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A proposal to increase federal funding of nanotechnology risk research to at least \$100 million annually

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Environmental Defense has called for the federal government to dedicate at least \$100 million annually, sustained for a period of at least several years, to research directly related to elucidating the health and environmental risks of nanotechnology.² This document summarizes our reasoning and support for calling for such an outlay.

There is, of course, no single “magic number” nor a precise means to determine the right dollar figure, given the wide-ranging set of research issues needing to be addressed and the significant associated uncertainty as to the anticipated results. Nevertheless, we believe that the amount we propose represents a reasonable, lower-bound estimate of what is needed.

Below we first provide some context appropriate to consider in assessing both the need for and costs of risk-related research on nanomaterials. We then describe the major complexities involved in assessing these risks and the broad scope of research needed to address them. Finally, we provide a number of benchmarks that we believe strongly support our proposal for spending at least \$100 million annually nanotechnology risk research. These benchmarks include: experts’ assessments of the expected research costs; hazard testing costs for conventional chemicals; and EPA budgets for airborne particulate matter risk research.

¹ Environmental Defense staff members Dr. John Balbus, Scott Walsh and Karen Florini reviewed and provided substantial input into this paper.

² See Environmental Defense’s written statement submitted to the National Academies’ Committee to Review the National Nanotechnology Initiative at its March 24-25, 2005 Workshop on Standards for Responsible Development of Nanotechnology, Washington DC; and letter dated November 15, 2004 from Environmental Defense to Dr. Mihail Roco, Chair, NSTC Subcommittee on Nanoscale Science, Engineering and Technology (also attached to our written statement).

Context for judging risk research spending

In our view, both the public and private sectors' best interests are served by an investment to identify and manage potential nanotechnology risks now, rather than to pay later to remediate resulting harms. History demonstrates that embracing a technology without a careful assessment and control of its risks can be extremely costly from both human and financial perspectives. The failure to sufficiently consider the adverse effects of using lead in paint, plumbing, and gasoline has resulted in widespread health problems that continue to this day, not to mention extremely high remediation costs. Asbestos is another example where enormous sums of money were spent by private companies for remediation, litigation, and compensation, even beyond that spent by the public sector to alleviate harm to human health and the environment. Standard & Poor's has estimated that the total cost of liability for asbestos-related losses could reach \$200 billion.³

Initial research raises serious concerns that nanomaterials have the potential to pose significant health and environmental risks. The limited data now available demonstrate the potential for some nanomaterials to be both persistent and mobile in the environment and in living organisms; to cross the blood-brain barrier; and to be capable of damaging brain, lung and skin tissue.⁴

These initial studies only highlight how little is known about the health and environmental effects of engineered nanomaterials. Despite the uncertainty, the rapid development of nanomaterial applications is outpacing efforts to understand their implications – let alone ensure their safety. Thousands of tons of nanomaterials are already being produced each year,⁵ and hundreds of products incorporating nanomaterials are already on the market.⁶ The global market for nanotechnology products is expected to reach at least \$1 trillion over the next decade.⁷ Given the length of time it will take to

³ Standard & Poor's, *Insurance: Property-Casualty Industry Survey*, July 15, 2004.

⁴ To assist the Committee, we attached a bibliography of references and associated abstracts of risk-related research studies on nanomaterials to our written statement provided to the Committee's at its March 24-25, 2005 workshop reviewing the National Nanotechnology Initiative.

⁵ See The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, July 2004, pp. 26-7, available online at www.nanotec.org.uk/finalReport.htm. This estimate is provided for the 2003-2004 timeframe, with rapidly escalating quantities projected thereafter.

⁶ See, for example, an unofficial list of nanomaterial-containing products compiled by EPA as of July 2004, posted by the ETC Group online at www.etcgroup.org/documents/nanoproducts_EPA.pdf; and a description of current nanotechnology applications at www.nanotech-now.com/current-uses.htm.

