

United States House of Representatives
Committee on Science

Hearing on:

"Environmental and Safety Impacts of Nanotechnology: What
Research is Needed?"

Testimony of:

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Washington, DC

November 17, 2005

10:00 a.m.

2318 Rayburn House Office Building

I would like to thank Chairman Sherwood Boehlert, Ranking Member Bart Gordon, and the Members of the House Committee on Science for holding this hearing on the environmental, health, and safety (EH&S) implications associated with the development of nanotechnology.

My name is David Rejeski, and I am the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars. This Project was created earlier this year in partnership with The Pew Charitable Trusts.

The Project on Emerging Nanotechnologies is dedicated to helping ensure that as nanotechnologies advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized. The Project collaborates with researchers, government, industry, nongovernmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology.

Our goal is to take a long-term look at nanotechnologies, to identify gaps in the nanotechnology information, data, and oversight processes, and to develop practical strategies and approaches for closing those gaps. We aim to provide independent, objective information and analysis that can help inform critical decisions affecting the development, use, and commercialization of nanotechnologies throughout the globe.

In short, both the Wilson Center and The Pew Charitable Trusts believe there is a tremendous opportunity with nanotechnology to "get it right." Societies have missed this chance with other new technologies and, by doing so, have made costly mistakes. We think nanotechnology's promised benefits are so great that we do not believe the United States and the rest of the world can afford to miscalculate or misstep with nanotechnologies.

As the Committee knows, nanotechnology is expected to become the transformational technology of the 21st century. It is the world of controlling matter at the scale of one billionth of a meter, or around one-100,000th the width of a human hair. Researchers are exploring new ways to see and build at this scale, reengineering familiar substances like carbon and gold in order to create new materials with novel properties and functions.

As the National Science Foundation (NSF) highlights, the ability to determine the novel properties of materials and systems at this scale implies that nanotechnology eventually could impact the production of virtually every human-made object—everything from automobiles, tires, and computer circuits to advanced medicine and tissue replacements—and lead to the invention of products yet to be imagined. Nanotechnology will fundamentally restructure the technologies currently used for manufacturing, medicine, defense, energy production, environmental management, transportation, communication, computation, and education.¹

¹ M.C. Roco, R.S. Williams and P. Alivisatos. *Nanotechnology Research Directions: IWGN Workshop Report*. Berlin, Germany: Springer, 2000, p. iii-iv.

NSF predicts that the world market for goods and services using nanotechnologies will grow to \$1 trillion by 2015. Lux Research calculates that in 2004 there were \$13 billion worth of products in the global marketplace incorporating nanotechnology.² Others estimate there are already over 700 products on the market that are made from or with nanotechnology or engineered nanomaterials. Worldwide about \$9 billion annually is being spent by governments and the private sector on nanotechnology research and development.

1. What impacts are environmental and safety concerns having on the development and commercialization of nanotechnology-related products and what impact might these concerns have in the future?

In the midst of the tremendous excitement over nanotechnology that exists in university research laboratories, government agencies, and corporate boardrooms, publics throughout the world remain largely in the dark. A major study, funded by NSF and conducted in 2004 by researchers at North Carolina State University (NCSU), found that 80-85% of the American public has heard "little" or "nothing" about nanotechnology. This is consistent with similar polling results in Europe and Canada. Anecdotally, some researchers believe that an even higher percentage of the public remains uninformed about nanotechnology.

Earlier this year (2005), the Project on Emerging Nanotechnologies commissioned a new report by Senior Associate Jane Macoubrie, who co-authored the NCSU study in 2004. This new report, "Informed Public Perceptions of Nanotechnology and Trust in Government," provides an in-depth look at what Americans know and do not know about nanotechnology.⁴

It indicates that U.S. consumers, when informed about nanotechnology, are eager to know and learn more. They generally are optimistic about nanotechnology's potential contribution to improve quality of life. The key benefits the public hopes for are major medical advances, particularly greatly improved treatment for cancer, Alzheimer's, and diabetes.

The Project's report findings track closely with work done last year (2004) by University of East Anglia researcher Nick Pidgeon for Great Britain's Royal Society. Pidgeon found there were few among the British public who knew much about nanotechnology. Those that did were optimistic that it would make life better. Study participants expressed concern about privacy issues and about the high costs of nanotechnology research and development to the British taxpayer. Some Britons also feared that nanotechnology

² "Sizing Nanotechnology's Value Chain." New York, NY: Lux Research, October 2004."

³ Michael D. Cobb and Jane Macoubrie. "Public Perceptions about Nanotechnology: Risk, Benefits and Trust." Raleigh, NC: North Carolina State University, 2004. Available at <http://vfww2.chass.ncsu.edu/cobb/me/Dast%20articles%20and%20working%20papers/Public%20Perceptions%20about%20Nanotechnology%20-%20Risks.%20Benefits%20and%20Trust.pdf>.

⁴ Jane Macoubrie. *Informed Public Perceptions of Nanotechnology and Trust in Government*. Washington, DC: Woodrow Wilson International Center for Scholars, 2005. Available at • <http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf>.

would turn out to be a case of "scientists trying to play God"—a phrase frequently attributed to the Prince of Wales in the press.^D

This general public optimism about nanotechnology is what I consider the "good news." In the NCSU study, only 22 percent of the U.S. participants believed that nanotechnology's risks would exceed its benefits. The rest anticipated nanotech's benefits would exceed risks (40 percent), or expected risks and benefits to be about equal (38 percent).

