 Fed. Reg. at 18,773-74. These terms could be interpreted to mean that studies used as the basis for regulations must be replicated. It would clearly be impossible to replicate many key studies based on data on human or ecological effects resulting from unintentional adverse events and disasters. Some extreme examples are data on the effects of radiation from atomic bomb survivors, data on wildlife toxicity from the Exxon Valdez oil spill, and data on the human health impacts of the September 11, 2001 World Trade Center disaster.[25] Other important data may come from older studies of human volunteers that could not be replicated under current ethical standards.

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[22] Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michael Abrahamowicz, & Warren H. White, Health Effects Institute, *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality* (2000), *available at* https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air; Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki & Warren H. White, *Validation of the Harvard Six Cities Study of Particulate Air Pollution and Mortality*, 350 New Eng. J. Med. 198, 198-99 (2004), *available at* https://www.nejm.org/doi/full/10.1056/NEJM200401083500225.

[23] *See Changing What Science the EPA Will Consider—Part I*, Environmental Law at Harvard (2018), http://environment.law.harvard.edu/2018/04/changing-science-epa-will-consider/.

[24] *Benefits and Costs of the Clean Air Act 1990-2020, the Second Prospective Study*, U.S. Envtl. Prot. Agency (Jan. 4, 2017), https://www.epa.gov/clean-air-act-overview/benefits-and-costs-clean-air-act-1990-2020-second-prospective-study.

[25] Comm. to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, Nat'l Research Council, *Health Risks From Exposure to Low Levels of Ionizing Radiation, Beir VII Phase 2* (2006), *available at* https://www.nap.edu/read/11340/chapter/1; Charles H. Peterson, Stanley D. Rice, Jeffrey W. Short, Daniel Esler, James L. Bodkin, Brenda E. Ballachey & David B. Irons, *Long-Term Ecosystem Response to the Exxon Valdez Oil Spill*, 302 Sci. 2082, 2082-

Laboratory animal studies are controlled studies which use genetically similar test subjects maintained under identical conditions, with the only difference between the control and treated groups being exposure to the chemical being tested. Although such studies are expected to give the same results if they are reproduced, scientists do not routinely perform laboratory experiments that are identical to previously reported studies, but rather, use results from the scientific literature as the basis for design of different studies that will add to the body of knowledge on the topic being studied. In contrast to the controlled conditions of animal studies, there is more variability among humans than the strains of lab animals utilized. Additionally, the exact underlying conditions of human studies can rarely be exactly replicated (i.e., under the same circumstances of exposure and other factors) even when the same protocols are followed. Thus even a contradictory result in a "reproduced" epidemiological study would not necessarily invalidate an observation from an earlier study, provided that the first study followed valid methods and conducted appropriate statistical analyses.

In addition, although it would depend on the specifics of the study and the nature of the endpoint investigated, a single human study would not generally be considered definitive by itself. Rather, all such well-conducted studies contribute to the weight of evidence supporting a scientific conclusion. Reliance on the weight of the evidence, rather than on any one individual study, is a safeguard that helps to ensure validity of the overall conclusions. Therefore, even if such studies could be replicated, their replication is not necessary for making a conclusion based on the overall weight of the evidence.

To the extent the proposal seeks to enable third parties to "re-run" an analysis using the same supporting data and the same models, this may not be possible where proprietary models, methods, designs, and/or data were used in the study. But, as EPA points out in its Information Quality Guidelines, in cases where the Agency relies on proprietary models that cannot be made publicly available, the model applications are subject to EPA's peer review policy and other validation checks. *Information Quality Guidelines* at 47. The Guidelines indicate that "[t]hese steps, along with transparency about the sources of data used, various assumptions employed, analytic methods applied, and statistical procedures employed should assure that analytic results are 'capable of being substantially reproduced.'" *Id.*

c. The Proposed Rule Would Favor Industry Contract Laboratory Toxicology Studies, Which May Not Evaluate the Most Sensitive and Relevant Effects

The proposed rule would also favor consideration of industry toxicology studies over equally valid peer reviewed studies from other institutions. It states that "where available and appropriate, EPA will use . . . standardized test methods, consistent data evaluation procedures, and good laboratory practices." 83 Fed. Reg. at 18,770. Under current EPA risk assessment approaches, all relevant scientific data are considered.[26] In contrast, this language indicates the

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2086 (2003); *available at* https://www.afsc.noaa.gov/Publications/misc_pdf/peterson.pdf; City of New York, Dept. of Health & Mental Hygiene, *World Trade Center Health Registry*, https://www1.nyc.gov/site/911health/about/wtc-health-registry.page.

[26] *See, e.g.*, Integrated Risk Info. System, Nat'l Ctr. for Envtl. Assessment, Office of Research &

proposed rule is significantly more restrictive than current EPA guidance as far as the types of valid peer-reviewed scientific data that can be considered.

It is critical to note that the phrase "good laboratory practices" (GLP) referenced by EPA is not a value descriptor. Rather, it is a technical term referring to a specific category of study conduct and reporting that is intended for specific regulatory purposes. GLP/standardized test method studies are typically conducted by industrial or contract laboratories, and test for limited parameters in order to meet specific regulatory requirements, such as for registration of pesticides, drugs, and other products. These protocols often have not been updated to incorporate recent approaches in toxicology, and they may not look at the most sensitive and relevant toxicological effects of the product being studied. In contrast, other equally scientifically valid studies, typically conducted in research laboratories in academic, industrial, or government institutions, use specialized approaches to evaluate specific toxicological effects of the chemical under study, and may not follow the standardized protocols specified in regulatory requirements. The use of GLP protocols does not necessarily mean that the study is of higher quality, and there is no scientific reason that the data generated under the highly circumscribed regulatory requirements for product registration should receive greater weight than any other valid scientific data. Rather, all studies should be evaluated on their own merits.

d. The Proposed Rule Would Exclude Studies for Which Underlying Data Are Not and May Not Be Available

The proposed rule would preclude consideration of studies – old and new – for which data are not and may not be available. Many of the standards that are developed or updated by EPA are for chemicals that have an extensive, older body of scientific literature on their effects, but that are not currently being actively researched. Thus, the vast majority of studies considered for standard-setting are not new and were not conducted, designed, or published with the goal of ensuring data availability. Accordingly, their data are likely unavailable and, even if data were kept, the formats in which older data are stored may not be accessible from currently available computers, potentially invalidating the use of those studies as the basis for future regulatory standards. Processes for additional data availability are currently being developed and will likely increasingly be incorporated into research protocols in the future; however, it is unknown whether these forthcoming protocols will meet the transparency requirements of the proposed rule.

In addition, even going forward, many academic scientists whose research is relevant to EPA regulations may not conduct and report their studies in a way that satisfies the requirements of the proposed rule. The proposed rule's provisions would require significant additional resources and could impose unreasonable and impractical requirements beyond those included in current protocols. Academic researchers, who often study sensitive and relevant health effects that are not evaluated in industry-sponsored GLP studies, typically focus on publishing their studies in peer-reviewed journals and obtaining research funding; they may not be concerned about or even consider whether their studies would qualify for use in establishing EPA

Dev., U.S. Envtl. Prot. Agency, *Toxicological Review of Benzo[a]pyrene*, xxxiii-xxxvi (2017), *available at* https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0136tr.pdf.

regulations, and/or may not have the resources to reshape their approach to maintaining data. Additionally, many researchers, particularly in other nations but also in the United States, may not even be aware of EPA requirements for a study's use in regulations. For those researchers who do attempt to comply with the proposed rule's requirements, the extent and nature of the data that must be maintained and made publicly available is vague and unclear, making compliance virtually impossible.

II. The Proposed Rule is Wrongly Premised on Unsupported Assumptions Regarding Scientific Studies

a. The Proposed Rule Assumes Erroneously and Without Explanation that Only Studies for Which the Underlying Data Are Publicly Available Are Valid

A fundamental premise of the proposed rule is that only studies for which the underlying data are publicly available are valid for decision-making. This premise is inconsistent with generally accepted practices for conducting and evaluating scientific research. Furthermore, the rationale for the premise is not provided: EPA presents no evidence for the conclusion that its current criteria for selecting studies result in scientifically invalid conclusions or overly stringent regulations. Indeed, the D.C. Circuit has already rejected EPA's proposed approach of excluding studies relying on non-public data as "impractical and unnecessary" when raised by a trade association as part of a challenge to an air quality standard. *Am. Trucking*, 283 F.3d at 372.

b. The Proposed Rule Incorrectly Assumes that the Studies and Data Upon Which EPA Relies Are of Questionable Validity

The proposed rule also assumes that the studies and data used in EPA's decision-making are of questionable validity. However, this assumption is unsupported. It is not the case that the studies and data EPA uses to establish regulations are selected simply because they report effects at the lowest levels. Rather, EPA performs an extensive hazard identification process prior to selecting key studies and specific health endpoints. This process evaluates the relevant human epidemiology, animal toxicology, and mode of action studies to ensure that the studies and endpoints ultimately chosen are supported by the overall body of scientific literature. Recently, a rigorous systematic review process has been developed and implemented by EPA's Integrated Risk Information System program to ensure even greater thoroughness and objectivity in hazard identification.[27] Thus, EPA already ensures that the studies and data upon which it relies are valid.

[27] Integrated Risk Info. System, Nat'l Ctr. for Envtl. Assessment, Office of Research & Dev., U.S. Envtl. Prot. Agency, *National Academy of Sciences Committee to Review Advances Made to the IRIS Process: A Workshop* (Feb. 1-2, 2018), *available at* https://www.epa.gov/sites/production/files/2018-02/documents/nas020118final.pdf.

III. The Proposed Rule's Data Availability Requirements Are Unnecessary and Unclear

a. EPA's Proposed Data Availability Requirements Are Not Necessary to Improve or Ensure the Scientific Basis of Regulations

Studies and associated data do not have to be publicly available or reproducible to ensure that they are scientifically valid. This point has already been made in statements of concern about the proposed rule by authoritative scientists, including the editors of the most prestigious scientific journals (Science, Nature, PLOS, PNAS, Cell) and the members of a Work Group of the SAB itself. *See Joint Statement* and SAB Work Group Memo. As stated by the journal editors, "scientists, including peer reviewers, are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results . . . . [I]t does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them . . . . Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes." *Joint Statement*.

In fact, there are longstanding methodologies for evaluating the strength of epidemiology findings that are commonly used to draw conclusions about causality.[28] The SAB Work Group notes that "the proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods," using as an example the Health Effects Institute's well-known re-analysis of the Harvard Six Cities and American Cancer Society air quality studies, which successfully replicated those studies' findings. SAB Work Group Memo at 4.

b. EPA's Proposed Data Availability Requirements Are Not Clearly Defined and Do Not Ensure Validity of Data

The extent and nature of the data that would be required to be made publicly available is not clearly defined in the proposed rule. The proposed rule states that information is considered "publicly available in a manner sufficient for independent validation" when it includes the "information necessary for the public to understand, assess, and replicate findings. This may include, for example: (a) Data (where necessary, data would be made available subject to access and use restrictions)[;] (b) Associated protocols necessary to understand, assess, and extend conclusions; (c) Computer codes and models involved in the creation and analysis of such information; (d) Recorded factual materials; and (e) Detailed descriptions of how to access and use such information." 83 Fed. Reg. at 18,774.

This could be interpreted to require maintenance of data down to the most basic level, verging on the absurd, and could impose unreasonable and impractical requirements that go well beyond those already included in current protocols. For example, it could require maintenance of records that are not routinely archived by academic research labs, such as printouts of data from all calibration curves and analyses from instruments that measure clinical parameters in

[28] *See, e.g.*, Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?* 58(5) Proc. Royal Soc'y Med. 295, 295-300 (1965) ("The Hill Criteria for Causality").

blood or other similar endpoints in animal and human studies, or photos of each individual organ as it is evaluated for gross pathology in toxicology studies. Even if such data are maintained for a period after a study is completed, it is not feasible for such records to be maintained indefinitely by research laboratories, which would then make the study that the data supports unavailable for use in future regulations.

For toxicology studies, such data availability requirements would result in favoring studies performed under GLP protocols, which typically retain more raw data than research studies. But, as discussed in more detail above, GLP studies may not evaluate the most sensitive and relevant toxicological effects of the chemical being studied and are not inherently of higher quality than studies conducted under other protocols.

IV. Provisions of the Proposed Rule Related to Modeling Conflict with Scientific Guidelines

The proposed rule would flout long-accepted scientific modeling methods and require undue justification and explanation of assumptions and uncertainty.

a. The Proposed Rule Encourages Deviation from Linear Dose Response Modeling, the Generally Accepted Choice for Modeling in Carcinogen Risk Assessment

The proposed rule would favor less protective threshold modeling, contrary to EPA's own guidance and generally accepted toxicology practice. It states that "EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis" and that "EPA shall give explicit consideration to high quality studies that explore . . . various threshold models across the dose or exposure range." 83 Fed. Reg. at 18,774. These requirements are inconsistent with EPA guidance, specifically the 2005 *Guidelines for Carcinogen Risk Assessment*. These guidelines state that EPA's default dose response modeling approach for carcinogenic substances is linear extrapolation from the point-of-departure (essentially the lower limit of the range of the experimental data) to the origin (zero exposure, zero risk). This default no-threshold approach assumes that any dose of a carcinogen results in some level of risk, making it the most protective of human health. Threshold models, by contrast, assume that there is some dose of a carcinogen at which there is no cancer risk, an assumption that is less health protective and that has not been conclusively established in most cases. It is unclear what EPA means by "explicit consideration," or what EPA would consider to be "high quality studies," but insofar as those terms are intended to mean that EPA will give preference to studies utilizing threshold models, such a preference would be inconsistent with EPA's 2005 *Guidelines for Carcinogen Risk Assessment* as well as generally accepted practice in the field of toxicology.

In most cancer risk assessments, dose response data within the low risk range, which is the range of interest for regulatory purposes, are lacking. Thus, low-dose extrapolation is used to estimate risks in the lower dose range where data are unavailable. For estimation of risks below the range of the data, there are an infinite number of possible threshold and non-threshold assumptions regarding the shape of the dose response curve that can be envisioned, with no substantive basis for assuming the general superiority of one assumption over another. To

deviate from the default assumption that any dose of a carcinogen results in some risk in the absence of chemical-specific data that demonstrate a threshold mode-of-action of carcinogenicity[29] would be mere speculation and would assume, with no scientific support, that Americans can be safely exposed to those substances. To "evaluate the appropriateness" of the linear, non-threshold approach for low-dose extrapolation by also considering non-linear and threshold models would provide no cognizable benefit in modeling accuracy or clarity, but instead could result in the manipulation of results, delay, and obfuscation.