⁷ See, for example, Lux Research, *Sizing Nanotechnology's Value Chain*, October 2004, summary available online at www.luxresearchinc.com/press/RELEASE_SizingReport.pdf: "Sales of products incorporating emerging nanotechnology will rise from less than 0.1% of global manufacturing output today to 15% in 2014, totaling \$2.6 trillion." Also see National Science Foundation, *Societal Implications of Nanoscience and Nanotechnology*, March 2001, p. 3, available online at

develop an adequate understanding of the potential risks posed by a wide variety of nanomaterials, and to apply this knowledge to inform appropriate regulation, it is imperative that we dedicate substantial funding for comprehensive risk research programs now.

The National Nanotechnology Coordination Office (NNCO) estimates that fiscal year 2004 spending for environmental and health implications research stood at only \$8.5 million, less than one percent of the total NNI budget.⁸ Since then, such spending appears to be rising somewhat: Requested funding for FY2006 from federal agencies under the NNI for health and environmental research totals \$38.5 million, just under 4% of the total FY2006 nanotechnology development budget for these agencies of \$1.05 billion.⁹ While an annual expenditure of \$100 million represents an additional significant increase over the current level, it is still a small fraction of the more than \$1 billion now being directed annually towards nanotechnology development through the National Nanotechnology Initiative (NNI). Moreover, it is a modest investment compared to the potential benefits of risk avoidance and to the \$1 trillion or more that nanotechnology is projected to provide to the world economy by 2015.¹⁰

Complexity of defining nanomaterial risks

There is broad agreement among stakeholders that addressing the potential risks of nanotechnology will be an unusually complex task. Despite its name, nanotechnology is anything but *singular*; it is a potentially limitless collection of technologies and associated materials. The sheer diversity of potential materials and applications – which is a source of nanotechnology’s enormous promise – also poses major challenges with respect to characterizing potential risks. Nanotechnology entails:

- many fundamentally different types of materials (e.g., metal oxides, quantum dots, carbon nanotubes), and hundreds or thousands of potential variants of each;
- many novel properties potentially relevant to risk (e.g., size, structure, reactivity, surface chemistry, electrical and magnetic properties)
- many potential types of applications (e.g., fixed in a matrix vs. freely available, captive vs. dispersive use);

www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf: “... projected total worldwide market size of over \$1 trillion annually in 10 to 15 years...”

⁸ E. Clayton Teague, *Responsible Development of Nanotechnology*, National Nanotechnology Coordination Office, April 2, 2004, available online at www.technology.gov/OTPolicy/Nano/04/0402_Teague-Infocast.pdf.

⁹ National Science and Technology Council, Nanoscale Science, Engineering and Technology Subcommittee of the Committee on Technology, *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry: Supplement to the President’s FY2006 Budget*, March 2005, p. 38.

¹⁰ See footnote 7.

- many categories and types of uses (e.g., medical devices, pharmaceuticals, environmental remediation, and consumer products ranging from cosmetics to electronics);
- multiple points of potential release and exposure over the full lifecycle of a given material/application (e.g., during production, use, disposal);
- multiple potential means of release (e.g., in emissions, in wastes, from products);
- multiple potential routes of exposure (e.g., inhalation, dermal, oral);
- multiple potentially exposed populations (e.g., workers, consumers as well as public); and
- potential to cause environmental as well as human health-related impacts.

Scope of needed research

Even before the research that will allow hazards and exposures to be quantified, a number of more fundamental needs must be addressed. We currently lack a good understanding of which specific properties will determine or are otherwise relevant to nanomaterials' risk potential. Many of the methods, protocols and tools needed to *characterize* nanomaterials, or to *detect and measure* their presence in a variety of settings (e.g., workplace environment, human body, environmental media) are still in a very early stage of development.

Nor is it clear the extent to which we can rely on our existing knowledge about conventional chemicals to predict risks of nanomaterials. The defining character of nanotechnology – the emergence of wholly *novel* properties when materials are reduced to or assembled at the nano-scale – carries with it the potential for novel risks and even novel mechanisms of toxicity that cannot be predicted from the properties and behavior of their bulk counterparts. By their very nature many nanomaterials are more reactive per unit mass than their conventional counterparts. For example, aluminum in the form used in many applications, such as the ubiquitous soda can, is prized because of its lack of reactivity, but it becomes highly explosive in nano-form – hence its potential use as a rocket fuel catalyst.