The "bad news" is that both the recent Project on Emerging Nanotechnologies report and last year's NCSU study highlight "no" or "low" American public trust in government and industry to manage any potential risks associated with nanotechnology. This is important because, both at home and abroad, the public's risk tolerance is weighed against a technology's direct benefit to them or to a group of people they consider important—children, senior citizens, the sick, the poor, and the disadvantaged. It also is highly dependent on their confidence or trust in the people making decisions about the technology's development, commercialization, and regulation.

Worse, the Project on Emerging Nanotechnologies' report showed that a lack of knowledge—about nanotechnology-based products, about possible health and environmental implications, and about the oversight process designed to manage any potential risks—breeds U.S. public mistrust and suspicion. In the absence of balanced information, people are left to speculate about the possible health and environmental impacts of nanotechnology. Rightly or wrongly, without information, they often draw on analogies of what they consider past failures to effectively manage risks—like dioxin, Agent Orange, or nuclear power.

A *Nature* magazine editorial described this Project report—along with a recent U.K. citizens' jury conducted by the universities of Cambridge and Newcastle—as providing governments with some "direct public guidance on citizens' interests that must be protected if nanotechnology is to flourish."⁶ For policymakers, the "take home" messages from a number of studies are quite clear:

- Consumers want more information to make informed choices about nanotechnology's use and greater citizen engagement in shaping how the technology is developed.
- There are low levels of trust in government and industry to manage any risks associated with nanotechnology. There is little support for industry self-regulation or voluntary agreements. A majority of the public believes that mandatory government controls are necessary.

⁵ *Nanotechnology: Views of the General Public*. London, U.K.: BMRB Social Research, January 2004, BMRB/45/1001-666. Available at www.nanotec.org.U.K./Market%20Research.pdf.

⁶ "Value-free nanotech?" *Nature* 437, September 22, 2005, 45 M52.

- People have clear ideas about how to improve trust. They want government and industry to practice *due diligence* to ensure manufacturing and product safety. In both U.S. and U.K. studies, this translated into strong support for research and safety testing before products go to market and a focus on better understanding long-term effects on both people and the environment.

In my view, there is still time to inform public perceptions about nanotechnology and to ensure that nanotechnology is developed in a way that citizens—as well as the insurance industry, corporate investors, NGOs, and regulatory officials—can trust. However, with the production of nanosubstances ramping up and more and more nanotech-based products pouring into the marketplace, this window is closing fast. Industry remains concerned about the possibility of liability for nanoproducts with unknown risks in an uncertain regulatory environment. Coordinated education and engagement programs will be needed, supported by both government and industry. These programs will have to be structured to reach a wide range of consumers, cutting across age, gender, and socioeconomic status, utilizing a variety of media going beyond traditional print, radio, television, film towards non-traditional media such as blogs and multiplayer on-line games.

2. What are the primary concerns about the environmental and safety impacts of nanotechnology based on the current understanding of nanotechnology?

Over the past 15 years, scientific data on the health and environmental impacts of nanostructured materials has been growing slowly. Three scientific reviews of the subject recently have been written, each of which notes that while some initial information as to environmental, health, and safety (EH&S) implications is available, much more work remains to be done in this area.

One overview of the subject by Günter, Eva, and Jan Oberdörster notes that laboratory studies have shown that airborne nanoscale materials depositing in the respiratory tract can cause an inflammatory response when inhaled.⁷ The small size of engineered nanomaterials also makes it easier for their uptake into and between various cells, allowing for transport to sensitive target sites in the body, including bone marrow, spleen, heart, and brain. Various kinds of nanomaterials, including C-60 fullerenes, single-walled nanotubes, and quantum dots, have been found to mobilize to mitochondria in cells, potentially interfering with antioxidant defenses. However, the translocation rates of these materials are uncertain.

In addition, Oberdörster *et. al.* report that there have been only a few studies looking at the effects of engineered nanomaterials on environmental systems. Water-borne carbon-60 was found to lead to oxidative stress in the brains of largemouth bass, although the mechanisms of action were uncertain. The bactericidal properties of carbon-60 in water have also been reported, and are being used as potential new anti-microbial agents.

⁷ Günter Oberdörster, Eva Oberdörster, Jan Oberdörster. "Nanotoxicology: An Emerging Discipline Evolving for Studies of Ultrafine Particles," *Environmental Health Perspectives*, July 2005, 113(7): 823-839.

However, such uses may have unforeseen consequences on delicate ecosystems if materials are released into the environment. Quoting the authors, "During a product's life cycle (manufacture, use, disposal), it is probable that nanomaterials will enter the environment, and currently there is no unified plan to examine ecotoxicological effects of [nanoparticles]."⁸

An article by Andrew Maynard and Eileen Kuempel⁹ on the impact of airborne nanostructured particles on occupational health notes that while a number of studies have investigated the toxicity and exposure of ultrafine aerosols, there are currently no studies on exposure and response to engineered nanomaterials in humans. Nevertheless, our experience with ultrafine aerosol particles (particles smaller than 100 nm that are typically a by-product of a process) in the workplace has shown that inhalation of micro- and nano-sized fibers and particles can lead to increased rates of cancer, lung disease, and adverse respiratory symptoms.