In the limited circumstances where the data support threshold modeling, EPA's 2005 *Guidelines for Carcinogen Risk Assessment* already provide for departure from the default linear extrapolation in risk assessment and instead allow for the use of threshold modeling. *Id.* at A-8. In fact, EPA has used a threshold approach for carcinogen risk assessment when there is clear, chemical-specific, empirical evidence of a threshold mode of action.[30] This careful, well-founded approach is generally considered both scientifically supportable and protective of public health, as opposed to the proposed rule's requirement for justification of the default linear approach on a case-by-case basis and "explicit consideration [of] high quality studies that explore various threshold models across the dose or exposure range." 83 Fed. Reg. at 18,774. Without a well-founded and substantiated scientific basis, EPA should not entertain such a fundamental departure from accepted, public-health protective risk assessment practices.

b. The Proposed Rule Would Unreasonably Require Consideration of Nonparametric Models

The proposed rule would require that "when available, EPA shall give explicit consideration to high quality studies that explore . . . [a] broad class of parametric dose response or concentration response models" *and* "nonparametric models that incorporate fewer assumptions." 83 Fed. Reg. at 18,774. Parametric models are those in which the number and nature of the parameters (i.e., assumptions) are fixed in advance, while nonparametric models are those in which the assumptions are determined from the data. For approximately 20 years, EPA has employed parametric modeling in risk assessment by providing and using benchmark dose response modeling software. Although the proposal implies that this is not the case, this software already allows investigation of the most appropriate parametric model(s) for risk assessment and currently provides "a broad class of parametric dose response, concentration-response models." *Id.*

There is no obvious benefit to adding an additional layer of analysis—nonparametric modeling—on top of this longstanding approach. Nonparametric models are useful only when the quantity and quality of the data are sufficient to infer a clear and plausible estimate of the overall pattern. But when there are few data and/or data are of poor quality, as is often the case

[29] Mode of action is defined by EPA as the "sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation." *Guidelines for Carcinogen Risk Assessment* at 1-10 n.2.

[30] *See, e.g.*, U.S. Envtl. Prot. Agency, *Toxicological Review of Chloroform* (2001), *available at* https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0025tr.pdf.

in situations to which the proposed rule would apply, nonparametric models can produce a wide variation of results with few, if any, constraints on plausibility. In such cases, the use of nonparametric models is not scientifically supportable, and moving forward, little would be gained from considering them in terms of accuracy and clarity of the predictions, while the potential for delay and obfuscation would again multiply. The proposed rule's requirement that nonparametric models be explicitly considered, without regard to the applicability of a particular model, is therefore misguided and scientifically unsound.

c. The Proposed Rule Would Unreasonably Require Justification of All Default Assumptions

The proposed rule would require EPA to "evaluate the appropriateness of using default assumptions" and "clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions." 83 Fed. Reg. at 18,774. This would effectively foreclose the important use of default assumptions, requiring a detailed justification for each of the many assumptions included in any given model—an inefficient, time-intensive, and unnecessary task.

Default assumptions are selected from a range of possible values based on both scientific considerations (e.g., whether they are supportable based on available data) and policy considerations (e.g., whether the upper or lower percentile, rather than the mean or median value, should be used to protect most of the population). In cases of significant variability and/or uncertainty in the available data, there are essentially an infinite number of alternative assumptions that can be chosen. The use of default assumptions thus provides a straightforward way to manage the complexity presented by variability and uncertainty.

And, while default assumptions do need to be justified when initially selected, EPA uses a well characterized set of default assumptions in risk assessment and updates them when indicated by newer scientific information.[31] Accordingly, the rationales and limitations underlying these assumptions are well documented, including (as would be required by the proposed rule) discussion of variability, as well as sensitivity analyses that evaluate the impact on the model results of changing the default value to a range of non-default alternative values. Default values have been selected as both scientifically valid and protective of human health; if alternative values are selected, they are likely to be less health-protective than existing defaults. There is thus little benefit to be gained at this point by reinventing the wheel each time a default assumption is employed. To forego these well-established default assumptions and require

[31] *See, e.g.*, Memorandum from Dana Stalcup, Acting Director, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation to Superfund National Policy Managers, Regions 1-10, *Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors* (Feb. 6, 2014), *available at* https://www.epa.gov/sites/production/files/2015-11/documents/oswer_directive_9200.1-120_exposurefactors_corrected2.pdf; Office of Water, U.S. Envtl. Prot. Agency, *Human Health Ambient Water Quality Criteria: 2015 Update* (2015), *available at* https://www.epa.gov/sites/production/files/2015-10/documents/human-health-2015-update-factsheet.pdf.

justification of each assumption chosen from a long list of potentially less health-protective assumptions would only give rise to prolonged debate, obfuscation, and manipulation of model outcomes, not improvement of the scientific basis of the risk assessment. The delay this would cause, for no supportable reason, can only lead to the conclusion that it is EPA's intent to inhibit, rather than improve, regulation.

d. The Proposed Rule Would Require a Description of, But Fails to Define, Uncertainty

The proposed rule would also require that EPA "describe and document any assumptions and methods used . . . and uncertainty." 83 Fed. Reg. at 18,774. However, uncertainty is not defined in the proposed rule, and it is unclear what type of uncertainty is implied. Uncertainty could mean discussion of the magnitude of the statistically based range of model predictions. There could also be uncertainties unrelated to the model, such as qualitative uncertainty about the human relevance of the animal toxicity endpoint used as the basis for the risk assessment. EPA's failure to define the type of uncertainty at issue makes the proposed rule impermissibly vague and deprives the public of a meaningful opportunity to comment on its impacts.

V. The Proposed Rule Would Undermine Protection of Human Health and the Environment, in Contradiction to EPA's Mission

Overall, the requirements of the proposed rule discussed above would lead EPA to adopt less protective standards across many regulatory programs, which is contrary to EPA's mission to protect human health and the environment. The proposed rule would allow for the use of less protective dose response models and assumptions in human health risk assessment. It would also preclude consideration of scientifically valid human and animal studies reporting sensitive and relevant toxic effects based on unjustified requirements for public availability of data, and instead favor consideration of studies that do not assess the most sensitive and relevant health effects endpoints.

For example, EPA is required to review its air quality standards (NAAQS) for criteria pollutants every five years and, if necessary, revise them to protect public health and the environment. *See* 42 U.S.C. § 7409(d). The NAAQS review process builds on the administrative record from prior rulemakings, including historic studies that are part of that record. Under the proposed rule, EPA may refuse to consider these studies and others because they rely on data pertaining to the personal medical histories of participants that cannot, by the studies' terms or by law, be divulged. Restricting the use of such studies would significantly undermine current and future NAAQS reviews.

And, indeed, the proposed rule appears to be especially aimed at such a restriction. EPA's April 30, 2018 rule proposal follows an April 12, 2018 memorandum issued by President Trump to former EPA Administrator Pruitt directing him to "examine the current NAAQS review process and develop criteria to ensure transparency in the evaluation, assessment, and characterization of scientific evidence in such reviews."[32] But, as explained above, it would be

[32] Memorandum from Donald J. Trump, President of the United States, to the Administrator of the U.S. Envtl. Prot. Agency, *Presidential Memorandum for the Administrator of the*

illegal for EPA, in setting standards, to ignore peer-reviewed, relevant science on the grounds that confidential, private patient data underlying a study have not been made public.

Relatedly, EPA's proposal may also restrict the health and welfare benefits tied to the NAAQS that support other rulemakings. For example, in calculating the costs and benefits of rules to reduce air emissions, in some cases the majority of the benefit estimates are attributable to reductions in one or more criteria pollutants that are not the primary objective of the rule. These reductions are referred to as co-benefits, and the health impacts and monetized benefits are based on studies used in the air quality standards-setting process for criteria pollutants. For example, in promulgating the Mercury and Air Toxics Standard rule governing air emission standards for hazardous air pollutants (including mercury) from power plants, EPA states "[i]t is important to note that the monetized benefits include many but not all health effects associated with $PM_{2.5}$ exposure." 77 Fed. Reg. 9304, 9431 (Feb. 16, 2012); *see also id.* at 9305. Thus, restricting the use of studies that underlie emission standards for criteria pollutants could significantly impact the cost-benefit analyses for various other health-related rules by failing to account for all the benefits, making it far more likely that the costs will be predicted to exceed the benefits and that the regulatory standards will, accordingly, be lowered.

Further, in developing regulations EPA uses other types of models in addition to dose response models. These include toxicokinetic models that predict a chemical's absorption, distribution, metabolism, and excretion, as well as fate and transport models that predict a chemical's movement in the environment and distribution to environmental media. The proposed rule's provisions that could decrease protectiveness of dose response analysis (e.g., requiring justification of default assumptions and precluding consideration of relevant studies due to data disclosure requirements) could similarly result in decreased protectiveness of these other types of models. In regulations based on dose response analysis combined with toxicokinetic and/or fate and transport analyses, the overall decrease in protectiveness would be magnified.

The proposed rule also does not differentiate between standards set to protect human health, and standards and models used to protect the environment, such as the CWA's aquatic life criteria and standards used in ecological risk assessments under CERCLA.[33] Many of the same serious concerns raised in these comments are equally applicable to such standards and models, including: EPA's lack of consultation with the SAB, the National Academy of Sciences, and the broader scientific community; the requirement that EPA conduct its own review of all pivotal regulatory science; and the proposed rule's potential to impose unreasonable data maintenance requirements. Also, the use of GLP protocols is inappropriate for studies involving ecosystems and associated biota. Consequently, the problems concerning EPA's ability to rely

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Environmental Protection Agency (Apr. 12, 2018), https://www.whitehouse.gov/presidential-actions/presidential-memorandum-administrator-environmental-protection-agency/.

[33] *National Recommended Water Quality Criteria*, U.S. Envtl. Prot. Agency (Apr. 2, 2018), https://www.epa.gov/wqc/national-recommended-water-quality-criteria; *Superfund Risk Assessment: Ecological Risk Topics*, U.S. Envtl. Prot. Agency (Feb. 16, 2018), https://www.epa.gov/ris/superfund-ris-assessment-ecological-risk-topics.

on the best available scientific studies would also limit EPA's ability to protect ecosystems and wildlife in a scientifically robust manner.

CONCLUSION

As the comments above demonstrate, the proposed rule is antithetical to EPA's mission to protect human health and the environment. The proposed rule is riddled with substantive and procedural infirmities and would achieve the opposite of its purported purpose. EPA's failure to consult with its own internal science experts when developing the proposal is, at best, gross malfeasance and, at worst, a conscious effort to subvert the Agency's statutorily mandated practice of using the best available science. We urge EPA to jettison this tainted vestige of the prior leadership and restore public confidence in the Agency's commitment to its core mission, and we stand ready to pursue legal remedies should EPA persist in this misguided effort.

Sincerely,

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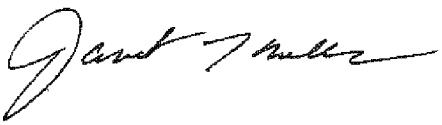

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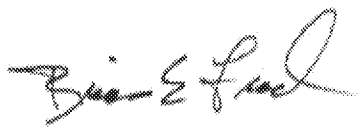

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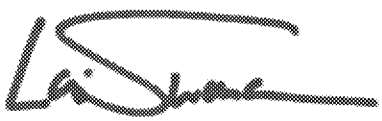

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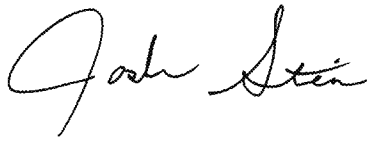

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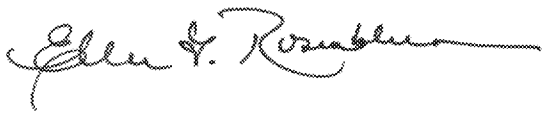

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JOSH SHAPIRO
Attorney General of the Commonwealth
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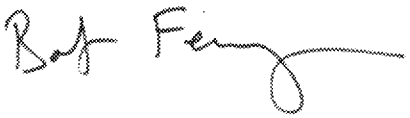
PATRICK MCDONNELL
Secretary of the Pennsylvania Department
of Environmental Protection



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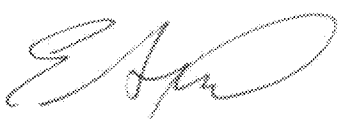

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Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 8/16/2018 4:13:50 PM
To: Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
Subject: FW: ASDWA Comments on Regulatory Transparency
Attachments: ASDWA Comments on Regulatory Transparency 08152018 Final.docx

Another for the docket

From: Orme-Zavaleta, Jennifer
Sent: Thursday, August 16, 2018 12:04 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>
Subject: FW: ASDWA Comments on Regulatory Transparency

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
Office of Research and Development
US Environmental Protection Agency
Cell [redacted] Personal Matters / Ex. 6
DC [redacted]
RTP [redacted] Personal Matters / Ex. 6

From: Darrell Osterhoudt [mailto:dosterhoudt@asdwa.org]
Sent: Thursday, August 16, 2018 11:40 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Ross, David P <ross.davidp@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Subject: ASDWA Comments on Regulatory Transparency

You were copied on these comments from the Association of State Drinking Water Administrators. We believe the current process, based on recommendations from the Science Advisory Board, for developing pivotal science for drinking water is adequate and provides good transparency, allowing states to evaluate the basis for the MCL and MCLG. Rather than this proposed rule, an enhancement state drinking water programs would recommend, is to always allow at least a 90 day comment period for new/revised rules.

See the attached file for more details.

If you have any questions, please let me know.

Darrell Osterhoudt
Regulatory Affairs Manager
Association of State Drinking Water Administrators
1401 Wilson Blvd. Suite 1225
Arlington, VA 22209
(703) 812-9508
Fax (703) 812-9506
dosterhoudt@asdwa.org

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 6/11/2018 3:10:51 PM
To: Benforado, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3adeee7efce4889992919103f16e006-Benforado, Jay]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Anand Mudambi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a94638932b49af8a6cf581262d5059-Mudambi, Anand]; Grifo, Francesca [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c4870bfab004fa0ac47bc8659d9903b-Grifo, Fran]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Nelson, Daniel K. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9bd641d949d4a96b2d6c307be288afa-Nelson, Dan]
Subject: RE: NYT article on science

Personal Matters / Ex. 6

From: Benforado, Jay
Sent: Monday, June 11, 2018 10:54 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>; Greene, Mary <greene.mary@epa.gov>; Anand Mudambi <Mudambi.Anand@epa.gov>; Grifo, Francesca <Grifo.Francesca@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Nelson, Daniel K. <Nelson.Daniel@epa.gov>
Subject: NYT article on science

https://www.nytimes.com/2018/06/09/climate/trump-administration-science.html

In the Trump Administration, Science Is Unwelcome. So Is Advice.