Moreover, we already know that even extremely subtle manipulations of a nanomaterial can dramatically alter its properties and behavior: Tiny differences in the diameters of otherwise identical quantum dots can alter the wavelength of the light they fluoresce; slight changes in the degree of twist in a carbon nanotube can affect its electrical transmission properties. We have yet to develop the means to sufficiently characterize or systematically describe such subtle structural changes – a clear prerequisite to being able to consistently and rigorously apply and interpret the results of toxicological testing. And only then can we begin to assess the extent to which such subtle structural changes may affect the toxicity of a material – or the extent to which such a property is stable or may be transformed in the environment or the human body.

Until these threshold questions about nanomaterials' potential risks are answered, it is unclear whether or to what extent we will be able to rely on methods widely used to reduce the amount of traditional toxicological testing needed to characterize conventional chemicals: the ability to identify "model" materials, which upon characterization could serve as a basis for extrapolation to "like" materials.

Among the types of risk research needed are the following:

- Material characterization (in manufactured form(s), during use, in emissions, in wastes, in products; in environmental media, in organisms)
- Biological fate (extent and rate of absorption, distribution, metabolism, elimination)
- Environmental fate and transport (persistence, distribution among media, transformation)
- Acute and chronic toxicity (related to both human and ecological health)

For each of these areas, existing testing and assessment methods and protocols need to be re-examined to determine the extent to which they can be modified to account for nanomaterials' novel characteristics or need to be supplemented with new methods. Similar challenges will arise with respect to methods and technologies for sampling, analysis and monitoring, all of which will be needed to detect nanomaterials and their transformation products in living systems and in various environmental media.

Benchmarks for risk research spending

Our view that significantly more needs to be spent on nanotechnology risk research is informed and supported by: a) other experts' assessments, b) our knowledge of testing costs associated with hazard characterization programs for conventional chemicals, and c) the research budgets recommended for and expended on a roughly analogous risk characterization effort, namely EPA's research on risks of airborne particulate matter. A summary of these various information sources is provided below.

Experts' assessments:

- Experts from a variety of fields have declared that NNI's current funding for nanotechnology risk research needs to be significantly increased. Invited experts to a workshop sponsored by the Nanoscale Science Engineering, Science and Technology Subcommittee (NSET) of the NNI, held in September 2004, called for at least a 10-fold increase in federal spending on nanotechnology risk-related research, relative to the approximately \$10 million spent in FY2004.¹¹

¹¹ Phibbs, P., *Daily Environment Report*, 9/13/04, p. A-3, "Federal Government Urged to Boost Spending on Managing Risks Posed by Nanotechnology," quoting experts invited to NSET's Research Directions II workshop held in Washington, DC on 9/8-9/04.

- At that same workshop, a representative of the Nanotechnology Initiative at the National Institute for Occupational Safety and Health (NIOSH) provided an estimate of the investment needed just to begin to address workplace safety issues – which accounts for only one of the numerous settings where release and exposure to nanomaterials may occur. That estimate, which is based on an internal analysis conducted by NIOSH researchers, is that an investment of \$10-20 million per year for at least 10 years will be needed – assuming the funds are able to be directed at targeted research to address specific predetermined issues. The representative further indicated that the investment necessary to identify the issues to target and to more broadly address nanotechnology implications in the workplace as the technology matures will be significantly larger.¹² (NIOSH’s current funding level for this research is considerably lower, \$2-3 million per year. In 2004, NIOSH initiated a five-year program to assess the toxicity of ultrafine and nanoparticles, funded at about \$1.7 million in FY2004 and about \$2.3 million in FY2005.¹³ According to NNI, NIOSH has requested \$3.1 million for FY2006 for this type of work.¹⁴)

- At a briefing held on March 22, 2005, to preview the findings of an upcoming report by the President's Council of Advisors on Science and Technology (PCAST) that has been charged with reviewing the NNI, John H. Marburger III, Science Adviser to the President and chief of the White House Office of Science and Technology Policy, noted that the toxicity studies now underway are "a drop in the bucket compared to what needs to be done."¹⁵

- The chemical industry has also concluded that nanotechnology risk research should be highly prioritized and highly funded relative to other activities by the NNI. In a nanotechnology development roadmap requested by the NNI, the industry identifies an essential need to increase our “understanding of the fundamental scientific principles operating at the nanoscale, including interdependent structure-property relationships.” The roadmap highlights as critical research needs the following:
 - development of characterization tools, including real-time characterization methods and tools and the associated infrastructure for their development and use; and

¹² Phibbs, P., *ibid.*, quoting NIOSH scientist Andrew Maynard’s statement at NSET’s Research Directions II workshop held in Washington, DC on 9/8-9/04; and A. Maynard, personal communication, 4-20-05.