In addition to size, the shape, solubility, surface chemistry, and surface area of ultrafine particles is known to increase inflammation and tissue damage. These are not properties that are usually considered when evaluating hazards and health impacts. **While it should be emphasized that little data exists in relation to the human health impact of these factors for engineered nanomaterials, similar responses can be expected and appropriate risk-management strategies will be needed.**

Finally, a recent paper sponsored by the International Life Science Institute¹⁰ (ILSI) highlights a number of these points by noting that the unknowns and uncertainties surrounding the current state of EH&S research imply that "there is a strong likelihood that biological activity of nanoparticles will depend on physiochemical parameters not routinely considered in toxicity screening studies." In short, the report concludes that "little knowledge exists regarding specific nanomaterial characteristics which may be indicators of toxicity," requiring additional investigations into the physiochemical characterization of these materials and the development of accurate *in vitro* and *in vivo* testing methods.

Overall, a comparative reading of these three overview articles and other published studies elucidates a number of key points, including:

- Since engineered nanomaterials show behavior that depends on their physical and chemical structure, risk assessment paradigms that have been developed based on traditional, bulk chemistry alone may no longer be valid.

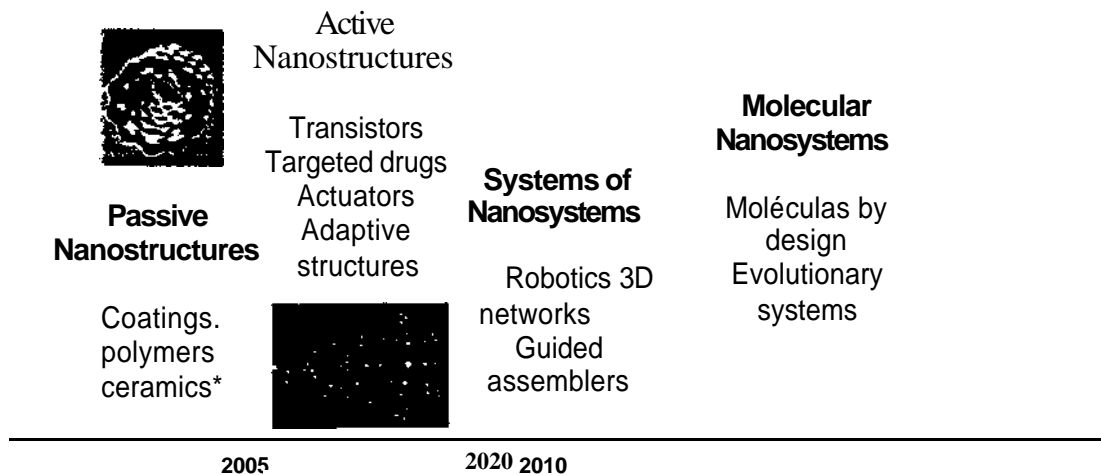
⁸ Günter Oberdorster, Eva Oberdorster, Jan Oberdorster, p. 836.

⁹ Andrew Maynard and Eileen Kuempel. "Airborne Nanostructured Particles and Occupational Health," *Journal of Nanoparticle Research*, 2005, forthcoming.

¹⁰ Günter Oberdorster et. al. "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy," *Particle and Fibre Toxicology*, October 2005,2(8): 1-35.

- Inhaled, nanometer-structured, insoluble particles can elicit a greater response in the lungs than their mass would suggest, indicating mechanisms of action that are dependent on particle size, surface area, and surface chemistry, among other properties. However, information is lacking on nanomaterials' structure-related behavior in the body.
- Inhaled, nanometer-diameter particles may leave the lungs through non-conventional routes and affect other parts of the body, including targeting the cardiovascular system, the liver, kidneys, and the brain. Next to nothing is known about the impact of engineered nanomaterials on these organs.
- Nanometer-diameter particles may be able to penetrate through the skin in some cases, although this is still an area of basic research and the chances of penetration appear to be significantly greater for damaged skin. The potential for nanostructured particles present in cosmetics and other skin-based products to do harm may be low, but remains unknown.
- Virtually nothing is known about the hazard of engineered nanomaterials ingested as a food additive or by accident.
- Although an understanding of the impact of engineered nanomaterials and nano-enabled products on the environment through their lifetime is considered critical, virtually nothing is known at present.

Much of the research undertaken so far has raised more questions than answers. To date, the majority of research has focused on relatively basic engineered nanomaterials. As nanomaterials move from simple to complex materials and on to active and multifunctional materials, major knowledge gaps need to be filled before useful quantitative risk assessments can be carried out and before comprehensive, lifecycle risk management strategies can be developed. As the image below indicates, the technology is developing more rapidly than our understanding of the EH&S risks and our ability to respond with effective policy measures.



The current state of the technologies
 The current state of our
 understanding of the risks and
 our policy thinking

Timeline adapted from Roco. M.,
 National Science Foundation

3. What should be the priority areas of research on environmental and safety impacts of nanotechnology? Who should fund and who should conduct that research?

A number of groups have developed, or are in the process of developing, lists of research priority areas and questions of interest. These organizations include the National Institute for Occupational Safety and Health (NIOSH)¹¹, Environmental Defense¹², the Semiconductor Research Corporation, and the Chemical Industry Vision 2020 Technology Partnership¹³. Despite the diversity of these organizations, these gap analyses are generally in broad agreement on the areas requiring further research and development. Common themes include: Toxicity (human and environmental), exposure and material release/dispersion, epidemiology, measurement and characterization, control of exposure and emissions, safety hazards, risk management models, and product life cycle analysis.