As the president prepares for nuclear talks, he lacks a close adviser with nuclear expertise. It's one example of a marginalization of science in shaping federal policy.

Image

President Trump is the first president since 1941 not to name a science adviser.CreditTom Brenner/The New York Times

By Coral Davenport

- June 9, 2018

WASHINGTON — As President Trump prepares to meet Kim Jong-un of North Korea to negotiate denuclearization, a challenge that has bedeviled the world for years, he is doing so without the help of a White House science adviser or senior counselor trained in nuclear physics.

Mr. Trump is the first president since 1941 not to name a science adviser, a position created during World War II to guide the Oval Office on technical matters ranging from nuclear warfare to global pandemics. As a businessman and president, Mr. Trump has proudly been guided by his instincts. Nevertheless, people who have participated in past nuclear negotiations say the absence of such high-level expertise could put him at a tactical disadvantage in one of the weightiest diplomatic matters of his presidency.

"You need to have an empowered senior science adviser at the table," said R. Nicholas Burns, who led negotiations with India over a civilian nuclear deal during the George W. Bush administration. "You can be sure the other side will have that."

The lack of traditional scientific advisory leadership in the White House is one example of a significant change in the Trump administration: the marginalization of science in shaping United States policy.

Image

Kim Jong-un, the North Korean leader, attending a performance in Pyongyang last year honoring nuclear scientists and technicians.CreditKorean Central News Agency

There is no chief scientist at the State Department, where science is central to foreign policy matters such as cybersecurity and global warming. Nor is there a chief scientist at the Department of Agriculture: Mr. Trump last year nominated Sam Clovis, a former talk-show host with no scientific background, to the position, but he withdrew his name and no new nomination has been made.

These and other decisions have consequences for public health and safety and the economy. Both the Interior Department and the National Oceanic and Atmospheric Administration have disbanded climate science advisory committees. The Food and Drug Administration disbanded its Food Advisory Committee, which provided guidance on food safety.

Government-funded scientists said in interviews that they were seeing signs that their work was being suppressed, and that they were leaving their government jobs to work in the private sector, or for other countries.

After Mr. Trump last year withdrew from the Paris climate agreement, the international pact committing nations to tackle global warming, France started a program called "Make Our Planet Great Again" — named in reference to Mr. Trump's slogan, "Make America Great Again" — to lure the best American scientists to France. The program has so far provided funding for 24 scientists from the United States and other countries to do their research in France.

The White House declined to comment on these and other suggestions that the role of science in policymaking has been diminished in the Trump administration. Regarding the

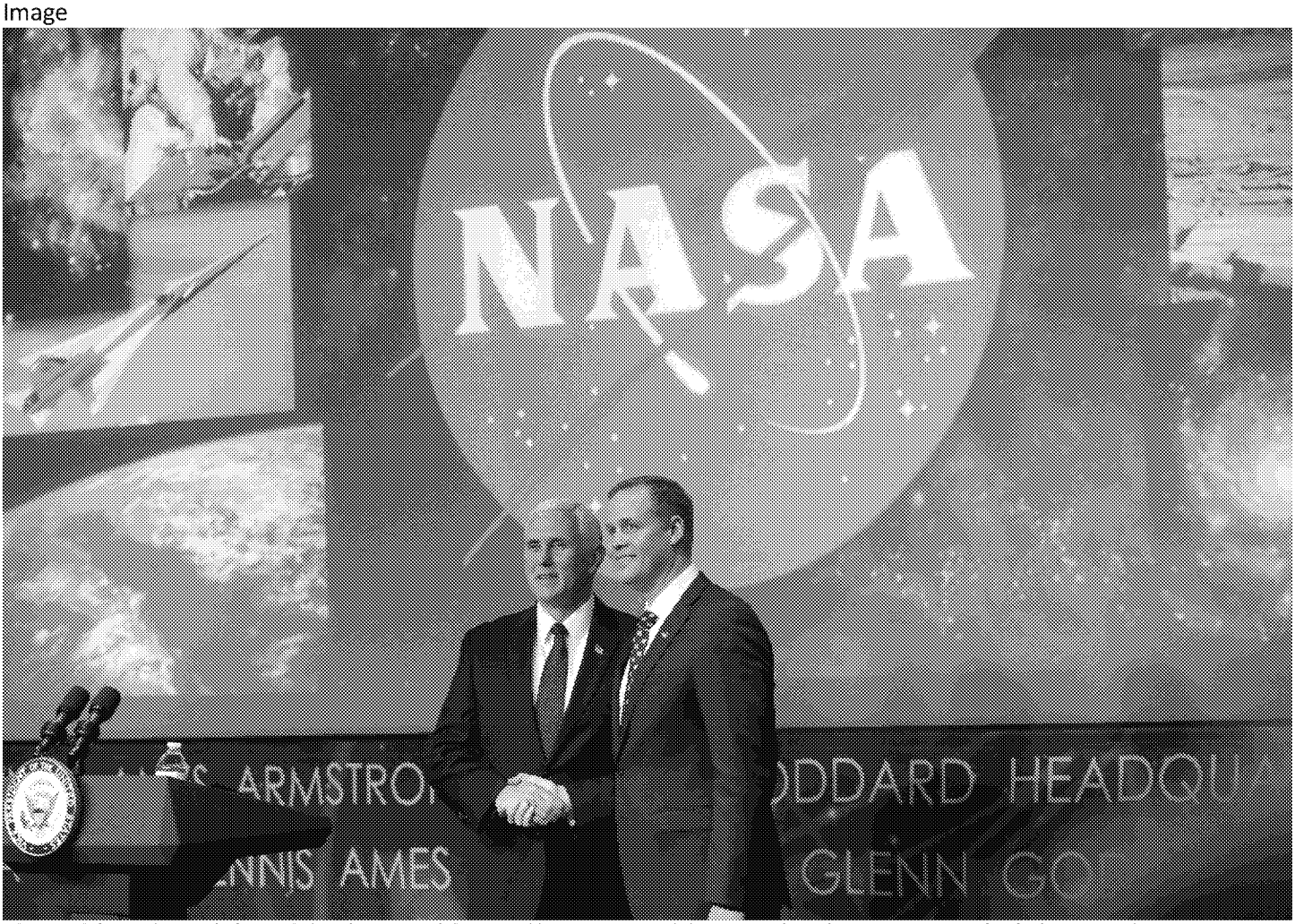
coming talks with Mr. Kim, a spokesman for the White House's National Security Council, Garrett Marquis, emphasized that "the president's advisers are experts in their fields."

The larger matter, though, is the president's lack of a close senior adviser at the White House level, someone who has Mr. Trump's trust and his ear, said Michael Oppenheimer, a professor of geosciences and international affairs at Princeton.

"I don't think there's ever been a time in the post-World War II period where issues as important as nuclear weapons are on the table, and there is no serious scientist there to help the president through the thicket," he said. "This reverberates throughout policy."

There are exceptions to the retreat from science. In April, scientists bristled when Jim Bridenstine, a former Republican congressman from Oklahoma who is not a scientist, took over the National Aeronautics and Space Administration. Mr. Bridenstine had questioned whether human activity is the primary cause of global warming.

Image



Jim Bridenstine, right, with Vice President Mike Pence at his swearing-in as NASA administrator in April.CreditPablo Martinez Monsivais/Associated Press

But last month Mr. Bridenstine testified before a Senate committee that he had experienced a climate-science conversion. Asked if he believed greenhouse gases are the primary cause of the warming planet, he responded, "Yes."

His own agency, he said, has found it "extremely likely that human activity is the dominant cause of global warming, and I have no reason to doubt the science."

Mr. Bridenstine described his views as an "evolution."

Moments like these are not the norm, however. More than 1,000 members of the National Academy of Sciences signed a statement in April criticizing the Trump administration's decision to withdraw the United States from the Paris Agreement. "The dismissal of scientific evidence in policy formulation has affected wide areas of the social, biological, environmental and physical sciences," the statement said.

The most pressing geopolitical need may be in the realm of nuclear diplomacy.

While the State Department declined to characterize the makeup of its preparatory team for the North Korea meeting, set for Tuesday in Singapore, Mr. Trump could of course tap any number of government nuclear physicists to accompany him.

And Mr. Marquis, the National Security Council spokesman, emphasized that many of the president's advisers "have advanced degrees and have worked on these complex issues in and out of government."

"The materials that have gone to the president ahead of the negotiation reflect the work of more than a dozen people at the Ph.D. level in relevant fields," he added, including "at least one" in nuclear engineering.

A State Department spokeswoman referred questions to the National Security Council.

Nevertheless, as Mr. Trump prepares for the talks, he has no close aides on par with those who helped President Barack Obama negotiate a nuclear deal with Iran. Mr. Obama's advisers included Ernest J. Moniz, a nuclear physicist who led the Energy Department and oversaw the nation's nuclear weapons arsenal, and John Holdren, a physicist and expert in nuclear arms control who served as the White House science adviser.

"There is going to be the requirement for trade-offs, and that judgment is best made by people with technical expertise who are also very senior politically," Mr. Moniz said. "That just does not exist in this administration."

Image

Ernest J. Moniz, left, an energy secretary under President Barack Obama, testifying at a congressional hearing on the Iran nuclear deal in 2015.CreditZach Gibson for The New York Times

Of course, Mr. Trump was an outspoken critic of Mr. Obama's Iran deal and withdrew from it last month.

As for Mr. Kim's advisers, "The North Korean nuclear scientists are very, very competent and I would expect them to advise their government well," said Siegfried S. Hecker, a former director of the Los Alamos weapons laboratory in New Mexico and an expert on North Korea's nuclear weapons program.

Ground Zero: The E.P.A.

In Washington, the administration's excising of science is particularly evident at the Environmental Protection Agency.

Scott Pruitt, the embattled head of the E.P.A., is the subject of at least 12 government investigations into his first-class travel, costly security detail and management of the agency. At the same time he has won praise from Mr. Trump for his speed at rolling back environmental regulations.

Mr. Pruitt has initiated more than a dozen regulatory rollbacks, including signing a measure declaring his intent to undo or weaken Mr. Obama's climate change regulations known as the Clean Power Plan.

However, his more enduring legacy may be in diminishing the role of academic, peer-reviewed science at the agency. "It's not Pruitt's exorbitant spending, but rather a lot of these less sexy things they're quietly doing on science that will cause the real long-term damage," said Gretchen Goldman, the research director for the Center for Science and Democracy at the Union of Concerned Scientists, a nonprofit group.
Image

Scott Pruitt, the Environmental Protection Agency administrator, has won praise from Mr. Trump for his speed at rolling back environmental regulations.CreditTom Brenner/The New York Times

Mr. Pruitt has begun to systematically change how the E.P.A. treats science. In April, he proposed a regulation that would limit the types of scientific research that E.P.A. officials could take into account when crafting new public health policies, a change that could weaken the agency's ability to protect public health.

The new rules would require that the data from all scientific studies used by the E.P.A. to formulate air and water regulations be publicly available. Mr. Pruitt has touted that as a step toward increasing scientific transparency. "The era of secret science at E.P.A. is coming to an end," he said in a statement. "The ability to test, authenticate and reproduce scientific findings is vital for the integrity of rule-making process."

However, the change could sharply limit the research available to the E.P.A., because health studies routinely rely on confidential data from individuals.

Last year, Mr. Pruitt significantly altered two major scientific panels that advise the E.P.A. on writing public health rules, restricting academic researchers from joining the boards while appointing several scientists who work for industries regulated by the E.P.A.

These and other changes "will diminish the characterization of pollution as risky," said William K. Reilly, who headed the E.P.A. under the first President George Bush. "This

tolerance for more exposure to pollution is altogether different from anything we are used to."

In a statement defending the changes to the committees, Jahan Wilcox, an E.P.A. spokesman, said that the agency "sought a wider range of voices" and "was thrilled with the response of over 700 applicants." The boards, he said, are not only highly qualified but also "independent and geographically diverse."

This year, Mr. Pruitt sent a memo to the E.P.A.'s Clean Air Scientific Advisory Committee ordering steps that could effectively diminish the role of scientific evidence in air pollution enforcement. The committee is required by law to prioritize the health effects of pollution, but Mr. Pruitt's memo orders it to consider potential economic consequences of meeting tighter clean-air rules — for example, the possibility that tougher pollution standards could make air-conditioning more expensive, leading to more deaths from heat.

"This memo flouts the clear evidence of medical science," said John Walke, an expert in clean-air policy at the Natural Resources Defense Council, an advocacy organization. "Pruitt wants to set a definition of clean air that is medically unsafe."

The agency, after heavy lobbying by the chemicals industry, is also in the process of scaling back the way the government determines risks associated with dangerous chemicals, The New York Times recently reported.

Image

A protester during the March for Science in Washington last year.CreditBill Clark/CQ Roll Call, via Getty Images

Jettisoning 'Guidance' Files

A little-noticed change at the Justice Department could have far-reaching impact on the role of science in federal policy across the government.

This year the Justice Department announced it would no longer use "guidance documents," which are written by experts at other agencies, to enforce laws. "This change makes a lot of the big, science-based laws unenforceable," said Dr. Goldman of the Union of Concerned Scientists.