¹³ See National Nanotechnology Initiative, “NNI Environment and Health Safety Research,” available online at www.nano.gov/html/facts/EHS.htm.

¹⁴ National Science and Technology Council, *op. cit.*

¹⁵ R. Weiss, “Nanotech Is Booming Biggest in U.S., Report Says,” *Washington Post*, March 28, 2005, p. A6, available online at www.washingtonpost.com/wp-dyn/articles/A5221-2005Mar27.html.

- environment, health and safety, including assessment of human health and environmental impact hazards, determination of exposure potentials for nano-sized materials, and handling guidelines for operations involving nanomaterials.

The report calls for sustained research in these areas over twenty years, and assigns its top or high priority ranking to each of the subtopics under these key elements. While actual dollar figures are not provided, the report indicates that two of these subtopics – development of real-time characterization methods and tools, and assessment of human health and environmental impact hazards – will require a level of cumulative R&D investment that is the highest of any assigned to the priority research requirements.

- Finally, other expert comments on nanotechnology risk research needs and costs indicate that even setting up the initial infrastructure for adequate risk research will involve significant resources. The United Kingdom's Royal Society and Royal Academy of Engineering, in its seminal July 2004 report, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, calls for the UK government to devote £5-6 million (\$9.5-11.3 million) per annum for 10 years just to do its part to develop the methodologies and instrumentation needed to set the stage for actual testing of nanomaterials.¹⁶

Hazard endpoint testing costs:

There are several estimates available from chemical hazard assessment programs that can be used as context for providing at least a lower bound on the costs of testing a nanomaterial for hazardous properties. These costs are for the testing of a conventional chemical for an assortment of hazard (toxicity plus environmental fate) endpoints of concern; notably, they do *not* include costs associated with assessing exposure, which is also needed to assess risk.

It must be noted that these estimates provide only a very rough means of extrapolating to the anticipated costs of hazard testing for a given nanomaterial. A definition of what constitutes the needed set of such endpoints sufficient to characterize hazard has yet to be defined. Moreover, the number of different nanomaterials requiring testing is another major unknown, but could be very large.

Below we discuss several available hazard testing cost estimates.

- At one end of the spectrum is the so-called Screening Information Data Set (SIDS), developed by the Chemicals Program of the Organization for Economic Cooperation and Development (OECD), which consists of about 20 data elements and – as its name indicates – represents the minimum hazard information considered necessary to screen chemicals in order to set priorities for further scrutiny. SIDS focuses primarily

¹⁶ The Royal Society and the Royal Academy of Engineering, *op. cit.*, p. 48.

on short-term toxicity to mammals (as models for human toxicity) and aquatic species (as a subset of indicators of potential ecological toxicity). The U.S. Environmental Protection Agency, which employs the SIDS in its High Production Volume (HPV) Challenge,¹⁷ estimates the cost of producing a full set of SIDS data at \$250,000 per chemical,¹⁸ which is generally consistent with an industry estimate of up to \$275,000 per chemical.¹⁹ While SIDS is useful in setting priorities for further action among conventional chemicals, the information it provides is too limited to be sufficient to characterize the risks posed by nanomaterials.