¹¹ National Institute for Occupational Safety and Health. *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps*. September 28, 2005. Available at <http://www.cdc.gov/niosh/topics/nanotech/stratplanINTRO.html>.

¹² Richard A. Denison. "A proposal to increase federal funding of nanotechnology risk research to at least \$100 million annually." Washington, DC: Environmental Defense, April 2005. Available at <http://www.environmentaldefense.org/documents/4442100milquestion1.Ddf>.

¹³ Semiconductor Research Corporation and Chemical Industry Vision 2020 Technology Partnership. "Joint NNI-ChI CBAN and SRC CWG5 Nanotechnology Research Needs Recommendations."

, There also appears to be agreement that the federal support for risk-related EH&S research has been spread too thin. As a result, EH&S research currently lacks enough depth to adequately address and provide substantial answers to many risk management questions that will emerge in both the near and long-term future. Therefore, an effective, forward-looking, internationally recognized EH&S research strategy needs to be developed to fill this gap.

A major barrier to developing a coherent risk-related research agenda of sufficient breadth and depth—within government and in conjunction with the private-sector—is a lack of coordination and information about the risk-related research the government is *currently* supporting.

To address this issue, **the Project on Emerging Nanotechnologies is in the process of compiling a publicly accessible inventory of government-supported, risk-related research—both domestically and internationally—that is addressing the EH&S implications of nanotechnology.** It is our hope that this inventory will be a useful tool for informing future EH&S-related research strategies and policy decisions. Although not comprehensive, it will provide the most complete overview of current federally funded research into the EH&S implications of nanotechnology to date.

The first generation of this inventory contains basic information on government-funded, risk-related research projects, including summaries, outputs, duration, funding sources, and budgets. The research is categorized on multiple levels. The first layer of categorization analyzes each research project by its relevance to the implications of nanotechnology, whether the nanomaterials under investigation are intentionally manufactured, incidental or naturally occurring, and whether the primary focus is on human health, environment, or safety impacts. A second layer of categorization classifies the research according to its focus within a simplified risk analysis framework. Finally, provision is made for a more detailed, third level of classification according to a range of searchable keywords and phrases.

As of early November, the inventory included a total of 154 ongoing and completed projects in the United States, accounting for roughly \$23 million per year of federally funded research across 8 different agencies. The inventory also currently includes 15 projects from sources around the world, including Canada, the U.K., and EU countries, accounting for roughly \$2.6 million per year.

This inventory will be made available online by November 29th and will include our initial analysis of research gaps. We would like to submit our preliminary analysis of the federal EH&S research portfolio to this Committee and request that the docket be held open until then, if possible. Additions to the inventory will be made as new information is received, and researchers and research managers will be encouraged to contribute new or updated information as their work progresses. The inventory is currently undergoing external peer review, along with internal checks for accuracy.

There are a number of key advantages provided by the inventory:

- It can enable the coordination of research between disciplines, agencies, and various stakeholders. It can also enable the coordination of research internationally, reducing the probability of duplicative research in different countries.
- It will allow the government to develop an integrated set of EH&S policies that are designed to make strategic investments based upon what work is already being undertaken. By helping to identify where the need for further funding lies, the current gaps in the EH&S research portfolio can be more easily addressed.
- It will satisfy the public's desire for greater transparency and disclosure of government activities, a desire that has been voiced repeatedly in the surveys and public perception studies discussed earlier.
- It will allow for the government to form partnerships with industry around pre-competitive research, as it becomes evident which exposure and toxicity issues are of interest to firms in the early stages of commercialization. Joint funding for EH&S research would be seen as a broad-based, long-term investment in nanoscale science and technology and would greatly increase our understanding and ability to manage potential risks.

Preliminary analysis of the data indicates that most critical research gaps are being addressed to a certain extent. However, it is also apparent that coverage of these issues is very limited, patchy, and uncoordinated. Research into exposure and hazard evaluation is relatively well represented in the database, and there are a number of projects providing information on nanomaterials' behavior that may determine impact. Research into how to control nanomaterials' releases and exposure effectively is being undertaken, and to a lesser extent, research into risk assessment and management methods and models.

i The areas of research that are underrepresented by comparison are human health effects and environmental impact, and human safety (such as fire and explosion hazards). It is also apparent that much of the current research portfolio focuses on first generation engineered nanomaterials, with very little strategic research addressing more complex materials currently under development. NIOSH, EPA, and NSF are leading the research highly relevant to the environmental, health, and safety implications of engineered nanomaterials, with DOD also making a significant contribution. Investigator-driven research funded by all four agencies is dominating mission-driven research addressing EH&S issues - raising questions over the degree to which currently funded projects address strategic issues.

Evaluating the number or value of research projects addressing specific issues in isolation does not provide insight into research gaps and strategy limitations. However, when used

in conjunction with complementary information on research and oversight needs, it provides a powerful tool for developing informed, focused, and long-range strategies.

Third, in addition to the need for increased funding and coordination, our analysis of the inventory data raises a host of more difficult questions related to structural issues. Does a trained workforce exist both domestically and internationally to undertake such novel research? Do governments have adequate human resources and the cooperative mechanisms necessary to manage such an effort effectively? Is there sufficient international agreement on technical definitions, metrology, and testing frameworks to collaborate and evaluate risk-related research among many countries?