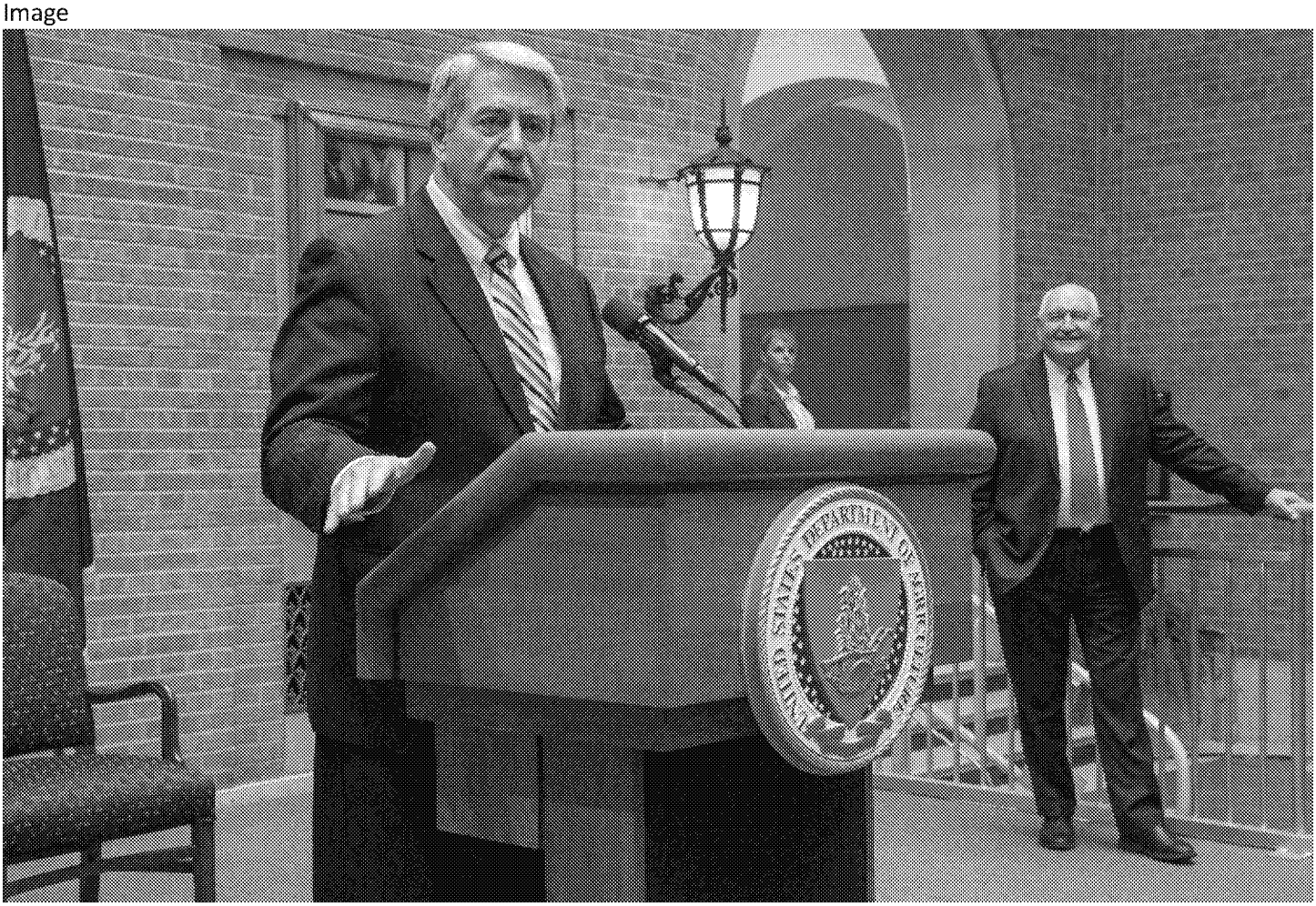
For decades, enforcement of major health and environmental laws — including the Clean Air Act, Clean Water Act, Endangered Species Act and laws governing food safety and exposure to chemicals — has relied heavily on guidance documents written by scientists at the E.P.A., Agriculture Department, Food and Drug Administration and other agencies that supply the specific interpretation of how to carry out the laws. Guidance documents might, for instance, detail how industries should monitor and report their pollution, or how food makers should watch for food-borne illnesses.

A spokesman for the Justice Department said in an email that the new guidance policy would not affect the enforcement of science-based laws. "The Department of Justice continues to aggressively and successfully enforce the nation's laws, including environmental and health laws," the spokesman said, on condition of anonymity because he was not authorized to speak on the record. "Assertions to the contrary are incorrect."

At the Department of Agriculture, the agency is redefining part of its core mission, the scientific monitoring of food safety, to emphasize promoting exports of American farm products. Last year, the agency's secretary, Sonny Perdue, created a new under secretary of trade to push exports worldwide. He also moved an office devoted to international food-safety issues from the agency's Food Safety and Inspection Service to its new Trade and Foreign Agricultural Affairs office.

Putting the management of food safety under the aegis of trade, rather than science, "undermines the whole history that the U.S. has for science-based standards for food," said Catherine E. Woteki, a former chief scientist at the agency from 2010 to 2017.

Image



Ted McKinney, left, at his swearing-in as under secretary for trade and foreign agricultural affairs at the Agriculture Department, with Sonny Perdue, the agency's chief.CreditUnited States Department of Agriculture

A department spokesman said the decision to move the office, known as Codex, came in response to aggressive trade measures by other countries, and that food safety would not be affected.

The agency "makes decisions based on sound science, data and evidence," said the spokesman, Tim Murtaugh. "Unfortunately, we have seen other nations use food safety standards as weapons in trade relations, manipulated for protectionist purposes," he said. "Moving Codex to the mission area where U.S.D.A. coordinates all international activity simply makes sense."

Scientists Resign

The Interior Department secretary, Ryan Zinke, is working to carry out Mr. Trump's campaign pledge to open public lands to extract oil, gas and coal. At the same time, though, his agency has pulled back from examining the health risks to fossil fuel workers.

In August, the department halted a study by the National Academies of Sciences, Engineering and Medicine into links between surface mining and health, specifically the exposure to coal dust in the air and drinking water. "We never got a clear reason why it was canceled," said Marcia McNutt, president of the National Academy of Sciences.

Her organization reached out to other possible donors to continue funding it, said Dr. McNutt, but was unable to find takers. "If the government didn't want to know the answers, it was hard to justify funding this," she said.

Several Interior Department scientists have resigned to protest actions like these that are perceived as undermining research.

Last June, at least two dozen senior career officials at the department were told they would be reassigned to new positions. While it is not unusual for new administrations to make personnel moves, some said the moves appeared intended to undermine the department's environmental research.

Among them was Joel Clement, a climate change scientist who was reassigned to an office overseeing fees from fossil fuel drilling. He viewed it as an effort to push him to resign. Months later, he did.

"The reassignment letter seemed clearly retaliatory," he said. "I was a top climate adviser, and they reassigned me to collect money from oil companies — come on."

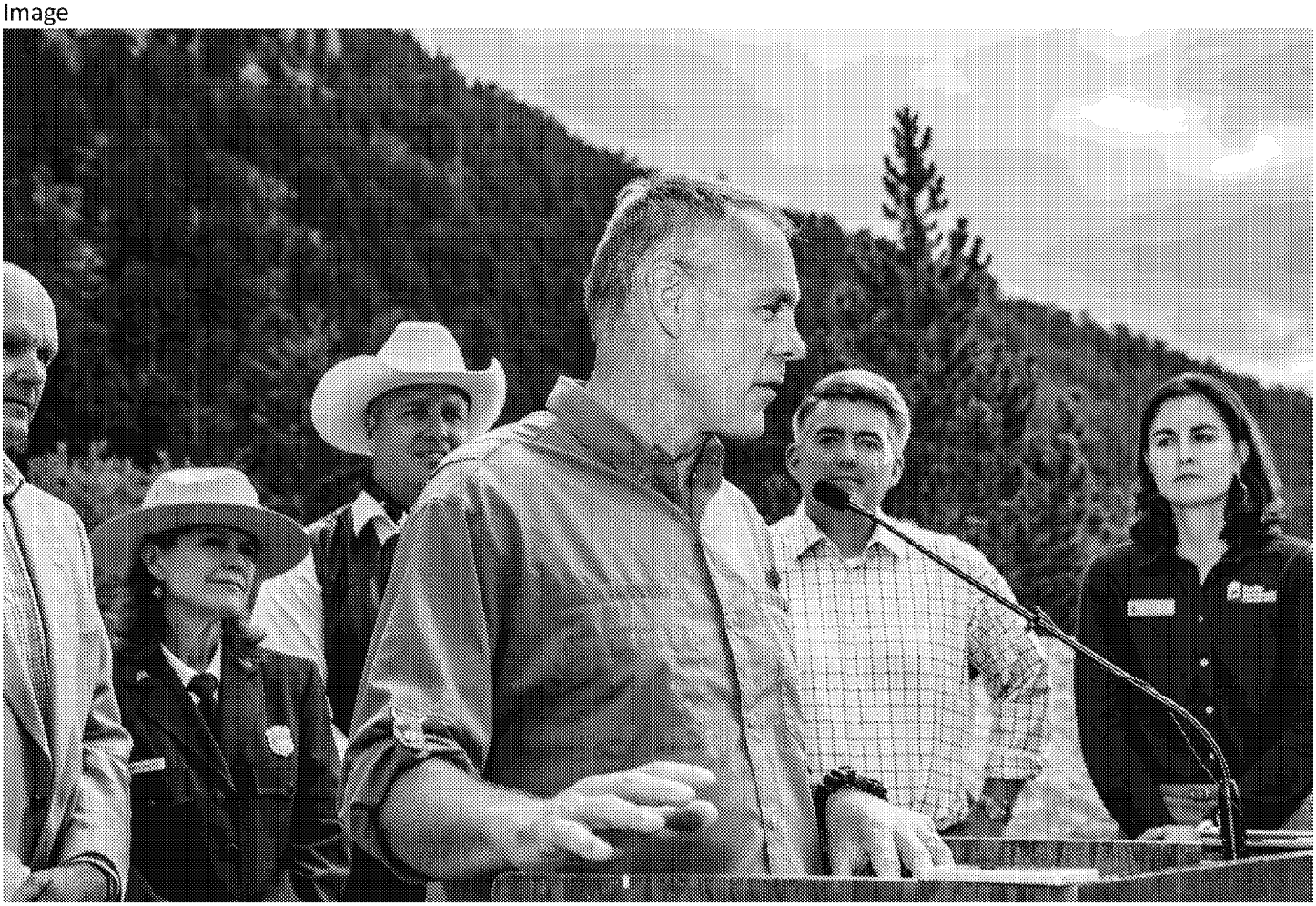
Heather Swift, a spokeswoman for the Interior Department, said, "The president signed an executive order to reorganize the federal government for the future and the secretary has been absolutely out front on that issue." She said that Mr. Clement and others took their jobs "knowing that they could be called upon to work in different positions at any time."

Ms. Swift did not respond to other questions about the agency.

In January, the majority of members of the Interior Department's National Park System Advisory Board, which advises on management of national parks, resigned to protest Trump administration policies. Tony Knowles, the former head of the board, said that Mr.

Zinke "appears to have no interest in continuing the agenda of science, the effect of climate change, pursuing the protection of the ecosystem."

Image



Ryan Zinke, the secretary of the Interior Department, which has abruptly halted a study into links between surface mining and health.CreditRyan David Brown for The New York Times

Beyond the Interior Department, government scientists say they are feeling a rising indifference to their work, as well as occasional open hostility, that is triggering a brain drain.

Among the scientists who have chosen to move on is Ben Sanderson of the National Center for Atmospheric Research in Boulder, Colo., whose research focuses on the impact of climate change on society. In the Trump administration, "To talk about climate risk when connected to human activity is now a no-no if you want to get government funding," Dr. Sanderson said.

Last year, he saw a way out: the French government's "Make Our Planet Great Again" program. Dr. Sanderson was awarded a $1.8 million, five-year grant to work for Météo-France, the national weather forecaster, at its campus in Toulouse.

"The French program was offering an opportunity to work on climate impacts — the work that's at the core of my research," Dr. Sanderson said. That kind of science, he said, "is increasingly difficult to do in the U.S."

Coral Davenport covers energy and environmental policy, with a focus on climate change, from the Washington bureau. She joined The Times in 2013 and previously worked at Congressional Quarterly, Politico and National Journal. @CoralMDavenport · Facebook

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 6/4/2018 7:34:08 PM
To: Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]
Subject: Fwd: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Maybe you can reach out to her and help her get to the landing page.

Sent from my iPhone

Begin forwarded message:

> **From:** "Franz, Christina" <Christina_Franz@americanchemistry.com>
> **Date:** June 4, 2018 at 2:17:12 PM EDT
> **To:** "Sinks, Tom" <Sinks.Tom@epa.gov>
> **Subject: RE: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations**
>
> Thanks for the reply. Perhaps you can also help with the link to the July 17 stakeholder meeting on the Transparency proposal. The link in EPA's announcement does not work. Can you help me locate a working link?
>
> Thank you,
>
> *Christina Franz*
> Senior Director, Regulatory & Technical Affairs
> American Chemistry Council
> 700 Second St., NE
> Washington, D.C. 20002
> 202-249-6406
> Christina_Franz@americanchemistry.com
>
> ---
>
> **From:** Sinks, Tom [mailto:Sinks.Tom@epa.gov]
> **Sent:** Thursday, May 24, 2018 11:12 AM
> **Cc:** Sinks, Tom <Sinks.Tom@epa.gov>
> **Subject:** EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations
>
> ---
>
> **From:** EPA Press Office [mailto:press=epa.gov@cmail20.com] **On Behalf Of** EPA Press Office
> **Sent:** Thursday, May 24, 2018 8:00 AM
> **To:** Kuhn, Kevin <Kuhn.Kevin@epa.gov>
> **Subject:** EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

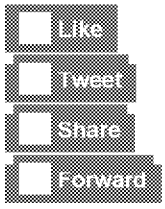
Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

Visit The EPA's Newsroom

<!--[if !vml]--> <!--[endif]-->



U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Unsubscribe

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 6/4/2018 7:29:50 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]
Subject: Re: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Sorry but I can't send from my phone. However if you google EPA OSA our website will come up. From there you can find the transparency in regulatory science page and from there the page to register If that doesn't work email me back and I will ask an OSA staffer to walk you through it.

Sent from my iPhone

On Jun 4, 2018, at 2:17 PM, Franz, Christina <Christina_Franz@americanchemistry.com> wrote:

> Thanks for the reply. Perhaps you can also help with the link to the July 17 stakeholder meeting on the Transparency proposal. The link in EPA's announcement does not work. Can you help me locate a working link?
>
> Thank you,
>
> *Christina Franz*
> Senior Director, Regulatory & Technical Affairs
> American Chemistry Council
> 700 Second St., NE
> Washington, D.C. 20002
> 202-249-6406
> Christina_Franz@americanchemistry.com
>
> **From:** Sinks, Tom [mailto:Sinks.Tom@epa.gov]
> **Sent:** Thursday, May 24, 2018 11:12 AM
> **Cc:** Sinks, Tom <Sinks.Tom@epa.gov>
> **Subject:** EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations
>
> **From:** EPA Press Office [mailto:press=epa.gov@cmail20.com] **On Behalf Of** EPA Press Office
> **Sent:** Thursday, May 24, 2018 8:00 AM
> **To:** Kuhn, Kevin <Kuhn.Kevin@epa.gov>
> **Subject:** EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

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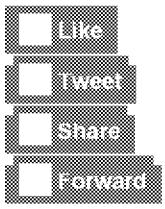
<!--[if !vml]--><image002.png><!--[endif]-->



U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 6/1/2018 2:02:41 PM
To: Staff_OSA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be69b6688a614ca39759d52ca5716ef3-OSA]
Subject: RE: Concern about Secret Science - FW: Form submission from: Stationary Sources of Air Pollution Contact Us About Stationary Sources of Air Pollution form

I think the regular response would be fine

From: Staff_OSA
Sent: Friday, June 01, 2018 10:01 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: FW: Concern about Secret Science - FW: Form submission from: Stationary Sources of Air Pollution Contact Us About Stationary Sources of Air Pollution form

Someone submitted their comments on the Transparency rule to an OAR website. I will forward this to the docket. Do you want any sort of reply to the person who submitted the comments?