- Testing cost estimates have been prepared in a Business Impact Assessment document prepared for the European Commission's Enterprise Directorate in support of the European Union's chemical policy proposal called REACH (for Registration, Evaluation and Authorization of Chemicals). REACH proposes different levels of testing that depend primarily on the production tonnage of a chemical. At the lowest production volumes, a base set of test data – roughly equivalent to the SIDS discussed above – would be required, the generation of which is estimated to cost €151,700 (about \$198,000). The most extensive test battery applicable to the highest-volume substances – and considered generally sufficient to inform a full risk assessment – is estimated to cost €1,664,260 (about \$2,170,000).²⁰
- An even more extensive test battery (and perhaps a more appropriate one for characterization of many nanomaterials, at least initially) is that required of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This hazard-only test battery consists of up to 100 individual data elements,²¹ with the actual requirements varying by factors such as use and volume of use. When supplemented with detailed exposure information, EPA generally considers this dataset sufficient to conduct a risk assessment for a pesticide. An upper estimate of \$10 million per chemical for testing costs has been indicated by the Agricultural

¹⁷ See EPA's website for the U.S. HPV Challenge, www.epa.gov/chemrtk/volchall.htm.

¹⁸ See www.epa.gov/chemrtk/hpvq&a.pdf.

¹⁹ See the American Chemistry Council's summary of the U.S. HPV Challenge, online at memberexchange.americanchemistry.com/randt.nsf/unid/nnar-4dfn3h.

²⁰ Risk & Policy Analysts Ltd, Revised Business Impact Assessment for the Consultation Document, Working Paper 4, prepared for the European Commission Enterprise Directorate-General, October 2003, Annex 1, available online at www.rpaltd.co.uk/tools/downloads/reports/reachrevisedbia.pdf. Figures cited here assume that all listed tests are required to be conducted, that none of the tests have previously been conducted, and that no estimation techniques are allowed as a substitute for testing.

²¹ Requirements are summarized at www.epa.gov/pesticides/regulating/data.htm. Regulations specifying testing requirements are at 40 CFR Part 158.

Research Service for a pesticide proposed for major food crop use, with costs for most pesticides being “significantly less.”²²

Recommended and actual EPA research budgets for risks of airborne particulate matter:

As an additional benchmark for judging the appropriate level of federal expenditure for nanomaterial risk research, we considered the recommended and actual budgets for EPA research conducted over the past several years on risks posed by airborne particulate matter (PM). In 1998, at the request of EPA, a committee of the Board on Environmental Studies and Toxicology (BEST) of the National Research Council assessed the state of research in this arena and additional needs, setting out a 13-year research agenda and associated recommended budget.²³ In 2004, in the fourth report in its series, the committee looked back over the research actually conducted and the associated budget expended by EPA in the six years since its first report.²⁴

We recognize, of course, the substantial differences between the nature of, state of knowledge concerning, and risk-related research needs for, airborne particulate matter (PM) and nanomaterials. Even in 1998, it was already clear that airborne PM exacts an enormous toll in terms of human morbidity and mortality – clearly not the case with nanomaterials, although we believe there is an opportunity through proactive research and action to identify and avoid such risks. Our aim here is not at all to claim any direct analogy between the two classes of materials or the magnitude of their risks, but rather to utilize the careful assessment done of the scope of research needed to assess risk.

If anything, the scope of needed research on nanomaterials is considerably broader – and hence likely to cost more – than is the case for airborne PM. Our reasoning is as follows. Airborne PM is a complex mixture of relatively well-characterized chemicals produced by a discrete (though highly diffuse) set of sources, to which exposure occurs through a single route, inhalation. In contrast, nanomaterials:

- are comprised of many entirely novel classes of materials;
- will be applied and used in ways that will create the potential for release and exposure through many more pathways (e.g., oral, dermal; via drinking water);
- in addition to being present in air emissions, may be present in wastes, water discharges and a wide array of products;

²² See “EPA and Pesticide Registration Issues,” USDA Agricultural Research Service, available online at www.ars.usda.gov/is/np/mba/jan97/epa.htm.

²³ Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: I. Immediate Priorities and a Long-Range Research Portfolio*, Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 1998, available online at books.nap.edu/catalog/6131.html.

²⁴ Board on Environmental Studies and Toxicology, *Research Priorities for Airborne Particulate Matter: IV. Continuing Research Progress*, Committee on Research Priorities for Airborne Particulate Matter, National Research Council, 2004, available online at books.nap.edu/catalog/10957.html.

- through incorporation into products, may result in exposure of consumers, as well as the general public and workers; and
- pose potential environmental as well as human health risks that need to be considered.