At this point, it is uncertain as to whether this emerging policy response to concerns over nanotechnology's EH&S implications will be able to match the pace of innovation. As developments in nanotechnology become more revolutionary, transformative, and discontinuous, the governance system must adjust and change accordingly. Failure to do so will perpetuate the public's low trust in the government's ability to manage technological risk.

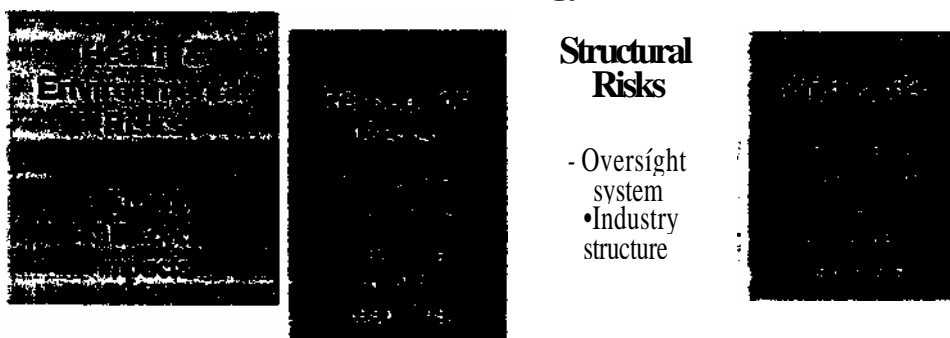
4. Are current federal and private research efforts adequate to address concerns about environmental and safety impacts of nanotechnology? If not, what additional steps are necessary?

Our ability to realize the promise of nanotechnology is becoming more and more linked to governance and management issues, not just science.

The country that wins the global nanotech race will be the country that can manage a > suite of potential risks and challenges involving public perception, effective oversight, and the possibility of surprise. Understanding the environmental and health risks is a necessary *but insufficient* condition for success.

If the goal of the National Nanotechnology Initiative is ultimately the creation of economic value, jobs, and innovative products that can change people's lives, we need a larger perspective on the tasks ahead and, in all probability, newer and smarter management and governance approaches that go beyond "another interagency workgroup." Let me discuss the risks we face as a society using a broader framework that goes beyond EH&S issues. I will focus on areas we need to tackle, and discuss what the federal government, along with other key stakeholders, might do.

Framework for Nanotechnology-Related Risks



Health and Environmental Risks

From a global perspective, the U.S. government has responded early and comparatively well to the EH&S challenge. As I outlined earlier, there are gaps in knowledge that must be closed and this requires more open debate and cooperation with industry and other countries. We need to acknowledge that the fiscal constraints we face in this country and elsewhere may limit our ability to significantly increase research dollars. As the analyses

by the American Association for the Advancement of Science have indicated, U.S. funding for environmental research has been flat (in real terms) for more than 20 years. The existence of very real fiscal constraints means that effective management of the EH&S research enterprise for nanotechnologies is imperative, not optional. Every dollar, every euro or yen matters, and must be leveraged. The United States should take the lead by putting our research cards on the table so we can build winning hands with other countries and industry.

I strongly feel it is time to launch an International Nanorisk Characterization Initiative (modeled roughly on the Human Genome Project) where we develop priorities across countries, align teams of researchers to address these priorities, and implement an information infrastructure to support global collaboration.

Engaging industry in supporting pre-competitive research projects in this portfolio will also be necessary. The risk characterization challenges we face today are relatively easy compared to what will come as nanotechnology and biotechnology converge and as we build ever-more complex and multifunctional nanostructure and systems of nanostructures. We are at the bottom of a very steep learning curve.

Perception Risks

Recently, a number of reports from the financial sector have underscored the importance of addressing and managing perception risks related to how the people perceive nanotechnologies.¹⁴ In the end, the success of nanotechnologies will depend on the public opening its mind and pocket book and embracing nanotechnology. This is not a given, as we have learned from other technologies such as genetically engineered foods and nuclear power. Recently, pharmaceutical companies have seen profits erode because of declining public trust in their organizations and products.¹⁵

Based on the public perception studies from multiple countries, which I summarized earlier, the public has clearly articulated their concerns about nanotechnologies and what they expect from government and industry. To summarize this, they are asking for better *due diligence* involving standardized testing (preferably by independent third parties), greater transparency, and the disclosure of test results.

The public's willingness to tolerate risks from new technologies also is linked to the perception of early and significant benefits. The large-scale benefits from nanotechnology have not yet materialized and may not for 3-10 years. For the foreseeable future, I believe there will be little public tolerance of oversight failures or mishaps, either in the United States or in most European countries. A mishap could rapidly chill investment and galvanize public opposition. More civil society actors are

¹⁴ Lux Research. *A Prudent Approach to Nanotech Environmental, Health and Safety Risks*. 2005 and Innovest Strategic Value Advisors. *Non-traditional Methods for Valuation of Nanotechnology Producers: Introducing the Innovest Nanotechnology Index for the Value Investor*, 2005. <http://www.innovestgroup.com/>.

¹⁵ "Big Drug Mergers See Sales Erode with Their Image." *The New York Times*. November 14, 2005, p. A1. This article cites a recent poll that shows only 9 percent of Americans believed that drug companies were generally honest.

becoming aware of nanotechnologies and carefully watching both government and industry response to possible risks.