Cheryl A. Hawkins, Ph.D.
US EPA/ORD/Office of the Science Advisor
RRB 41259
(202)564-7307
hawkins.cheryla@epa.gov

From: AirAction
Sent: Wednesday, May 30, 2018 1:07 PM
To: Staff_OSA <Staff_OSA@epa.gov>
Subject: Fw: Concern about Secret Science - FW: Form submission from: Stationary Sources of Air Pollution Contact Us About Stationary Sources of Air Pollution form

Forwarding this inquiry that was submitted via an OAR website about stationary sources and air pollution and appears to be about the proposed rule titled, "Strengthening Transparency in Regulatory Science."

Thank you.

-----Original Message-----
From: drupal_admin@epa.gov [mailto:drupal_admin@epa.gov] On Behalf Of Sue Miller via EPA
Sent: Wednesday, April 25, 2018 10:02 AM
Subject: Form submission from: Stationary Sources of Air Pollution Contact Us About Stationary Sources of Air Pollution form

Submitted on 04/25/2018 10:01AM
Submitted values are:

Name: Sue Miller
Email Address: Personal Email / Ex. 6
Comments:
I understand there is a proposed rule change which would, in part, eliminate the confidentiality of test subjects. It's pretty obvious no one wants their individual personal data available for public scrutiny. And it's also obvious this rule is attempting to dial back air pollution standards by eliminating landmark research. This rule change needs to go away. I'm old enough to remember when our cities' air were filled with smog. It was awful.

Message

From: Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]
Sent: 5/30/2018 2:59:57 PM
To: Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]
CC: Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Anand Mudambi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a94638932b49af8a6cf581262d5059-Mudambi, Anand]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Kumar, Manisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497133a6697a45f9bea221a07f4359f6-Kumar, Mani]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]
Subject: RE: FYI

Excellent great thanks

From: Perry, Dale
Sent: Wednesday, May 30, 2018 10:37 AM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Cc: Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Anand Mudambi <Mudambi.Anand@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>; Kumar, Manisha <Kumar.Manisha@epa.gov>; Greene, Mary <greene.mary@epa.gov>
Subject: RE: FYI

Hi Tom,
Room 1153 can hold 150 people and has three sections with 50 chairs each. When I have previously attended such events there weren't any issues with lack of seating and staff came and went at their leisure. We can definitely discuss further. Regarding your other question about live streaming, I spoke to Nancy Grantham/OPA this morning and she mentioned this briefly. OPA, OGC, and OARM are meeting today to discuss public events in general, based on lessons learned from the PFAS meeting, and will also discuss the July 17th hearing. After they meet today, she is going to pull everyone together to discuss these kinds of logistics so stand by for more on these topics.
Thanks – looking forward to working with everyone,
Dale

Dale H. Perry, Ph.D.
Deputy Chief of Staff, Office of Research & Development
Desk: 202-564-7338
Mobile: 202-380-6517

From: Sinks, Tom
Sent: Wednesday, May 30, 2018 9:53 AM
To: Perry, Dale <Perry.Dale@epa.gov>
Cc: Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Anand Mudambi <Mudambi.Anand@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>; Kumar, Manisha <Kumar.Manisha@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Greene, Mary <greene.mary@epa.gov>
Subject: FW: FYI

Hi Dale – here is another issue I'd like your advice/recommendation on. How should we best accommodate requests from EPA staff and EPA programs wanting to attend the hearing? . Maybe we should reserve a small number of seats for EPA attendees and let them know they will be available on a 1st come 1st serve basis or hold a chair for each interested program. I'm not sure how many people the MAP room can accommodate so we will need to calculate this into how many people can attend at any one time.

From: Lowit, Anna
Sent: Friday, May 25, 2018 3:05 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: FW: FYI

Hey Tom

Quick question.... To attend in person to listen to the comments, do we need to register?

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Vogel, Dana
Sent: Thursday, May 24, 2018 3:41 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: FW: FYI

From: Sinks, Tom
Sent: Thursday, May 24, 2018 3:40 PM
To: Burden, Susan <Burden.Susan@epa.gov>; STPC_SSP <STPC_SSP@epa.gov>
Subject: FYI

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/18/2018 3:59:53 PM
To: Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]
Subject: Fwd: Updated Data Access Notice
Attachments: Data Access Draft - EPA - 4-17-18 - CLEAN.docx; ATT00001.htm

Sorry about that - He had some minor edits we're working in

Begin forwarded message:

> **From:** "Woods, Clint" <woods.clint@epa.gov>
> **Date:** April 18, 2018 at 9:18:20 AM EDT
> **To:** "Ford, Hayley" <ford.hayley@epa.gov>
> **Subject: Fwd: Updated Data Access Notice**
>
> Hayley,
>
> Here's the current version of the data access proposal - I'm tied up giving a presentation but can run down a copy for the Administrator in 15 mins (Think he had asked Brittany for a copy at the 8:30 meeting)
>
> Clint
>
> Begin forwarded message:
>
> > **From:** "Woods, Clint" <woods.clint@epa.gov>
> > **Date:** April 17, 2018 at 3:46:54 PM EDT
> > **To:** "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Gunasekara, Mandy" <Gunasekara.Mandy@epa.gov>, "Harlow, David" <harlow.david@epa.gov>
> > **Subject: Fwd: Updated Data Access Notice**
> >
> > FYI - Updated data access draft attached. Event planned for next Tues afternoon.
> >
> > Begin forwarded message:
> >
> > > **From:** "Bolen, Brittany" <bolen.brittany@epa.gov>
> > > **Date:** April 17, 2018 at 12:28:09 PM EDT
> > > **To:** "Rosario A. EOP/OMB Palmieri" EOP / Ex. 6
> > > **Cc:** "Woods, Clint" <woods.clint@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
> > > **Subject: Updated Data Access Notice**
> > >
> > > Hi Rosario,
> > > As discussed, please see attached updated notice. Deliberative Process / Ex. 5
> > > Deliberative Process / Ex. 5 Let me know

when you're available to discuss next steps.
Thanks,
Brittany

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/18/2018 3:41:29 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]
Subject: Op-Ed & TPs
Attachments: Science Op-Ed WL cw.docx; Science Transparency TPs cw.docx

Attached are a few suggested edits upon Will's cleaned up op-ed draft. I also added a couple pages of bullets to the talking points – These are overkill, but I wanted to make sure you had them to pull them as necessary. Thanks!

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/17/2018 9:07:33 PM
To: Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]
Subject: FW: Updated Data Access Draft
Attachments: Data Access Draft - EPA - 4-17-18 - CLEAN.docx

Thought this might be helpful – Thanks!

From: Woods, Clint
Sent: Tuesday, April 17, 2018 12:25 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Schwab, Justin <schwab.justin@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Beck, Nancy <beck.nancy@epa.gov>
Subject: Updated Data Access Draft

Attached version addressed comments from SP, OMB, and you all - Note that one has changes tracked and the other is clean. Thanks!

Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 5/23/2018 9:41:22 PM
To: Daniell, Kelsi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd867173479344b3bda202b3004ff830-Daniell, Ke]; Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]; Schwab, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eed0f609c0944cc2bbdb05df3a10aadb-Schwab, Jus]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]
Subject: RE: FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Good from my end

From: Daniell, Kelsi
Sent: Wednesday, May 23, 2018 5:05 PM
To: Lovell, Will (William) <lovell.william@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: RE: FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Great, thanks Will

From: Lovell, Will (William)
Sent: Wednesday, May 23, 2018 5:04 PM
To: Daniell, Kelsi <daniell.kelsi@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: RE: FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Inserting template language at the bottom for posting a pre-pub document.

From: Daniell, Kelsi
Sent: Wednesday, May 23, 2018 4:57 PM
To: Schwab, Justin <Schwab.Justin@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Woods, Clint <woods.clint@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Konkus, John <konkus.john@epa.gov>

Subject: RE: FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Made that edit below. Please let me know what else.

From: Schwab, Justin
Sent: Wednesday, May 23, 2018 4:53 PM
To: Lovell, Will (William) <lovell.william@epa.gov>; Woods, Clint <woods.clint@epa.gov>
Cc: Daniell, Kelsi <daniell.kelsi@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: Re: FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

Looping in Clint.

Attorney Client / Ex. 5

Sent from my iPhone

On May 23, 2018, at 4:47 PM, Lovell, Will (William) <lovell.william@epa.gov> wrote:

> Looping in Richard.
>
> ---
>
> **From:** Daniell, Kelsi
> **Sent:** Wednesday, May 23, 2018 4:45 PM
> **To:** Bolen, Brittany <bolen.brittany@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>; Schwab, Justin <Schwab.Justin@epa.gov>
> **Cc:** Beach, Christopher <beach.christopher@epa.gov>; Konkus, John <konkus.john@epa.gov>
> **Subject:** FOR REVIEW -- EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations
>
> Please review ASAP. We'd like to schedule this to go out at 8:00am tomorrow morning. We're just waiting for a link from Will/ORD for the pre-publication document. Thanks!

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 5/10/2018 9:59:02 PM
To: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Koerber, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c513901d4fd49f9ab101a6f7a7a863e-Koerber, Mike]
Subject: Fwd: Transparency in Science Updated Draft FR notice
Attachments: FRN extension and hearing 5.10.18 .docx; ATT00001.htm

Follow up

Begin forwarded message:

From: "Siciliano, CarolAnn" <Siciliano.CarolAnn@epa.gov>
Date: May 10, 2018 at 5:46:44 PM EDT
To: "Sinks, Tom" <Sinks.Tom@epa.gov>, "Woods, Clint" <woods.clint@epa.gov>, "Feeley, Drew (Robert)" <Feeley.Drew@epa.gov>, "Nickerson, William" <Nickerson.William@epa.gov>
Cc: "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Cawiezell, Thomas" <Cawiezell.Thomas@epa.gov>, "Hawkins, CherylA" <Hawkins.CherylA@epa.gov>, "Sheppard, Tracy" <Sheppard.Tracy@epa.gov>, "Simons, Andrew" <Simons.Andrew@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>, "Green, Noelle" <Green.Noelle@epa.gov>
Subject: Transparency in Science Updated Draft FR notice

Tom – Attached is a new draft of an Federal Register notice **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Carol Ann Siciliano
Associate General Counsel
Cross-Cutting Issues Law Office
Office of General Counsel
U.S. Environmental Protection Agency
(202) 564-5489
siciliano.carolann@epa.gov

From: Sinks, Tom
Sent: Thursday, May 10, 2018 5:16 PM
To: Woods, Clint <woods.clint@epa.gov>
Cc: Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Cawiezell, Thomas <Cawiezell.Thomas@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>
Subject: FW: Draft FR notice

Hi Clint – CarolAnn dropped by my office to discuss this proposed FRN. She made some notes and will be sending a revised version before she heads home tonight. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Tom Cawiezell manages my calendar. I will be off tomorrow but available if needed by cell phone Personal Phone / Ex. 6 Personal Phone / Ex. 6

Tom

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 5/10/2018 9:56:28 PM
To: Lewis, Josh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b22d1d3bb3f84436a524f76ab6c79d7e-JOLEWIS]; Koerber, Mike [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c513901d4fd49f9ab101a6f7a7a863e-Koerber, Mike]
CC: Atkinson, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2155adef6a44aea9410741f0c01d27-Atkinson, Emily]
Subject: Fwd: Draft FR notice
Attachments: FRN for Hearing and to Extend the Comment Period for Proposed science transp rule.docx; ATT00001.htm

FYI - Would we have anyone available Deliberative Process / Ex. 5 regarding the logistics of an FRN to extend a comment period/announce a public hearing? Deliberative Process / Ex. 5
Deliberative Process / Ex. 5

Begin forwarded message:

From: "Sinks, Tom" <Sinks.Tom@epa.gov>
Date: May 10, 2018 at 5:15:52 PM EDT
To: "Woods, Clint" <woods.clint@epa.gov>
Cc: "Siciliano, CarolAnn" <Siciliano.CarolAnn@epa.gov>, "Sinks, Tom" <Sinks.Tom@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Cawiezell, Thomas" <Cawiezell.Thomas@epa.gov>, "Hawkins, CherylA" <Hawkins.CherylA@epa.gov>
Subject: FW: Draft FR notice

Hi Clint – CarolAnn dropped by my office to discuss this proposed FRN. She made some notes and will be sending a revised version before she heads home tonight. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Tom Cawiezell manages my calendar. I will be off tomorrow but available if needed by cell phone Personal Phone / Ex. 6
Personal Phone / Ex. 6

Tom

From: Siciliano, CarolAnn
Sent: Thursday, May 10, 2018 4:48 PM
To: Sinks, Tom <Sinks.Tom@epa.gov>
Subject: Fwd: Draft FR notice

Carol Ann Siciliano
Associate General Counsel
Cross-Cutting Issues Law Office

Office of General Counsel
U.S. Environmental Protection Agency
(202) 564-5489
siciliano.carolann@epa.gov

Begin forwarded message:

From: "Sheppard, Tracy" <Sheppard.Tracy@epa.gov>
Date: May 10, 2018 at 3:52:24 PM EDT
To: "Siciliano, CarolAnn" <Siciliano.CarolAnn@epa.gov>, "Simons, Andrew" <Simons.Andrew@epa.gov>
Subject: RE: Draft FR notice

I've made the edit.