Hence – independent of the ultimate magnitude of risk identified – the *assessment* of that risk is likely to be considerably more involved and costly for nanomaterials than for airborne PM.

The research agenda and budget for airborne PM recommended by NRC in 1998 called for EPA to spend \$40–60 million annually for the first six years, and declining amounts thereafter, from \$31 million in year 7 to 15 million in year 13. The NRC noted explicitly that its recommended budgets should *not* be interpreted as sufficient to encompass all of the airborne PM risk research needed to be conducted by EPA or the nation as a whole.²⁵

Actual EPA expenditures during the first six years of the research program (FY1998–2003) were relatively similar to the recommended amounts, as reported by NRC in its 2004 report:

TABLE S-1 EPA Funding for PM Research and Related Technical Work (in millions of dollars)²⁶

	Fiscal Year Budgets					
	1998	1999	2000	2001	2002	2003
PM research	42.0	47.3	53.7	59.0	61.1	58.1
Related technical work	8.2	8.3	8.7	6.3	6.6	8.8
TOTAL	50.2	55.6	62.4	65.3	67.7	66.9

The NRC’s 2004 report, which represents a “mid-course” review of EPA’s airborne PM research, found that the allocated money had been well spent, noting rapid progress in some areas, slower in others, and with much work remaining to be done.

Given that addressing the potential risks of nanomaterials will very likely entail considerably greater complexity than is the case for airborne PM, we believe the NRC’s assessment of research needs and associated budget needs for airborne PM risk-related research strongly supports our call for the federal government to be devoting at least \$100 million annually over a number of years to address the major unknowns and uncertainties associated with the burgeoning field of nanotechnology.

²⁵ Board on Environmental Studies and Toxicology, 1998, *op. cit.*, Table 5.1, page 101. Amounts include research management, including research planning, budgeting, oversight, review, and dissemination, cumulatively estimated by the committee at 10% of project costs.

²⁶ Board on Environmental Studies and Toxicology, 2004, *op. cit.*, Table S-1, page 6.

Conclusion

The rapid commercialization of nanotechnology, coupled with the clear risk potential of at least certain nanomaterials demonstrated in initial studies, lends urgency to the need for the federal government to direct more of its major investment in nanotechnology development toward research aimed at identifying the potential risks and the means to address them. There is a remarkable degree of agreement among experts and stakeholders from a range of perspectives on both the need and the urgency. There is also considerable agreement that assessing these risks will be a complex task, given the range of materials and potential applications involved and the current lack of knowledge and experience with such materials. A broad scope of research will be needed, first to identify the key characteristics of nanomaterials relating to hazard and exposure; second, to adapt existing or develop new testing methods; and third, to actually assess the magnitude of hazard and exposure potential of specific nanomaterials.

We have also provided a number of benchmarks, which taken together strongly support our call for the federal government to spend at least \$100 million annually on a sustained basis to fund research directly related to understanding the potential health and environmental risks of nanotechnology:

- Experts' assessments of the costs of conducting the needed research – including basic material characterization, development of the needed infrastructure (e.g., methods, tools, instrumentation) and assessment of risks in specific exposure settings (e.g., workplaces). Each of these tasks by itself is estimated to require at least a major fraction of the \$100 million investment we call for.
- Actual testing costs for identifying hazard potential for conventional chemicals, which indicate the potential for testing costs *per substance* to extend into the millions of dollars.
- The recommended and actual EPA research budgets for characterizing the risks of airborne particulate matter, which have totaled at least half of the amount we have proposed be devoted to risk research on nanomaterials. As made clear by the National Research Council in recommending these amounts, they cover only a portion of EPA's and the nation's needs for research to understand the risks of airborne PM. While this task is complex, it is considerably more restricted in scope than what is expected to be needed to assess potential risks of nanomaterials.

Federal initiatives on nanotechnology to date have done a great job in accentuating and accelerating the enormous potential benefits of nanomaterials. To date, however, federal agencies have yet to come to terms with their equally critical role in identifying, managing and ideally avoiding the potential downsides. A far better balance between these two roles must be struck if nanotechnology is to deliver on its promise without delivering unintended and unforeseen adverse consequences.

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