How growing numbers of the public learn about nanotechnologies, from whom, and with what message, may be critical in shaping long-term popular acceptance. The U.S. government needs a public engagement strategy, which is not the same as education. Educating people on nanotechnology assumes there is a deficit in their understanding. Engagement forces us to admit that the public may have something important to say to scientists, industry, and policymakers and that they deserve being part of the larger conversation about how nanotechnology develops. Engagement cannot be a public relations campaign. As Physicist Richard Feynman once noted, "For a technology to succeed, reality has to take precedence over public relations."

The U.S. government, for example, should set a goal of engaging at least 3,000 citizens and public opinion leaders around the nation over the next year. This would require 20-25 town meetings, "listening sessions," and civic forums, but it would be time and money well spent and would help to raise public awareness and public confidence.

Associated with this effort, we also need to establish an ongoing and scientifically robust mechanism to track public knowledge and attitudes toward nanotechnology over time (on a regular six-month basis, for instance). Let's call this a NanoBarometer - designed to take the pulse of the public and to continually monitor and help to evaluate our public engagement efforts.

Industry also plays a critical role in shaping perception risks. Few companies have talked openly about their involvement with nanotechnology, no doubt because of large uncertainties concerning public reaction and government regulatory intentions, but this situation needs to change. In the long run, silence is likely to breed suspicions and mistrust on the part of the public.

Structural Risks

With more and more nanotech-based products entering commerce, a key question is whether significant gaps exist in our oversight structure and how we can address these. Though agencies have been meeting to discuss oversight and the EPA has begun developing a voluntary program, our approach on the regulatory side so far has been ad hoc and incremental. **It is particularly worrisome that many nanotechnology-based products are entering the market in areas with little, or no, government oversight**, such as cosmetics and consumer products. The U.S. government approach has been limited by the following:

- A focus on single statutes such as the Toxic Substances Control Act.(TSCA) rather than taking an integrated, multi-statute approach
- A focus on products more than the facilities and processes where production occurs. *: V

- A general lack of concern with the full lifecycle impacts of emerging nanotechnologies (an approach recommended in the U.K. Royal Society Report)¹⁶
- Too few resources devoted to pollution prevention and the "greening" of nanotechnology products and production processes, which could help industry ultimately avoid potential risks from the beginning
- Too little discussion of the resource constraints to effective oversight (for instance, do we have the personnel and dollars in the agencies needed for enforcement or testing?).

Most important, we have not looked forward to consider where nanotechnology is heading, assuming decades-old policies and analogies to the past will help us respond to the risks of the future. Today, nanotechnology is largely chemistry. But in a very short time, it will be chemistry and biology, and after that we will be dealing with multifunctional machines operating at the interface of classical and quantum physics.

Many of the assumptions that governed our approach to chemicals regulation may no longer hold. Because the risks of nanomaterials are poorly related to mass (and depend on other characteristics like surface volume, chemistry, charge, etc.), governments and industry will have to rethink the mass-based approaches that have historically shaped our toxicology, regulations, and regulatory-related monitoring systems.

We need a systemic analysis across agency statutes and programs, across agencies, and across the international landscape. This should include existing regulations, voluntary programs, information-based strategies, state and local ordinances, and tort law. All these measures need to be evaluated not just in terms of their applicability to nanotechnology today, but also in terms of their efficacy in five or ten years. We need an oversight blueprint that is proactive, transparent, and, for industry, predictable both now *and into the foreseeable future*.

In 2003, the Congress asked the National Academy of Sciences to evaluate the National Nanotechnology Initiative, largely from the perspective of the science. We urgently need to examine the governance. **Now it is time to ask the General Accountability Office or National Academy of Public Administration to undertake (within one year) a systematic analysis of the governance structure for nanotechnologies and develop a government-wide blueprint that will work not only today, but also 10 or 20 years from now. We owe that to consumers, to workers, and to industry.**

There are also risks that arise from the structure of the nanotechnology industry itself. Nanotechnology will not play out in a handful of large and well-staffed facilities where oversight and proper workforce training are relatively easy. The scientific investment strategies of the U.S. government and dozens of other countries have been designed to distribute nanotechnology R&D efforts across hundreds, and eventually thousands, of

¹⁶ *Nanoscience and nanotechnologies: opportunities and uncertainties*. London, U.K.: The Royal Society and Royal Academy of Engineering, July 2004. Available at <http://www.nanotec.org.U.K./finalReport.htm>.

laboratorios globally. These labs will in turn incubate thousands of small firms involved in a Darwinian struggle to push products to market.

Already there are 1,200 nanotech start-ups worldwide, with more than 60 percent in the United States. Added to the university laboratories, we have thousands of people working at the messy and often unpredictable interface between novel technologies and human judgment. Assume that much of the workforce is young—graduate and post-doctoral students, and other Generation-Y types with newly minted science or engineering degrees—a cohort of people that often tend to ignore safety protocols in the workplace.

The government-needs "push strategies" directed at small businesses, start-ups, and small labs. If someone is running an 8-10 person nanofirm, we cannot assume they will have significant time and resources to devote to environmental, health, or safety issues. The government (at federal, state, and local levels) needs to knock on their doors with useful technical and, potentially, financial assistance. Mounting information on government websites will not adequately address this problem.