Tracy L. Sheppard, Attorney-Advisor,
US EPA, Office of General Counsel
Sheppard.Tracy@epa.gov
(202) 564-1305 office
(202) 839-2038 mobile

From: Siciliano, CarolAnn
Sent: Thursday, May 10, 2018 3:44 PM
To: Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Simons, Andrew <Simons.Andrew@epa.gov>
Subject: RE: Draft FR notice

Deliberative Process / Ex. 5

Carol Ann Siciliano
Associate General Counsel
Cross-Cutting Issues Law Office
Office of General Counsel
U.S. Environmental Protection Agency
(202) 564-5489
siciliano.carolann@epa.gov

From: Sheppard, Tracy
Sent: Thursday, May 10, 2018 3:43 PM
To: Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Simons, Andrew <Simons.Andrew@epa.gov>
Subject: RE: Draft FR notice

Deliberative Process / Ex. 5

Tracy L. Sheppard, Attorney-Advisor,

US EPA, Office of General Counsel
Sheppard.Tracy@epa.gov
(202) 564-1305 office
(202) 839-2038 mobile

From: Siciliano, CarolAnn
Sent: Thursday, May 10, 2018 3:30 PM
To: Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Simons, Andrew <Simons.Andrew@epa.gov>
Subject: RE: Draft FR notice

Thank you, Tracy. I hope to talk to Tom Sinks today. I'll keep you & Andy informed. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Carol Ann Siciliano
Associate General Counsel
Cross-Cutting Issues Law Office
Office of General Counsel
U.S. Environmental Protection Agency
(202) 564-5489
siciliano.carolann@epa.gov

From: Sheppard, Tracy
Sent: Thursday, May 10, 2018 3:27 PM
To: Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Simons, Andrew <Simons.Andrew@epa.gov>
Subject: Draft FR notice

Here's the draft notice for the comment period extension and hearing. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

I hadn't planned to work tomorrow but I will be available before 10am and after 1pm if there's anything you need me to do.

Tracy L. Sheppard, Attorney-Advisor,
US EPA, Office of General Counsel
Sheppard.Tracy@epa.gov
(202) 564-1305 office
Personal Phone / Ex. 6

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 4/17/2018 11:51:39 AM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
Attachments: ehp.1204942_508.pdf; ATT00001.txt

https://ehp.niehs.nih.gov/pdf-files/2013/Feb/ehp.1204942_508.pdf

Data Disclosure for Chemical Evaluations

Randall Lutter,[1] Craig Barrow,[2] Christopher J. Borgert,[3] James W. Conrad Jr.,[4] Debra Edwards,[5] and Allan Felsot[6]

[1]Independent Consultant, Bethesda, Maryland, USA; [2]Craig Barrow Consulting, Gibsonia, Pennsylvania, USA; [3]Applied Pharmacology and Toxicology Inc., Gainesville, Florida, USA; [4]Conrad Law & Policy Counsel, Washington, DC, USA; [5]Independent Consultant, Alexandria, Virginia, USA; [6]Food and Environmental Quality Lab, Washington State University, Richland, Washington, USA

Background: Public disclosure of scientific data used by the government to make regulatory decisions for chemicals is a practical step that can enhance public confidence in the scientific basis of such decisions.

Objectives: We reviewed the U.S. Environmental Protection Agency's (EPA) current practices regarding disclosure of data underlying regulatory and policy decisions involving chemicals, including pesticides. We sought to identify additional opportunities for the U.S. EPA to disclose data and, more generally, to promote broad access to data it uses, regardless of origin.

Discussion: We recommend that when the U.S. EPA proposes a regulatory determination or other policy decision that relies on scientific research, it should provide sufficient underlying raw data and information about methods to enable reanalysis and attempts to independently reproduce the work, including the sensitivity of results to alternative analyses. This recommendation applies regardless of who conducted the work. If the U.S. EPA is unable to provide such transparency, it should state whether it had full access to all underlying data and methods. A timely version of submitted data cleared of information about confidential business matters and personal privacy should fully meet the standards of transparency described below, including public access sufficient for others to undertake an independent reanalysis.

Conclusion: Reliable chemical evaluation is essential for protecting public health and the environment and for ensuring availability of useful chemicals under appropriate conditions. Permitting qualified researchers to endeavor to independently reproduce the analyses used in regulatory determinations of pesticides and other chemicals would increase confidence in the scientific basis of such determinations.

Key words: chemicals, data disclosure, information quality, pesticides. *Environ Health Perspect* 121:145–148 (2013). http://dx.doi.org/10.1289/ehp.1204942 [Online 11 December 2012]

The evaluation of chemicals is an important topic of public interest. Against this backdrop, CropLife America (Washington, DC), an association of agricultural pesticide manufacturers, sponsored a meeting of experts from a variety of backgrounds to address how to judge the quality of scientific work in chemical evaluation and, if possible, to seek consensus or agreement. Here we present a proposal from some of those experts addressing a more specific topic: disclosure of and access to data underlying regulatory determinations concerning pesticides and other chemicals.

It is axiomatic that scientific work used in regulatory determinations should be of high quality [e.g., Information Quality Act (IQA) 2000]. Greater public disclosure of data and methods is a practical step toward ensuring that scientific work used in regulatory determinations meets this standard for quality. Greater disclosure should reduce bias because it makes masking of bias more difficult. In addition, the reliability of scientific work used in regulatory evaluations of chemicals is likely to improve if greater disclosure leads to increased evaluation of data quality and that evaluation then leads to improved designs and generally higher-quality studies. Furthermore, access to the underlying raw data and methodology may be required for the public to provide more informed comments to regulatory agencies that will rely on the study (Portland Cement Association *v.* Ruckelshaus 1973). Ultimately, the reliability of scientific work can be judged definitively only if researchers have disclosed sufficient data and information about methods and results to permit others to evaluate data quality and to try to reproduce or replicate key findings, including the sensitivity of results to alternative analyses.

This does not mean that independent replicability is by itself a standard sufficient for quality. Replicability by independent entities is one of the three generally accepted tenets of valid regulatory science. The other two tenets are that the identity and authenticity of scientific measurements be verifiable within a defined range of precision, and that measurements and observations not be confounded by extraneous factors known to corrupt their accuracy and precision (Borgert et al. 2011; Gori 2009a, 2009b). The heads of the National Institute of Environmental and Health Sciences and the Agency for Toxic Substances and Disease Registry have endorsed these tenets in testimony (Birnbaum and Falk 2010). Henry and Conrad (2008) discussed a variety of other standards and practices (e.g., peer review) that can be used as indications of quality. Although disclosure by itself may not be sufficient to ensure quality, it is necessary.

The IQA requires the U.S. Office of Management and Budget (OMB) and agencies such as the U.S. Environmental Protection Agency (EPA) to issue guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies. The OMB's guidelines under the IQA embrace a disclosure principle, stating that when agencies disseminate "influential scientific, financial, or statistical information," they "shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties" (OMB 2002). The OMB guidelines explain that the standard they use, "capable of being substantially reproduced," is less stringent than a "confirmation" standard because it simply requires that an agency's analysis be sufficiently transparent that another qualified party could replicate it through reanalysis. The U.S. EPA has its own information quality guidelines, which are consistent with those of the OMB (U.S. EPA 2002). Although one federal district court found that the IQA "does not create a legal right to access to information" (Salt Institute *v.* Leavitt 2006), two more recent federal appeal courts left open the possibility of judicial review of agency actions measured against IQA requirements

Address correspondence to R. Lutter, 5024 Newport Ave., Bethesda, MD 20816 USA. Telephone: (240) 271-8430. E-mail: rwlutter@gmail.com

This commentary is based in part on discussions that occurred during a meeting convened by CropLife America on 13 May 2011, in Washington, DC. Participants in the meeting included the authors of this work and the following experts, whose helpful comments we gratefully acknowledge: V. Dellarco (U.S. Environmental Protection Agency), D. Epstein (U.S. Department of Agriculture), M. Fry (American Bird Conservancy), G. Gray (George Washington University), S. Krimsky (Tufts University), J. McFarland (Syngenta Crop Protection Inc.), J. Sass (Natural Resources Defense Council), and J. Schroeder (New Mexico State University).

The views expressed in this document are entirely those of the authors and not necessarily those of any organization(s) with which any author is affiliated.

R.L., an independent consultant, consults for CropLife America (CLA) and received financial support from the CLA to moderate a forum and serve as principal author of this paper. C.B. consults for Dow AgroSciences LLC, an R&D-based agrochemical producer, registrant, and marketer. C.J.B. received CLA funding to review and analyze scientific literature on data quality. J.W.C. has previously received funding from the American Chemistry Council to author work on the quality of scientific research evaluating chemicals. D.E. consults for a variety of pesticide manufacturers and for the CLA. A.F. has consulted with nonprofit organizations funded by the CLA about pesticide issues.

Received 9 January 2012; accepted 5 December 2012.

(Americans for Safe Access *v.* U.S. Department of Health and Human Services 2010; Prime Time International Co. *v.* Vilsack 2010). Thus, the IQA at a minimum provides support for the disclosure concepts discussed here and may provide opportunities for enforcing such disclosure.

Legislation commonly known as the "Shelby Amendment" (Treasury and General Government Appropriations Act 1998) led the OMB to revise its Circular A-110 so that, in response to a Freedom of Information Act (FOIA 1966) request, federal agencies must release research data relating to published research findings produced under an award (e.g., federal grant or contract) that were considered by the agency in developing action that has the force and effect of law (American Association for the Advancement of Science 2005; OMB 1999). Much of the research that the U.S. EPA relies on in making decisions regarding regulated chemicals, particularly pesticides, is not federally funded, although published studies cited in the U.S. EPA's Integrated Risk Information System (IRIS) often received federal funding.

In describing implementation of the Shelby Amendment, Conrad and Becker (2011) stated that

> [i]t seems only fair for privately-funded work to be subject to the same disclosure requirement, at least when the persons conducting or funding it submit it to an agency.

Similarly, in their report *Improving the Use of Science in Regulatory Policy*, the Bipartisan Policy Center (2009) recommended that

> Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Shelby Amendment and its implementing Circular regardless of who funded the study.

Several prominent journals have adopted data disclosure policies intended to facilitate replication. *Nature*'s policy (Nature Publishing Group 2012) states:

> An inherent principle of publication is that others should be able to replicate and build upon the authors' published claims. Therefore, a condition of publication in a *Nature* journal is that authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications.

Similarly, the policy of the *Proceedings of the National Academy of Sciences* (PNAS 2012) states: "To allow others to replicate and build on work published in *PNAS*, authors must make materials, data, and associated protocols available to readers." *Science* has similar policies (Science 2012) and recently published a special section on the importance and challenges of data replication and reproducibility in different fields (Jasny et al. 2011).

Our recommendations are consistent with the Shelby Amendment, recommendations of the Bipartisan Policy Center, and the practices of prominent journals, as well as the recommendations of Conrad and Becker. Our goal is to promote the broadest possible access to data used by the U.S. EPA, regardless of who prepared or compiled the data.

Discussion

The U.S. EPA already has access to considerable data underlying studies submitted by pesticide registrants that it uses in regulatory decisions regarding pesticides. For example, if a regulated entity submits to the U.S. EPA a Good Laboratory Practice (GLP) study (Good Laboratory Practice Standards 1989) required for a pesticide registration, it must retain all "raw" data to comply with GLP requirements (e.g., 40 CFR 160.190 and 40 CFR 160.195; U.S. EPA 1989). The U.S. EPA has access to such data because, for the purpose of supporting a pesticide registration, it may refuse to consider reliable any data from a study that is not conducted in accordance with those GLP rules (40 CFR 160.17). On the other hand, a U.S. EPA request for data used in a peer-reviewed or "gray literature" study may be fulfilled completely, partially, or not at all.

We recommend that when the U.S. EPA proposes a regulatory determination or other policy decision for pesticides or other chemicals that relies on scientific research, it should provide sufficient disclosure of data and information about methods to enable reanalysis and attempts at independent replication of the work, including the sensitivity of results to alternative analyses. This recommendation applies whether the decision is a discrete compound-specific decision, such as setting an uncertainty factor or determining a benchmark dose, or a programmatic policy decision, such as adoption of a particular study design or method for particular types of testing. Such disclosure should include all raw data—that is, data as originally collected in accordance with research protocols, the research protocols themselves, and all methods (including computer programs used for statistical modeling). Thus it would extend from the supporting science (e.g., animal toxicity studies used to calculate cancer slope factors) to risk assessments (i.e., analytic work that takes as given the results of toxicological and epidemiological work and integrates them into an assessment of risk). The recommended disclosure would be sufficiently detailed to include recorded ages and sex of test animals, all laboratory results, and all recorded observations about health and clinical conditions, with all disclosed data recorded according to research protocols. Disclosure should be sufficient to provide for a full understanding of the operation of any proprietary models used in supporting studies.

Further, this recommendation applies regardless of who conducted the work (e.g., researchers with industry, government, or academic institutions). In instances where the U.S. EPA is unable to provide such a level of transparency because of lack of access or legal restrictions on disclosure, it should state the degree of access it had to such data. Finally, if the U.S. EPA did not enjoy full access, it should offer a cogent explanation of why it decided to make regulatory or policy decisions using results of analyses that lacked the ideal level of transparency and how, specifically, it weighed such results relative to other evidence.

The U.S. EPA has taken some constructive steps in this direction. Its Office of Pesticide Programs issued *Evaluation Guidelines for Ecological Toxicity Data in the Open Literature* (U.S. EPA 2011) that partially implements the ideas discussed here. In particular, the guidelines (U.S. EPA 2011) acknowledge that the "most reliable means of determining whether study conclusions can be verified is through access to the raw data" and state that

> [w]here raw data are not available to verify the study endpoints, the reviewer must discuss the uncertainties associated with quantitative use of the data relative to studies where raw data are provided.

Finally, the U.S. EPA (2011) advised analysts that

> [d]epending on the importance of the open literature study to the risk assessment conclusions, attempts should be made to obtain missing information from the study, including the raw data, if possible.

Although these steps represent improvements in access to and disclosure of underlying data, they fall short of our recommendations. First, they do not apply generally to all data used for chemical evaluation. Second, the U.S. EPA (2011) guidelines discuss access to raw data as important for verification of conclusions. However, there is no mention of replication of results, although replication (including an assessment of the robustness of results) is an essential part of ensuring validity. In addition, these U.S. EPA guidelines are silent about access to detailed information about methods (e.g., computer code). Fourth, the guidelines require an analyst to "discuss the uncertainties associated with quantitative use of the data." A better approach, adopted here, would be for the U.S. EPA to state that it will explain how, specifically, it weighed such results relative to other data. Finally, the guidelines (U.S. EPA 2011) limit instructions to obtain raw data "depending on the importance of the open literature study," and appear focused on "missing information" instead of declaring that all raw data underlying studies used in quantitative regulatory determinations should be generally available to the U.S. EPA and the public.

Our recommendation does not mean that the U.S. EPA should require that all disseminated data be subjected to a reproducibility requirement. As explained in the OMB information quality guidelines (OMB 2002), constraints related to ethics, feasibility, or confidentiality may preclude disclosure or a replication exercise (i.e., a new experiment, test, or sample) prior to each dissemination. Instead, we recommend that the U.S. EPA generally provide sufficient transparency about data and methods that a qualified member of the public could undertake an independent reanalysis. These standards for transparency should apply to agency analyses of data from a single study as well as to analyses that combine information from multiple studies.

Section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA 1972) provides for public access to safety and efficacy information (U.S. EPA 2010). There are two types of exceptions, which are important to respect and which have been implemented without undermining the objectives of disclosure discussed here. First, certain information that is generally not related to assessing risks or making regulatory determinations is excluded from disclosure as confidential business information. By law, the U.S. EPA may not make public information that discloses *a*) manufacturing or quality control processes, *b*) methods for testing and measuring the quantity of deliberately added inert ingredients, and *c*) the identity or percentage quantity of deliberately added inert ingredients (FIFRA 1972). [We note that on 23 December 2009 the U.S. EPA issued an advance notice of proposed rule making to increase the public availability of information regarding the identity of the inert ingredients of pesticide products (U.S. EPA 2009).]

Second, FIFRA protects the proprietary interests of the pesticide manufacturers that first made the investments necessary to produce the data by requiring the U.S. EPA to ensure that the release of data does not unfairly benefit the competitors of those companies (FIFRA 1972). To accomplish this, the U.S. EPA must obtain—before disclosure of such data—affirmations from recipients that they will not give the data to multinational business interests that might seek to register in other countries the pesticide products that are the subject of the testing (U.S. EPA 2012a). In addition, the agency must keep lists of the people who obtain such data and who they represent.

The U.S. EPA currently reviews and redacts data before a version cleared of confidential business information (CBI) can be made public. This process currently requires the public to file a formal request under FOIA for each study for which it wants undisclosed information. The U.S. EPA reported to Congress in 2010 that it has "completely redesigned its electronic FOIA reading room to make tens of thousands of highly sought after pesticide science and regulatory records publicly available without the filing of a FOIA request" (Gottesman 2010). To further advance such reforms, we suggest that the U.S. EPA convene a diverse stakeholder group (e.g., through its Pesticide Program Dialogue Committee; U.S. EPA 2012b) to solicit specific ideas about ways to streamline the current process to facilitate timely disclosure of data consistent with legal protections under FIFRA and FOIA. A timely CBI-cleared version of industry-submitted data should fully meet the standards of transparency described here, including public access to enough data and details of the study design that others could undertake an independent replication effort.

The timing of data disclosure matters. The U.S. EPA should make publicly available data underlying a regulatory determination or other policy decisions for pesticides by the beginning of the applicable public comment period to provide interested members of the public a meaningful opportunity for review before commenting on the proposal. Disclosure would generally occur after publication of academic articles. An exception would occur if the publication process was unavoidably so lengthy that the study was forthcoming rather than published when used by the regulator in a proposed regulatory or policy decision. If the agency uses data submitted by a manufacturer that are protected from release by federal law, the regulatory agency should provide information on the data and methods generally in a manner that facilitates efforts at independent analysis by qualified members of the public.

Conclusion

Evaluating chemicals within a science-based framework is essential to protecting public health and the environment and ensuring availability of useful chemicals under appropriate terms and conditions. Public access to data and methodologies used in regulatory determinations is equally essential to maintaining public trust in regulators' decisions. The principles and recommendations we describe here regarding data access will help achieve these goals by permitting qualified researchers to endeavor to replicate analytic results independently.

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Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 6/6/2018 1:11:03 PM
To: Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]
CC: Daniell, Kelsi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd867173479344b3bda202b3004ff830-Daniell, Ke]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: Re: "Strengthening transparency..." story

Agree

On Jun 6, 2018, at 9:05 AM, Lovell, Will (William) <lovell.william@epa.gov> wrote:

> Looping in Clint and Richard and taking off Brittany.
>
> **Deliberative Process / Ex. 5**
>
> **From:** Daniell, Kelsi
> **Sent:** Tuesday, June 5, 2018 5:26 PM
> **To:** Bolen, Brittany <bolen.brittany@epa.gov>; Block, Molly <block.molly@epa.gov>; Lovell, Will (William) <lovell.william@epa.gov>
> **Subject:** Fwd: "Strengthening transparency..." story
>
> See below. Anything we want to say here?
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **Resent-From:** <Press@epa.gov>
> > **From:** "Eric Roston (BLOOMBERG/ NEWSROOM:)" <eroston@bloomberg.net>
> > **Date:** June 5, 2018 at 10:19:17 AM MDT
> > **To:** "Wilcox, Jahan" <wilcox.jahan@epa.gov>, Press <Press@epa.gov>
> > **Subject: Fwd:"Strengthening transparency..." story**
> > **Reply-To:** Eric Roston <eroston@bloomberg.net>
> >
> > Hi, resending this in case it fell in a crack, thanks. Best, Eric

Eric Roston
212-617-5464

----- Original Message -----
From: ERIC ROSTON
To: press@epa.gov
At: 04-Jun-2018 16:15:42

Greetings,

I'm writing an overview/catch-up piece about the proposed "Strengthening Transparency in Regulatory Science" rule. It's an introduction to the debate(s). It explains what the rule would appear to do, why many scientists and organizations say they oppose it in its current form, and shares some of the comments from the public docket. I'd like to run the below questions and comments by you, in the event that EPA would like to respond to any or all of them, or flag anything specific you would like considered for inclusion. Thank you. Eric

1) Any thoughts on these things?:

- A public comment from the Bipartisan Policy Center says that the proposal "is not consistent with the [2009] BPC report in substance or intent" [https://bit.ly/2Js0NIR].

- The SAB's Friday agreement to include the transparency rule in its coming letter to the Administrator.

- Five leading peer reviewed journals in a public comment suggest that the rule would "limit the scientific evidence" that can inform policy [https://bit.ly/2Lm2vZI].

- The Ranking Member of the House Science Committee, U.S. Rep. Johnson, sent in a public comment that accuses the agency of executive "overreach" [https://bit.ly/2J86kFb].

- This recent essay by Stanford's John Ioannidis: https://bit.ly/2IopXYl

Some other questions:

- A comment from a GWU Regulatory Studies Center scholar concludes that "The requirements proposed here are not a radical departure from existing guidelines." What in the proposal is a departure, and why is it necessary?

- Is "secret science" fraudulent science? What studies specifically are the best examples of it? (I noticed that that phrase does not appear in the rule.)

- Is this line from the 2002 "Guidelines for Ensuring and Maximizing the Quality…" a plausible summary of the overall "transparency" v "best available science" debate [https://bit.ly/2J8qA9r]? "However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." Is this sentence consistent with the proposed rule?

- The same 2002 guidance cites the HEI work on the Harvard Six Cities study and the ACS PM study as an example how to verify studies without absolute public disclosure. Is that 3rd-party verification by HEI still a useful reference for reproducibility? Would this rule vacate that guidance?

- Could small business owners be disproportionately affected by the rule?

- Can you describe the review process for the proposal before it went out on April 30? How deeply were career staff involved in its drafting?

- This question may sound petty, but I'm actually just curious, probably because it relates to my own nightmares when publishing stories on any topic. Copy-editing errors are rare in regulations, but there are at least two in the 4/30

proposal. It just made me wonder if anything about the rule was rushed:

- Footnote 3: "…Historically, EPA has not consistently observed the policies underlying this proposal, and courts have at times upheld EPA's use non-public data in support..."
- Section §30.7 heading: "What role does independent peer review in this section?" [This question is written correctly on the prior page.]

Thanks again for any insight.

*****
Eric Roston
212.617.5464 desk
202.253.5723 cell/Signal

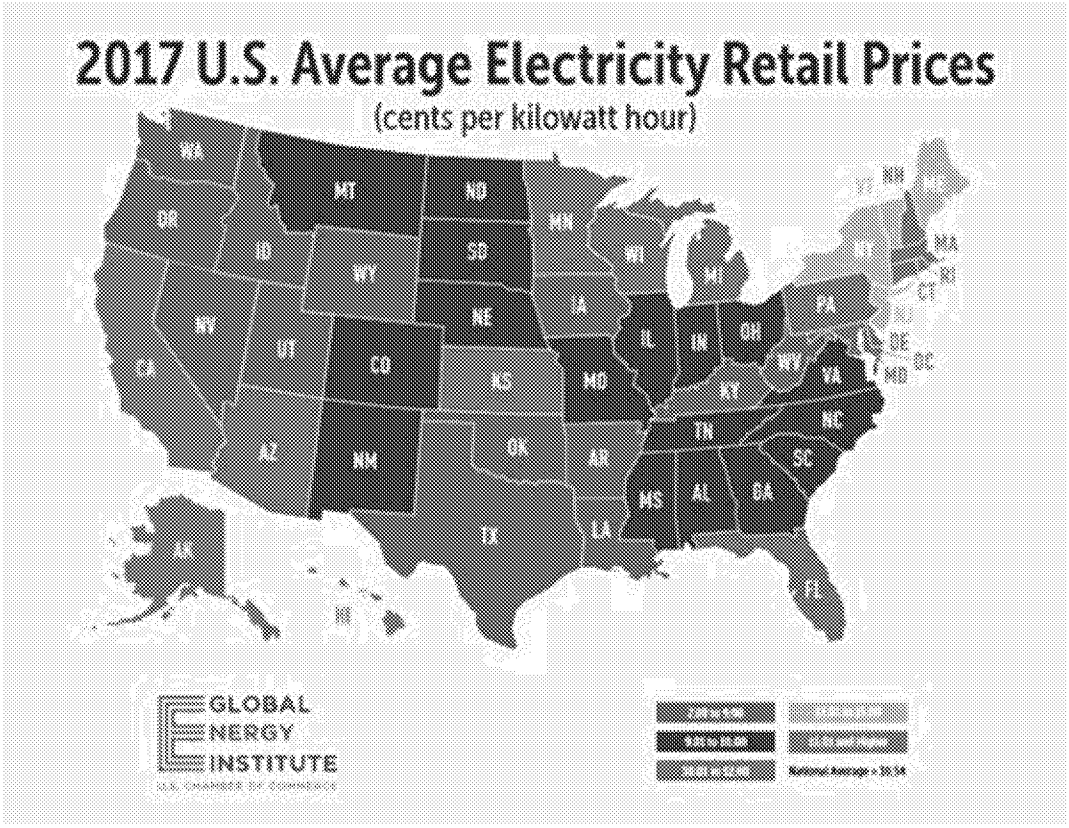
Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 3/27/2018 1:36:55 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: FW: Articles of Interest - 3/27/18

FYI – Highlighted a couple you might find interesting

From: Woods, Clint
Sent: Tuesday, March 27, 2018 9:35 AM
To: Wehrum, Bill <Wehrum.Bill@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Harlow, David <harlow.david@epa.gov>; Dominguez, Alexander <dominguez.alexander@epa.gov>
Subject: Articles of Interest - 3/27/18

- Bloomberg, 3/27/18: California's Ready to Retaliate If Trump Cuts Auto Rules, Sources Say
- Bloomberg BNA, 3/26/18: Faster Air Pollution Permits Prominent on EPA's Agenda
- Climate Wire, 3/26/18: EPA: Pruitt's attack on 'secret science' to affect climate rule
- Inside EPA, 3/22/18: Wehrum Said To Favor Quick Ozone NAAQS Review Over Reconsideration
- Climate Wire, 3/27/18: White House: Meet Trump's new climate guy
- Climate Wire, 3/27/18: CLEAN POWER PLAN: Critics blast rule in coal country
- Gina McCarthy & Janet McCabe, NYT, 3/26/18: Scott Pruitt's Attack on Science Would Paralyze the E.P.A
- Steve Milloy, WSJ, 3/26/18: The EPA Cleans Up Its Science
- New York Magazine, 3/25/18: The Paris Climate Accords Are Looking More and More Like Fantasy
- Inside EPA, 3/26/18: Bolstering IRIS, FY18 Spending Deal Urges EPA To Continue Reform Effort
- Inside EPA, 3/26/18: Pruitt's Bid To End 'Secret Science' Faces Legal, Implementation Hurdles
- Inside EPA, 3/26/18: FY18 Bill Boosts Diesel Cleanup Funds, Raising Questions Over Glider Plan
- Bloomberg BNA, 3/27/18: Pruitt's Open Data Plan Could Limit Usable Research, Critics Say
- EDF, 3/26/18: Environmental Groups Sue to Stop EPA Loophole Allowing Industrial Plants to Turn off Pollution Controls
- Environmental Integrity Project, 3/26/18: New Report Shows Rollback of Federal Air Pollution Control Rule Will Multiply Toxic Emissions
- Senate EPW, 3/22/18: Bipartisan Group of Senators Introduce Bill to Promote Carbon Capture Research and Development
- Washington Post, 3/27/18: The Energy 202: Meet the government insiders quietly shaping Trump's energy and environment agenda
- EDF, 3/22/18: New Oil and Gas Study Shows – Once Again – Industry is Severely Underreporting Methane Emissions
- Journal of Geophysical Research: Atmospheres, 3/2018: Multimodel Surface Temperature Responses to Removal of U.S. Sulfur Dioxide Emissions (pages 2773–2796); Spatial and Temporal Variability and Trends in 2001–2016 Global Fire Activity (pages 2524–2536); The Wintertime Covariation of CO2 and Criteria Pollutants in an Urban Valley of the Western United States (pages 2684–2703)
- U.S. Chamber, 3/26/18: MAP: 2017 Average Electricity Retail Prices



Clint Woods
Deputy Assistant Administrator
Office of Air and Radiation, U.S. EPA
202.564.6562

Message

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 1/24/2018 9:01:24 PM
To: Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]
Subject: Re: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION

I should be able to join w/ updated time

On Jan 24, 2018, at 2:55 PM, Dominguez, Alexander <dominguez.alexander@epa.gov> wrote:

> Was about to say not a problem then saw it has been moved to 2:00. The one meeting I am actually required to be at is the scheduling meeting so I will not be able to jump on the call.
>
> **From:** Woods, Clint
> **Sent:** Wednesday, January 24, 2018 12:49 PM
> **To:** Dominguez, Alexander <dominguez.alexander@epa.gov>
> **Subject:** Re: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
>
> Will join late (CSAPR briefing). Want to represent us for 1st half?
>
> On Jan 24, 2018, at 11:47 AM, Dominguez, Alexander <dominguez.alexander@epa.gov> wrote:
>
> > Since you're in Austin just wanted to confirm you'll still be able to take this call and I can decline for Mandy.
> >
> > **From:** Dominguez, Alexander
> > **Sent:** Tuesday, January 23, 2018 4:28 PM
> > **To:** Gomez, Laura <Gomez.Laura@epa.gov>
> > **Cc:** Woods, Clint <woods.Clint@epa.gov>
> > **Subject:** RE: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
> >
> > Laura – Can you please forward the invite to Clint Woods and include him on all subsequent HONEST Act discussions. Thank you.
> >
> > **Alex Dominguez**
> > Policy Analyst to the Principal Deputy
> > Office of Air and Radiation
> > U.S. Environmental Protection Agency
> >
> > -----Original Appointment-----
> > **From:** Gomez, Laura
> > **Sent:** Tuesday, January 23, 2018 4:19 PM
> > **To:** Lewis, Josh; Dominguez, Alexander; Atkinson, Emily
> > **Subject:** EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
> > **When:** Friday, January 26, 2018 11:30 AM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
> > **Where:** DIAL IN: 1-202-991-0477 CONFERENCE ID: 2720374

Purpose: To internally discuss EPA implementation of HR 1430 (ATTACHED)

This is an internal call in preparation for a briefing with Committee on House Science, Space and Technology (HSST). DAA Ringel (OCIR) will lead a discussion with respective program offices regarding the agency's implementation efforts of the HONEST ACT.