One of the best ways of delivering this information is to use "intermediaries" such as professional societies along with technical assistance programs at universities and in the extension services of the government. Policymakers need to constantly ask themselves the question, "Will this program or policy work for small nanotech businesses?" In addition, large companies with the resources to address EH&S issues need to develop strategies to push this know-how down their supply chains to smaller firms involved in nanotech production. Government programs and policies should support and reward such supply-chain approaches in industry.

Small and medium sized firms also need relatively inexpensive and rapid methods to screen emerging nanosubstances and products for human and ecotoxicity. The federal government could help by supporting the development of fast-turnaround, standardized toxicity screens that can fit into the product development cycles of companies. Such screening techniques hopefully would allow environmental and human health problems to be identified early and engineered out of products before they enter the marketplace.

Wildcards

Finally, let me say a few words about what I would characterize as "wildcard" risks such as accidental or intentional releases. Here, I can only comment that I hope we are doing more than I can presently detect. Ed Tenner, a historian of science at Princeton University, once observed that there is a "tendency of advanced technologies to promote self-deception." Nanotechnology is not something we want to get smug or overconfident about. We could be surprised in unpleasant ways, either by the technology itself or by people who mishandle, mislabel, or misuse the technology. Unfortunately, we have no Department of Unintended Consequences in the federal government.

An accidental release of engineered nanomaterials into the environment, while probably not posing significant risks, could be a public relations nightmare, with a chilling effect on global investment. For example, the chief executive of a nanotechnology company recently was quoted in the media boasting that his company is manufacturing 50 tons of Polyhedral Oligomeric Silsesquioxanes (POSS ®) chemicals at its supply plant in Mississippi.¹⁷ A patently harmless industrial accident at that facility unrelated to the manufacture of these nano-structured chemicals—first discovered 30 years ago by General Electric Co.—has the potential to create unnecessary public and first responder panic simply because of their association with a technology that is unfamiliar and undefined to most citizens, EH&S professionals, and government safety officials.¹⁸ Planning to address this gap at the federal, state, community, and factory level is essential. I know of no emergency response plans that have been developed by the federal government or local first responders to address such a scenario. Such an accident could occur anywhere, which means we need to prepare globally. We need to anticipate, plan for, and rehearse every possible scenario we can imagine, to prepare for the unthinkable. Of special importance is the consideration of so-called "black swans," events with large impacts, incalculable probabilities, and surprise effects. 19

In addition, we should assume that bad practices will occur along with good practices as nanotechnology evolves. Everyday, vigilant and intelligent people recognize errors around them and can often come up with ingenious ways to correct problems. Taken one at a time, these bad practices seldom lead to a disaster if recognized early and addressed. The challenge is to develop ways for "error correcting knowledge" to be collected, managed effectively, and channeled into solutions. One model for this is the Aviation Safety Reporting System, which collects and analyzes voluntarily submitted reports from pilots, air traffic controllers, and others involving safety risks and incidents. The reports are used to remedy problems, better understand emerging safety issues, and generally educate people in the aviation industry about safety. A similar system in the U.K., called CHIRP, is designed to promote greater safety in both the aviation and maritime industries and is run by a charitable trust.

We Should create a Nano Safety Reporting System where concerned people working with nanotechnologies—in laboratories, companies, or in shipping and transport situations—can share safety issues and concerns. The purpose is not finger pointing but encouraging proactive learning. This information could be used to design educational materials, structure technical assistance programs, and provide a heads-up on a host of possible safety issues. Again, the goal is early warning of emerging risks and the reduction of possible wildcards.

¹⁷ Pat Phibbs. "Manufacture of New Carbon Nanotube Approved by EPA Under an Exemption." *Daily Environment*. No. 203, October 21, 2005, page A1.

¹⁸ Robert T. Dixon. "Hybrid Plastics' nanomaterials: From inner molars to outer space," *Small Times*. October 28, 2002.

¹⁹ See: Talib, N. *The Black Swan: Why Don't We Learn that We Don't Learn?*, The United States Department of Defense Highlands Forum papers, February 2004, at: <http://www.fooledbyrandomness.com/blackswan.pdf>

Management and Coordination

Addressing the issues outlined above requires a properly resourced coordination function and smart management.

A recent GAO report on results-oriented government makes it clear that effective federal collaboration is key to addressing many 21st century challenges.² For the most part, we have yet to develop a winning formula for collaboration. The National Nanotechnology Initiative is one of the most complex interagency endeavors ever undertaken by the U.S. government, now involving over \$1 billion per year in funding and 25 separate agencies. This increase in the number of possible partners across the government leads to an almost exponential increase in the number of possible collaborations - of both productive and potentially nonproductive natures.²¹

The sum of 25 agency missions does not necessarily add up to a coherent federal strategy for addressing risks, engaging the public, providing adequate oversight, or managing the unexpected. It is simply the sum of the missions, or less. As the GAO report points out, these missions are often not mutually reinforcing or can even be in conflict. "You end up with a patchwork of programs that can waste funds, confuse and frustrate program customers, and limit the overall effectiveness of the federal effort." •

Our approach to social and ethical issues has largely involved an "outsourcing" model where the scientists do the science and "ethics" are dealt with in separate institutions and centers. Policy considerations have been dealt with as "add-ons" rather than being fully integrated into the research planning process. Given the pace of development, neither one of these approaches is likely to provide government with adequate "early warning" and the necessary lead time to structure effective policies or responses to emerging social and ethical issues.