Appointment

From: Woods, Clint [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BC65010F5C2E48F4BC2AA050DB50D198-WOODS, CLIN]
Sent: 1/24/2018 8:41:21 PM
To: Gomez, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=575BA24FC19D429C8302A05102353238-LGOMEZ]

Subject: Accepted: CONFIRMED: EPA PRE-INTERNAL CALL : HONEST ACT IMPLEMENTATION
Location: DIAL IN: **Conference phone and code/Ex.6**

Start: 1/26/2018 7:00:00 PM
End: 1/26/2018 8:30:00 PM

Recurrence: (none)

Message

From: Ford, Hayley [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4748A9029CF74453A20EE8AC9527830C-FORD, HAYLE]
Sent: 4/18/2018 3:20:53 PM
To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: RE: Updated Data Access Notice
Attachments: image2018-04-18-111356.pdf

Clint – Wanted to get you his comments back. **Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

Thanks!

Hayley Ford
Deputy White House Liaison and Personal Aide to the Administrator
Environmental Protection Agency
ford.hayley@epa.gov
Phone: 202-564-2022
Cell: 202-306-1296

From: Woods, Clint
Sent: Wednesday, April 18, 2018 9:18 AM
To: Ford, Hayley <ford.hayley@epa.gov>
Subject: Fwd: Updated Data Access Notice

Hayley,

Here's the current version of the data access proposal - I'm tied up giving a presentation but can run down a copy for the Administrator in 15 mins (Think he had asked Brittany for a copy at the 8:30 meeting)

Clint

Begin forwarded message:

> **From:** "Woods, Clint" <woods.clint@epa.gov>
> **Date:** April 17, 2018 at 3:46:54 PM EDT
> **To:** "Wehrum, Bill" <Wehrum.Bill@epa.gov>, "Gunasekara, Mandy" <Gunasekara.Mandy@epa.gov>, "Harlow, David" <harlow.david@epa.gov>
> **Subject: Fwd: Updated Data Access Notice**
>
> FYI - Updated data access draft attached. Event planned for next Tues afternoon.
>
> Begin forwarded message:
>
> > **From:** "Bolen, Brittany" <bolen.brittany@epa.gov>
> > **Date:** April 17, 2018 at 12:28:09 PM EDT
> > **To:** "Rosario A. EOP/OMB Palmieri" **EOP / Ex. 6**

Cc: "Woods, Clint" <woods.clint@epa.gov>, "Schwab, Justin" <Schwab.Justin@epa.gov>
Subject: Updated Data Access Notice

Hi Rosario,
As discussed, please see attached updated notice. This version incorporates OIRA's feedback received yesterday. Let me know when you're available to discuss next steps.
Thanks,
Brittany

Message

From: Christian, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64A0F5E0E9D94271B23CAD28DB653851-LIZOTTE, ME]
Sent: 4/2/2018 2:52:34 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: FW: Meeting request with Richard Yamada regarding EPA & Secret Science Act

We have you scheduled to speak with Joanne on Wednesday at 1:30pm.

Best,
Megan

Megan Christian, MPH
Office of Research and Development
U.S. Environmental Protection Agency
Christian.Megan@epa.gov
202-564-6184

From: Gentry, Nathan
Sent: Monday, April 02, 2018 10:43 AM
To: Joanne Carney <jcarney@aaas.org>; Christian, Megan <Christian.Megan@epa.gov>
Subject: RE: Meeting request with Richard Yamada regarding EPA & Secret Science Act

I'll send out a meeting request for 1:30pm on Wednesday. You can call Richard at 202-578-7282.

Nathan Gentry
Scheduler for Jennifer Orme-Zavaleta, Richard Yamada, Chris Robbins and Bruce Rodan
Assistant Deputy Ethics Official
EPA Office of Research and Development
Phone: 202-564-9084
Fax: 202-565-2430

From: Joanne Carney [mailto:jcarney@aaas.org]
Sent: Monday, April 02, 2018 10:38 AM
To: Christian, Megan <Christian.Megan@epa.gov>
Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: RE: Meeting request with Richard Yamada regarding EPA & Secret Science Act

Good morning, Megan. Many thanks for the follow-up. I'm available on Wednesday, April 4th between 1:30 and 2:30 pm if that still works for Richard. Let me know what number I should call.

Best,
Joanne

Joanne Padrón Carney
Director, Office of Government Relations
American Association for the Advancement of Science
1200 New York Avenue, NW 20005
Telephone: 202/326-6798
Email: jcarney@aaas.org

AAAS

From: Christian, Megan [mailto:Christian.Megan@epa.gov]
Sent: Monday, April 02, 2018 9:38 AM
To: Joanne Carney <jcarney@aaas.org>
Cc: Gentry, Nathan <Gentry.Nathan@epa.gov>
Subject: Meeting request with Richard Yamada regarding EPA & Secret Science Act

Good morning Joanne,

This email serves as a follow-up to a voicemail I left earlier this morning.

We would be happy to schedule a time for you and Richard Yamada to speak this week over the phone. Wednesday, April 4th (after 1pm) or Thursday, April 5th are days when Richard has the most availability.

I have copied Nathan Gentry, Richard's scheduler, to help us find an appropriate time.

Best,
Megan Christian

Megan Christian, MPH
Office of Research and Development
U.S. Environmental Protection Agency
Christian.Megan@epa.gov
202-564-6184

On Mar 30, 2018, at 5:15 PM, Yamada, Richard (Yujiro) <yamada.richard@epa.gov> wrote:

> Hi Megans! Could one of you reach out and set up a time for me to speak with Joanne on he phone? Thanks much, Richard
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** Joanne Carney <jcarney@aaas.org>
> > **Date:** March 29, 2018 at 1:49:44 PM EDT
> > **To:** "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>
> > **Subject: Q: EPA & Secret Science Act**
> >
> > Hi Richard,
> > Hope all is well with you and you are more settled within ORD at EPA. We've been monitoring the prospect that EPA would implement a policy that reflects the legislation you worked on during your time at House Science regarding the Secret Science Reform Act.
> >
> > If you have time to chat by phone, I'd welcome an opportunity to discuss. I have some practical questions if and when a policy would be introduced, and I thought you might be able to help. For example, how would a policy impact existing OMB/OIRA guidelines

and policies? Would it require public comment and be subject to rulemaking procedures?

I appreciate any insights. Thanks!

Best,

Joanne

Joanne Padrón Carney
Director, Office of Government Relations
American Association for the Advancement of Science
1200 New York Avenue, NW 20005
Telephone: 202/326-6798
Email: jcarney@aaas.org

<image003.png>

Message

From: Traynham, Ben [Ben.Traynham@mail.house.gov]
Sent: 7/23/2018 3:17:54 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: Updated Bill Text
Attachments: Improving Science in Chemical Assessments Act.pdf

Ben Traynham
Counsel | Subcommittee on Environment
Committee on Science, Space, and Technology
2321 Rayburn House Office Building
202-225-6371

Message

From: Christian, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64A0F5E0E9D94271B23CAD28DB653851-LIZOTTE, ME]
Sent: 7/23/2018 9:19:01 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
CC: Kuhn, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be20941b4c1144b8b3635e4df015924a-Kuhn, Kevin]
Subject: RICHARD REVIEW: Transparency Rule and PFAS
Attachments: 2018-07-13 Draft McNerney Tonko Pallone PFAS-Science rulemaking Response - OW Reviewed 7-16-18_BRedits.docx

Hi Richard,

For your review, I have dropped on your chair a folder with ORDs edits to a draft response for a letter from Congressmen Tonko, Pallone, and McNerney regarding sci transparency and PFAS.

OCIR drafted the response to the Congressmen's letter, OW reviewed and provided edits (in the document) and Andy Gillespie and Bruce also reviewed/edited. The folder on your chair contains the original letter and the red-line strike-out and clean versions of the response letter.

Sam originally requested that we provide input by last week, so we're running a bit behind on this one.

Can you please let me know if you'd like to see any additional edits to the response?

Thank you,
Megan

Megan Christian, MPH
Office of Research and Development
U.S. Environmental Protection Agency
Christian.Megan@epa.gov
202-564-6184

From: Fleming, Megan
Sent: Monday, July 23, 2018 1:17 PM
To: Christian, Megan <Christian.Megan@epa.gov>
Subject: FW: FOR BRUCE REVIEW: Transparency Rule and PFAS

Hi Megan – Bruce has completed his review on the Congressional letter response regarding the transparency rule and PFAS. Please see attached for edits. Bruce says you can move this version on to Richard for review.

Thanks,
Megan

Megan Fleming
Immediate Office of the Assistant Administrator
U.S. EPA Office of Research and Development
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
202-564-6604 (desk), 202-389-2487 (mobile)

From: Bruce Rodan Personal Email / Ex. 6
Sent: Sunday, July 22, 2018 5:34 PM
To: Fleming, Megan <Fleming.Megan@epa.gov>
Subject: Fwd: FOR BRUCE REVIEW: Transparency Rule and PFAS

Minor edits … OK to go to Richard.

Begin forwarded message:

From: "Rodan, Bruce" <rodan.bruce@epa.gov>
Subject: Fwd: FOR BRUCE REVIEW: Transparency Rule and PFAS
Date: July 22, 2018 at 5:25:18 PM EDT
To: Personal Email / Ex. 6

Message

From: Brazauskas, Joseph [Joseph.Brazauskas@mail.house.gov]
Sent: 7/11/2018 3:30:39 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: Chemical Assessment Legislation
Attachments: Chem Assessment Improvement Act DD 071018.pdf

Attached.

Joseph A. Brazauskas
Staff Director and Senior Counsel
Subcommittee on Environment
Committee on Science, Space and Technology
Lamar Smith, Chairman
P: (202) 225-6371

Message

From: EPA Press Office [press=epa.gov@cmail20.com]
on behalf of EPA Press Office [press@epa.gov]
Sent: 5/24/2018 12:00:19 PM
To: Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]
Subject: EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

EPA Announces Extended Comment Period and Public Hearing on Proposed Rule to Strengthen Science Transparency in EPA Regulations

WASHINGTON (May 24, 2018) - Today, the U.S. Environmental Protection Agency (EPA) announced an extension of the comment period on the proposed rule, "Strengthening Transparency in Regulatory Science." EPA is also announcing a public hearing for the proposed rule, which will be held on July 17, 2018, in Washington, D.C.

"EPA is committed to public participation and transparency in the rulemaking process," said EPA Administrator Scott Pruitt. **"By extending the comment period for this rule and holding a public hearing, we are giving stakeholders the opportunity to provide valuable input about how EPA can improve the science underlying its rules."**

On April 30, 2018, EPA announced the proposed rule with a 30-day comment period that was scheduled to close on May 30. With today's extension, the comment period will now close on August 17. EPA is soliciting comments on all aspects of the proposal and specifically on the issues identified in Section III. The public hearing will provide a forum for interested parties to present data, views, and arguments regarding EPA's proposed rule.

The proposed rule will strengthen the science used in regulations issued by EPA. It will require that underlying scientific information be publicly available. Also, this rule is consistent with data access requirements for major scientific journals and builds upon Executive Orders 13777 and 13783.

Comments should be identified by Docket ID No. is EPA-HQ-OA-2018-0259 and submitted through the Federal eRulemaking Portal: http://www.regulations.gov.

The public hearing will be held at the U.S. Environmental Protection Agency Headquarters, William Jefferson Clinton East Building, Main Floor Room 1153, 1201 Constitution Avenue NW, in Washington, D.C. 20460. The public hearing will convene at 8:00 a.m. EST and continue until 8:00 p.m. EST. Parties interested in presenting oral testimony at the public hearing should register online by July 15, 2018, at https://www.epa.gov/osa/strengthening-transparency-regulatory-science.

While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of public comment. Please refer to the official version in a forthcoming *Federal Register* publication.

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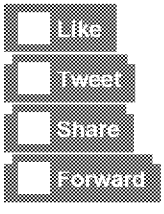

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue Northwest
Washington, D.C. 20004

Message

From: Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]
Sent: 5/17/2018 11:39:51 PM
To: Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]
Subject: Fwd: Draft press release on comment period extension and hearing
Attachments: extended comments and hearing strengthening transparency draft release 5.17 v2.docx; ATT00001.htm

See below - keeping you in the loop - thanks

Sent from my iPhone

Begin forwarded message:

> **From:** "Maguire, Megan" <Maguire.Megan@epa.gov>
> **Date:** May 17, 2018 at 6:14:03 PM EDT
> **To:** "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>, "Sinks, Tom" <Sinks.Tom@epa.gov>
> **Cc:** "Christian, Megan" <Christian.Megan@epa.gov>, "Kuhn, Kevin" <Kuhn.Kevin@epa.gov>, "Hubbard, Carolyn" <Hubbard.Carolyn@epa.gov>
> **Subject: Draft press release on comment period extension and hearing**
>
> Hi Jennifer, Richard & Tom- We drafted a press release based on the FRN about the comment period extension and public hearing for the proposed strengthening transparency in regulatory science rule. It's attached. Please review and let me know if you have edits or questions.
>
> Thanks,
> Megan
>
> Megan Maguire
> US EPA, Office of Research and Development
> RRB 41261
> O: (202)564-6636
> C: (202)731-9378