Nanotechnology is just the latest in a series of upheavals in our scientific and industrial landscape, which is being shaped simultaneously by rapid and disruptive changes in areas such as information technology, biotechnology, and cognitive science. Many agencies like FDA and EPA are grappling with the implications of the genomics revolution and are hard-pressed to consider nanotechnologies. These agencies are stretched thin. The depth of expertise in the individual agencies on nanotechnology often involves only 2-3 professionals. Again, most of these people are scientists, not people with public policy or public administration experience.

The managerial and coordination infrastructure in place simply does not match the enormity and importance of the task. We need a beefed up, visible federal face for

²⁰ General Accountability Office (2005). Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies, GAO-06-15, October 21, 2005. Summary available at: <http://www.gao.gov/docsearch/abstract.php?rptno=GAO-06-15>

²¹ See: Bryan, L. & Joyce, C. (2005). "The 21st Century Organization," *McKinsey Quarterly*, Number 3.

nanotechnologies sending a coherent message to the public and industry. I believe that the National Nanotechnology Coordinating Office (NNCO) can help in this regard, but it is understaffed and under-funded by orders of magnitude. This is not about creating an additional bureaucracy; it is about creating coherence and the capacity to manage a complex enterprise.

Again, let me emphasize that we can succeed with the science but fail on governance, compromising our competitive position.

I hope these observations will be helpful to the Committee as they consider what steps might be taken to ensure that the promise of nanotechnology can be realized.

Key Questions from Different Perspectives

Scientific/Technical

Which properties or attributes of engineered nanomaterials are particularly significant to health/environmental impacts?
Are nanomaterials capable of interacting in ways we are currently unaware of, or targeting biological/environmental systems we are unaware of?
Are there classes of nanomaterials that present a greater or lesser hazard?
Can we predict chronic/long-term impacts to both humans and ecosystems?
How will risks change as nanotechnologies evolve (nanobio, nanosystems, systems of systems)? How will we anticipate, evaluate, and manage these risks?
What are the beneficial applications of nanotechnology to environmental and human health problems? Can nanotechnology be developed so that the benefits outweigh the risks?
How can we prevent risks posed by the pollution generated in the production of nanomaterials and their associated products?

Policy/Regulatory

What mechanisms work best to regulate nanotechnology-based products? Have potential chronic and long-term risks, issues, and consequences been analyzed by policymakers and government agencies? Does sufficient expertise exist in the government to address the EH&S implications of nanotechnology? If not, how will we attract and retain talent? What opportunities exist for public-private and international partnerships? Will our policies and programs work for small and medium-sized enterprises? How can risk management and regulatory models be developed which are relevant to an ever-changing technology?
How does the structure of the emerging nanotechnology industries affect their response to EH&S issues?
How have uncertainties and "domains of ignorance" been taken into account during the decision-making, policymaking, and standard-setting process? Who will be responsible, and who will be held accountable, for any unforeseen harm, ill-used, or dangerous applications of nanotechnology? Who is responsible for collecting data on nanotechnology industries that can inform policymaking (the Bureau of Labor Statistics, the Census Bureau, etc.)? Are we trying to anticipate possible accidental misuse of nanotechnologies? Who in the government should be doing this?
Is there a need for new legislation or a new department specifically-focused on nanotechnology?

Public Perception

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- Who *does* the public trust to handle and manage the EH&S risks?

How is information related to nanotechnology communicated and made available?
What media are most effective (for which age groups, for instance)? Are public perceptions being included and used to inform debates about proposed and pending regulations?
How will the public react in the event of an accident, mishap, or product recall?
What would the government message be?

Biography of David Rejeski

David Rejeski directs the Project on Emerging Nanotechnologies. For the past four years he has been the Director of the Foresight and Governance Project at the Woodrow Wilson Center, an initiative designed to facilitate better long-term thinking and planning in the public sector.

He was recently an adjunct affiliated staff at the RAND Corporation and a Visiting Fellow at Yale University's School of Forestry and Environmental Studies. Before joining the Wilson Center he served as an agency representative (from EPA) to the White House Council on Environmental Quality (CEQ) and, earlier, worked at the White House Office of Science and Technology (OSTP) on a variety of technology and R&D issues, including the development and implementation of the National Environmental Technology Initiative.

Before moving to OSTP, he was head of the Future Studies Unit at the Environmental Protection Agency. He spent four years in Hamburg, Germany, working for the Environmental Agency, Department of Public Health, and Department of Urban Renewal and, in the late 1970's, founded and co-directed a non-profit involved in energy conservation and renewable energy technologies.

He has written extensively on science, technology, and policy issues, in areas ranging from genetics to electronic commerce and pervasive computing and is the co-editor of the recent book *Environmentalism and the Technologies of Tomorrow: Shaping the Next Industrial Revolution*, Island Press, 2004.

He sits on the advisory boards of a number of organizations, including the EPA's Science Advisory Board, the Greening of Industry Network, the Journal of Industrial Ecology, and the University of Michigan's Corporate Environmental Management Program. He is a member of the External Advisory Board of Nanologue, a European project to bring together leading researchers to facilitate an international dialogue on the social, ethical and legal benefits and potential impacts of nanosciences and nanotechnologies. He has graduate degrees in public administration and environmental design from Harvard and Yale.